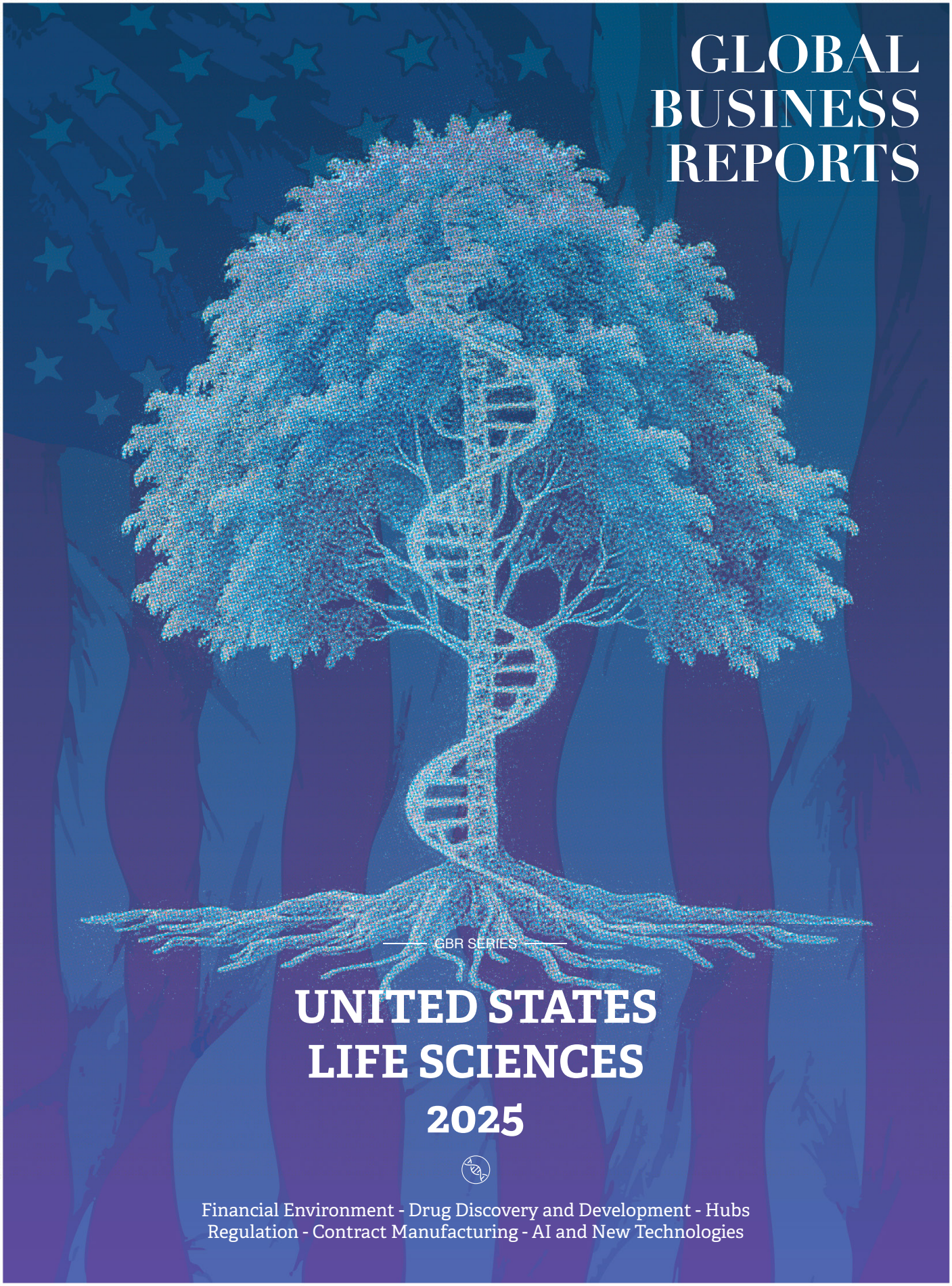


GLOBAL BUSINESS REPORTS

GBR SERIES

# UNITED STATES LIFE SCIENCES 2025

Financial Environment - Drug Discovery and Development - Hubs
Regulation - Contract Manufacturing - AI and New Technologies

# Dear Readers,

Welcome to the 2025 edition of GBR's *United States Life Sciences* industry report.

Resilience amid uncertainty. These words encapsulate the US life sciences sector as it navigates 2025. While the industry has largely rebounded from the recent biotech bear market, with clinical trial starts and funding showing signs of rebound, headwinds remain. Political uncertainty, the specter of tariffs, and evolving regulatory landscapes create a complex operating environment. Yet, the fundamental strengths of the US ecosystem endure.

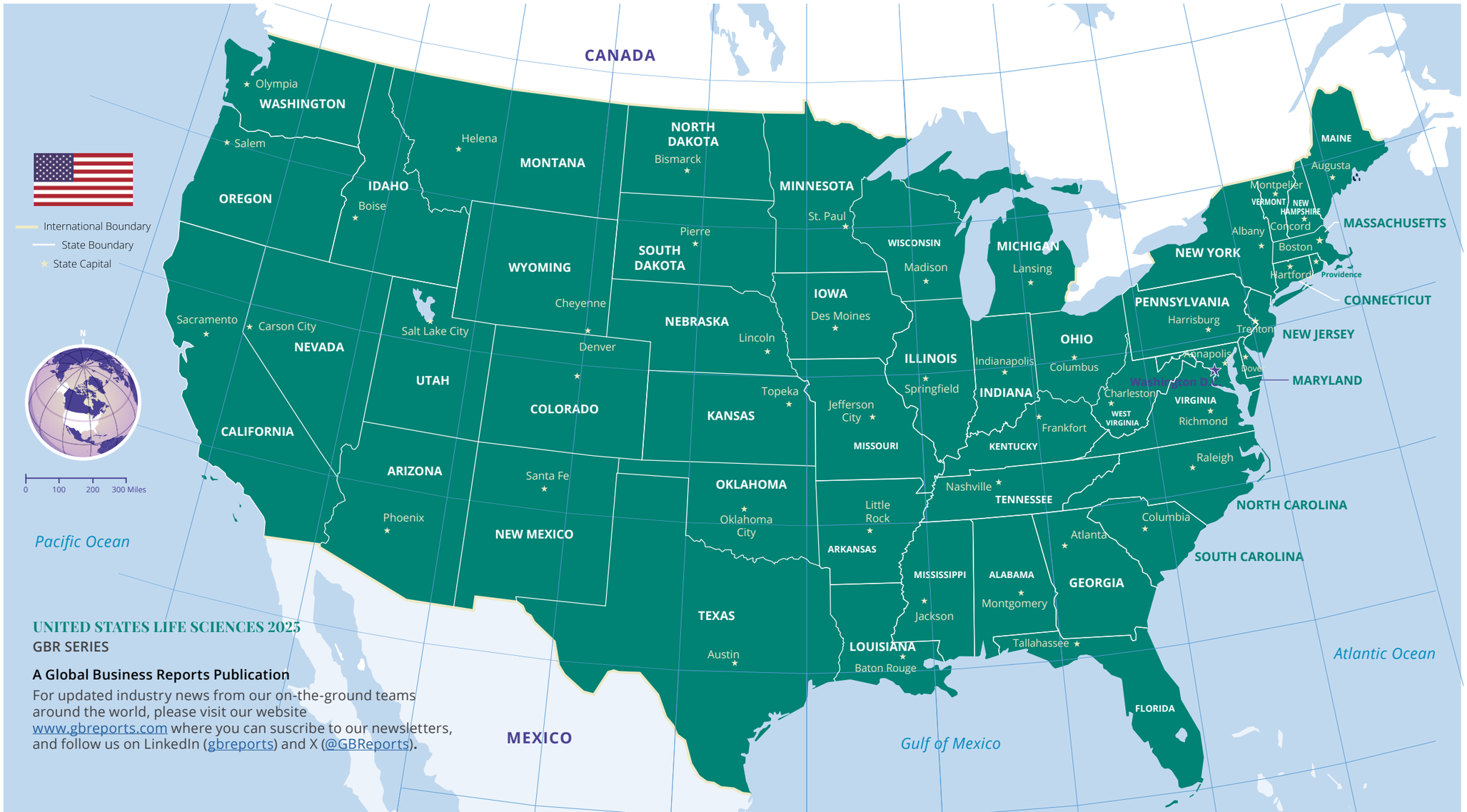
The nation remains the undisputed global leader, powered by world-class research, robust investment, and dynamic innovation hubs stretching from the established centers in California and the Northeast to burgeoning regions across the country. This landscape continues to attract global players.

Challenges are awry. Big Pharma faces immense pressure from patent expirations, driving strategic M&A to acquire innovation often originating from biotech. Both must adapt business models in an era demanding greater efficiency and value demonstration, even amidst breakthroughs in areas like metabolic disease and advanced therapies.

Supporting this ecosystem are vital partners: CDMOs are rapidly expanding to meet the demand for biologics manufacturing, CROs offer pathways to accelerate development, and logistics providers are innovating to handle complex personalized medicines. This crucial segment faces its own pivotal moment, grappling with supply chain vulnerabilities and the potential reshaping spurred by geopolitical tensions and legislation like the BIOSECURE Act, accelerating diversification strategies.

We extend our gratitude to our partners at Biocom California, MassBio, BioNJ, and Ohio Life Sciences, as well as the many executives who generously shared their insights with us. We hope this report aids all stakeholders in navigating the evolving landscape of the US Life Sciences sector.

Alfonso Tejerina
Director and General Manager
**Global Business Reports**




**UNITED STATES LIFE SCIENCES 2025**
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# INTRODUCTION

> The industry may seem cloudy now, but above those clouds there is clear momentum.

Matthew Gardner
Americas Advisory Leader Life Sciences
**CBRE**

GBR Series
UNITED STATES LIFE SCIENCES 2025

Image courtesy of Edward Jenner at Pexels

# A 2025 US Life Sciences Dissection

Image courtesy of Johnson & Johnson

## The Pharmaceutical Body

The pharmaceutical industry is akin to a human body – a living, breathing force supplying life-saving therapies to an ever-increasing global population. This intricate system, driven by human demographics and global health needs, comprises numerous interconnected parts working together to systematically discover, develop and deliver medicines. If a single part was removed, the body would cease to function.

The current environment presents significant challenges like cybersecurity risks, regulatory compliance, and policy uncertainty. Playing at parity is insufficient; companies must focus on their unique strengths and direct capital and talent where they can truly outperform. Greg Rotz, pharmaceutical and life sciences advisory leader at PwC, said: "A few years ago, everyone was focused on execution and then during COVID, it was business continuity and speed. Now, the focus is really on reinvention. We are standing at the edge of significant change."

**The heart: The biotech beat**

Biotechnology remains the heart of this body, continuously pumping the lifeblood of innovation throughout the system. After the cardiac arrest of the biotech in 2022 and 2023, it seems 2024 delivered a much-needed AED, and 2025 will see the biotech heart begin to beat again.

While investor caution persists, the biotech investment cycle appears to be rebounding, breathing life back into the sector. Venture capital, the oxygen for this heart, is flowing, albeit cautiously, towards companies demonstrating proven science, strong data, and clear pathways. However, a tale of two cities exists, with mega-rounds dominating funding while smaller Series A and B companies face struggles. The IPO market reflects this caution. While 2024 saw 16 IPOs, a 46% increase over 2023's 11, many struggled, and the environment remains challenging. As Christiana Bardon, managing partner at MPM BioImpact puts it: "Companies hesitate to go public, and when the best do, investors hesitate to participate. It is a classic chicken-and-egg problem."

There were eight IPOs in Q1 2025, which is only one greater than 2024's seven IPOs during Q1. "If 20–30 venture-backed IPOs happen in 2025, it would be a positive signal", said Jonathan Norris, managing director at HSBC Innovation Banking.

Innovation increasingly originates from small to medium-sized companies, with nearly 80% of new molecules coming from these nimbler players, many without their own manufacturing. High-growth areas attracting significant interest include oncology, advanced cell and gene therapies (CGTs), rare diseases and platforms leveraging AI. CGTs are gaining momentum with more products reaching the commercial stage, though significant safety and CMC challenges remain. Experts anticipate a continued rise in CGT approvals through 2025.

**Lungs and oxygen: Capital markets' vital breath**

Funding and capital markets act as the lungs, supplying the essential oxygen (capital) that allows the entire pharmaceutical body to function. However, the breathing has been strained. "The uncertainty on the capital markets over the last two years created a narrative of 'cautious optimism' which ultimately led to 'optimism fatigue'," said Arda Ural, life sciences sector leader at EY Americas.

Investors are prioritizing reduced risk, often favoring mega-rounds in later-stage assets over earlier, riskier ventures. Many companies that raised funds in 2021-2022 relied on smaller insider rounds later, creating pressure to hit milestones in 2025 or face difficult consolidation. "Life sciences companies are focusing on managing cash burn and ensuring that their runway lasts as long as possible," remarked John Pennett, partner-in-charge of the national technology and life sciences group at EisnerAmper.

There is a need for innovation beyond science. "The biggest theme is the ongoing paradox between advances in science and lagging shareholder returns for the sector. With a few notable exceptions, great science is not enough to drive outperformance in the capital markets," said Rotz.

A potential easing of Fed rates in 2025 could spur a rebound in IPO activity based on historical correlations, but investor sentiment remains key.

**The organs: Big Pharma's specialized roles**

The large pharmaceutical companies function as the body's vital organs, each playing a specialized role and bringing expertise in different domains.

Modality shifts are coming in waves: "The tsunami of interest in RNA has touched virtually every entity in the pharmaceutical industry. Eli Lilly has a massive interest in genomic medicines, Pfizer goes without saying, and even companies like Novo Nordisk that had not previously had collaborations or partnerships in this area are now looking to enter the field," said Kate Broderick, chief innovation officer at Maravai LifeSciences and TriLink BioTechnologies.

In 2025, Big Pharma remains a strong force, but the operating environment is undeniably shifting. They face a significant loss of exclusivity (LOE) wave, projected to impact revenues by an estimated US$300 billion by 2028. This patent cliff, reminiscent of the 2008-2010 period, is driving portfolio reshaping and M&A activity. The balance between top-line revenue and pipeline strength turned negative in 2023 and is expected to remain so until 2028. "Leaders must recognize that market economics are changing and decide where they can truly excel. Some companies will disrupt R&D, accelerating speed and reducing costs through AI, data, and startup partnerships. Others will focus on consumers, expanding beyond therapeutics to holistic healthcare solutions. Companies must choose how they will win in this evolving landscape," emphasized Rotz.

This often involves acquiring innovation externally, as historically, 70% of top-selling products originated outside Big Pharma, primarily from biotech. "Heading to 2025, the outlook is positive, particularly with Fire Power of US$1.3 trillion of capital available for dealmaking. This positions the industry to pursue external growth aggressively if internal pipelines fall short," highlighted Ural.

Many large pharma companies are also restructuring, potentially divesting plants, which could create opportunities for CDMOs.

**Arteries and muscles: CDMO/CRO powerhouses**

Contract research firm arteries move oxygenated blood (funded innovations) away from the heart and into the ecosystem. Contract manufacturers perform the heavy lifting—producing APIs, formulating drugs, and scaling manufacturing. They support movement initiated by the heart (biotech). Without CDMOs and CROs, ideas would not become actions, and innovation, the lifeblood, would not be delivered.

The US pharmaceutical CDMO market alone is valued at US$43.62 billion for 2025 and projected to grow steadily. Significant investments are being made in expanding capacity and capabilities across the globe. Dirk Lange, CEO of Pyramid Labs, a US-based CDMO, elaborated on trends that are trickling down into the CDMO space: "The pharmaceutical landscape is rapidly evolving, with biologics, peptides and oligonucleotides gaining prominence. While monoclonal antibodies have long dominated the field, more complex modalities such as bispecific antibodies and fusion proteins are becoming increasingly common. The success of GLP-1 receptor agonists has fueled further investment in peptides, solidifying their place as a viable drug class."

The acquisition of Catalent by Novo Nordisk significantly impacted the market, reducing available capacity (especially for injectables) and forcing clients to seek new partners. This has created opportunities for other CDMOs, particularly those serving smaller players underserved by the consolidation. It also created challenges reminded Andrew Mears, CEO and co-founder of Lead Candidate, a life sciences recruitment company: "The expanding GLP-1 market is increasing demand for specialized talent. Companies must adapt to secure the right talent, with growth-focused organizations needing individuals skilled in expansion."

**The Nervous System: Regulators in control**
Regulators, particularly the FDA, function as the body's nervous system, controlling its movement and direction. The current regulatory environment can be described in a single word: unpredictable.

The proposed US BIOSECURE Act, restricting federal funding for work with certain Chinese companies, has created significant uncertainty. While full decoupling is unrealistic, some version is expected to pass, shifting spending and prompting supply chain reengineering, likely at added cost to patients. Despite user fees (PDUFA) intended to speed up reviews, the process can remain slow, with FDA requests for information extending timelines, particularly compared to Europe. Regulatory scrutiny, especially for foreign manufacturers, has intensified. Proposed cuts to NIH funding raise long-term concerns, particularly for research hubs like Massachusetts. "While cuts do not immediately impact industry, long-term reductions in research funding slow the creation of new companies. Fewer companies mean less innovation and fewer clinical trials —delaying life-changing treatments for patients," said Ben Bradford, head of external affairs at MassBio.

Messing with the pharmaceutical industry is not the way to go. "Science is apolitical — both Republicans and Democrats get brain cancer and need treatment," warned Bardon.

**The frontal cortex: Data and AI**
Technology, particularly Artificial Intelligence (AI), acts as the frontal cortex, processing vast amounts of intelligence and accelerating decision-making across the pharmaceutical body. The market for AI in life sciences is projected to expand rapidly, from US$2.14 billion in 2024 towards US$9.17 billion by 2032. Early AI-discovered products are already in development. "From clinical trial optimization to procurement, AI and machine learning can expedite drug development by helping companies fail faster or find more likely successful paths. These technologies could also improve capital efficiency, which is crucial in an industry where traditional methods can be slow and fraught with failure," said Pennett.

AI tools are becoming more accessible to smaller biotechs, leveling the playing field. Adoption faces hurdles. The biggest challenge is not generating ideas but executing those ideas in ways that truly deliver transformation. Data readiness is another issue; many companies lack the necessary data foundation despite investments. Risk avoidance can also slow adoption for legacy products.



**The medulla: Patients**
The medulla is a part of the brainstem (the connection point between the brain and nervous system) which controls the things that keep you alive without having to think about like heartbeat, circulation, and breathing. While not consciously directing the body's lifesaving functions, patients—given the prevalence of diseases and need for treatments—fundamentally dictate the industry's direction, influencing funding flows and R&D focus.

There is a major shift towards patient-centricity, influencing everything from drug delivery to logistics. Demand is soaring for user-friendly formats like pre-filled syringes and autoinjectors for at-home administration. "Convenience remains a strong trend. Consumers want portable, easy-to-use products," said Jeff Reingold, COO of Contract Pharmacal Corp.

This shift requires CDMOs to be well versed in more complex and advanced drug delivery technologies, said Robert Lee, senior vice president, BD at Particle Sciences: "There is growing interest in patient-centric dosage forms—long-acting injectables, nanomilling, engineered particles, PLGA microspheres, and implants (both bioerodible and biodurable). We are getting more interest in bioerodible implants, including intraocular and intraarticular administration."

Major health challenges guide investment. The obesity epidemic fueled massive growth for companies like Novo Nordisk and Eli Lilly with GLP-1 drugs, generating billions that will flow back into R&D and M&A. Cancer also remains a primary focus.

**An evolving body**
The pharmaceutical industry body in 2025 is a dynamic, complex organism navigating significant change. Innovation beats strongly from the biotech heart, oxygenated with recovering (though cautious) capital flows. Big Pharma organs adapt to patent cliffs through M&A and restructuring. CDMO muscles grow stronger and more specialized. AI provides new cognitive power, while the regulatory system attempts to maintain balance. Ultimately, patients are at the center, directing the body's purpose. ■





# Tools and Materials Providers

## Growth through innovation

For the companies providing the essential tools and materials that power discovery, development, and manufacturing, 2025 is shaping up to be a year defined by strategic transformation and a laser focus on delivering next-generation solutions. As the market recovers and evolves, leading providers are differentiating themselves not just through scale, but through their commitment to innovation across portfolios, processes and partnerships. The overall life science tools market, estimated at well over US$100 billion globally, continues to benefit from strong secular trends, with analysts anticipating long-term market growth in the 4-6% range.

**The productivity imperative: Efficiency through innovation**
The pressure on laboratories across pharmaceutical, biotech and diagnostic sectors to enhance efficiency has never been greater. Factors including rising R&D complexity, the need for faster turnaround times in QA/QC, persistent labor shortages, and the sheer volume of data generated necessitate smarter, faster and more automated solutions. As Agilent CEO Padraig McDonnell noted at JPM: "As I go around the world talking to laboratories, the thing that is really top of mind for scientists is productivity."

Agilent Technologies is tackling this head-on through its "IGNITE" transformation, focusing explicitly on enhancing lab productivity. "We are seeing strong adoption of our new LC platform, Infinity Tree, which boosts lab productivity by 10–20%. We are also collaborating with ABB Robotics to build automated lab solutions. We are shifting our R&D strategy—aggregating product lines and making asymmetric investments in the highest-growth areas," McDonnell reiterated in his interview with GBR.

**Riding the wave of novel modalities**
The therapeutic landscape is undergoing a profound shift. While small molecules remain important, the pipeline is increasingly dominated by complex biologics, including cell and gene therapies (CGT), antibody-drug conjugates (ADCs), mRNA vaccines and therapeutics, and advanced peptides like GLP-1s. Markets for novel modalities are expanding rapidly; for instance, the ADC market is valued at approximately US$12-16 billion in 2025 with projected CAGRs exceeding 10%, while the CGT market is forecast to grow even faster, with some estimates projecting CAGRs above 18%. The rise of proteomics promises deeper biological insights. These novel modalities present unique challenges and opportunities, requiring specialized tools, reagents, delivery systems, and manufacturing expertise far beyond those needed for traditional drugs. The high therapeutic potential and market opportunity are driving intense investment and innovation in enabling technologies.

MilliporeSigma, the US life science business of Merck KGaA, is heavily investing in capabilities to support the development and manufacturing of novel modalities, particularly ADCs and CGT. A significant US$76 million expansion in ADC manufacturing capacity, coupled with the launch of the innovative Mobius® ADC Reactor – the first single-use reactor specifically for ADC production – demonstrates their leadership. "The company's goal is to ensure clients can bring their innovations to market more effectively and with shorter turnaround times. This investment is designed to triple our existing manufacturing capacity to meet the increased global client demand for ADCs," reinforced Benjamin Hein, head of life science services.

The Mobius® reactor itself is an innovation, eliminating potent liquid waste and improving efficiency compared to traditional methods.

Beyond ADCs, the acquisition of Mirus Bio strengthens MilliporeSigma's position in viral vector manufacturing, crucial for CGT, by adding expertise in transfection reagents like TransIT-VirusGEN®. Innovation permeates their services as well, with platforms like AptegraTM reducing genetic stability testing time by 66%, and the Blazar® platform enabling rapid virus detection. As Sebastián Arana, head of process solutions, stated: "MilliporeSigma is focused on advancing its position in high-growth areas by strengthening offerings across the molecule and modality journey from discovery to commercial manufacturing. Strategic investments, such as the recent acquisition of Mirus Bio for transfection reagents and the expansion of ADC and HP-API capabilities, support the company's ambition to lead in novel modalities including viral vectors, ADCs, and mRNA."

**The rise of the integrated provider**
A growing number of leading life science tools and materials companies are strategically expanding into CDMO services. This trend is driven by several factors: the desire to capture greater value across the drug lifecycle, the opportunity to leverage deep technical expertise and existing customer relationships (particularly with emerging biotechs needing integrated support), the increasing manufacturing complexity of novel modalities requiring specialized capabilities, and the appeal of adding high value, often recurring, service revenue streams.

The contract manufacturing landscape is as dynamic and demanding as ever, which Marc Caspar, CEO of Thermo Fisher Scientific noted at JPM: "Catalent has been acquired by Novo Nordisk. From our lens, as the market leader in sterile fill-finish, it takes an option off the table. Biosecure, whether passed or not passed, I do not think the dialogue is going to end. That is leading to a shift in focus to more of the work moving to Western-based facilities."

Agilent Technologies exemplifies a targeted CDMO strategy, particularly through its US$1 billion acquisition of BIOVECTRA in July 2024. This move expands its CDMO capabilities into specialized areas like microbial fermentation, peptide precursors, ADCs, and sterile fill-finish, complementing its leading position in oligonucleotide manufacturing. "We are not aiming to be a generalist CDMO. We are building a specialized, high-capability business in strategic swim lanes."

As the industry moves beyond recent volatility, the commitment to innovation positions these providers not just to capitalize on market recovery but to actively drive the next wave of scientific discovery and therapeutic breakthroughs. ■

## Padraig McDonnell

CEO

**AGILENT TECHNOLOGIES**

**What is the company's approach to innovation?**
We are seeing strong adoption of our new LC platform, Infinity Tree, which boosts lab productivity by 10–20%. We are also collaborating with ABB Robotics to build automated lab solutions. We are shifting our R&D strategy—aggregating product lines and making asymmetric investments in the highest-growth areas.

Customers are buying the whole productivity solution. The Infinity Lab Assist Automation Software and OpenLab CDS are all part of that. Through IGNITE, we are accelerating how we bring new capabilities to market.

**What role does biopharma play in Agilent's overall strategy?**
We are embedded in this space through our analytical platforms—supporting R&D, development, and QA/QC for biologics. Our oligonucleotide manufacturing business in Colorado is a world leader; we invested US$750 million and see strong uptake in clinical and commercial batches. Customers asked for more capabilities, leading to our US$1 billion acquisition of BIOVECTRA, which brings microbial fermentation, peptide precursors, ADCs, and sterile fill-finish capabilities.

**What emerging areas are you most excited about?**
We are also looking at proteomics and spatial biology as areas of future growth. With opportunity, it is critical to stay focused.

**How is artificial intelligence (AI) leveraged to drive the company forward?**
We are using AI in modeling, planning, and integrating robotics with the human workforce, helping us create more knowledge-based roles and upskill our employees. Externally, we apply AI to improve customer experience and asset performance. Our acquisition of SixSense helps customers monitor the effectiveness of their installed base and enables predictive maintenance.

**What is Agilent's long-term approach to this ever-changing market?**
Pharma is a fast-moving, innovation-driven space. There is incredible science coming out of pharma and biotech, and Agilent is there to help scientists get to outcomes quicker and more productively. ■

SA

BH

## Sebastián Arana and Benjamin Hein

SA: Head of Process Solutions

BH: Head of Life Science Services

**MILLIPORESIGMA**

**Can you introduce MilliporeSigma and the firm's strategy to address US industry needs?**
SA: The US market is vital due to its expansive academic research, pharmaceutical development, and biotech manufacturing. Proximity to this innovation ecosystem with multiple manufacturing and distribution sites and R&D centers in the US enables us to develop novel solutions for our customers.

We have numerous manufacturing and distribution sites. Some of our largest manufacturing sites include St. Louis, Missouri; Jaffrey, New Hampshire; Danvers, Massachusetts; and Milwaukee and Sheboygan, Wisconsin.

The US is a strategically important region for our CDMO and testing business as well, supporting ADCs, high-potent active pharmaceutical ingredient (HPAPIs), viral vectors, and product characterization and release testing services.

**Can you discuss how recent investments will help advance ADC manufacturing, Millipore's dominance in the space, and the potential of the modality?**
BH: MilliporeSigma made several significant advances in Antibody Drug Conjugates (ADCs) manufacturing capabilities over 2024, including the US$76 million expansion and the launch of the Mobius ADC Reactor. The investment represents a critical step in the company's ongoing growth journey to partner with new and existing clients as they advance their drug development pipelines. With additional capacity and by scaling utilities and enhancing Process and Analytical Development (PAD) labs, MilliporeSigma can provide industry- leading support for early-stage and commercial bioconjugates. The company's goal is to ensure clients can bring their innovations to market more effectively and with shorter turnaround times.

This investment is designed to triple our existing manufacturing capacity to meet the increased global client demand for ADCs.

We are shaping tomorrow's cancer care today with ADCs, which signify a groundbreaking advancement in first-line treatment strategies. By moving beyond traditional, one-size-fits-all therapies, ADCs empower drug developers to deliver highly targeted treatments that effectively destroy tumor cells while preserving healthy tissue. ■





Image courtesy of Johnson & Johnson

# Pulse Check

## Taking the industry's vitals

Predications are difficult in the current market environment. Trump, and his tariffs, took a bull stock market and almost turned it into a bear quicker than any president in modern history (as of April 2025). If the stock market closes in bear territory – a drop of 20% from a recent peak – it would be the earliest in a new administration a bull market turned into a bear in the history of the S&P 500, which dates back to 1957.

Take a pulse check. Since 2023, the industry approved the first CRISPR-based therapy, achieved more FDA approvals for novel drugs than ever before and brought the first therapy for MASH to market. "Uncertainty remains with a new administration, but the industry's core strengths are intact," underscored Jonathan Norris, managing director of HSBC Innovation Banking.

Let us put our ear to the stethoscope and listen to the heartbeat of the industry. If I were to make predictions about how the Trump administration would impact the financial environment it would be outdated by the time this hits print anyways.

**Big Pharma: healthy organs**
According to Evaluate Pharma, pharmaceutical product sales are forecasted to increase by US$82 billion in 2025, which is the largest jump since the Covid-19 pandemic. Additionally, combined industry revenues are predicted to top US$1 trillion for the first time ever. Seems like healthy fundamentals to me.

For sales, GLP-1 antagonists dominate the top table. Novo Nordisk's Ozempic and Wegovy along with Eli Lilly's Mounjaro and Zepbound are predicted to generate US$70 billion in combined sales in 2025, according to Evaluate Pharma's consensus forecasts. Sales of Merck's Keytruda are set to peak in 2025. Patent expiration is set for 2028. However, the firm plans to file for a subcutaneously administered version of the drug in 2025 to extend its runway. "We see the KEYTRUDA LOE as more of a hill than a cliff," Robert Davis, Merck's chairman, president, and CEO said in his JPM presentation.

The loss of exclusivity (LOE) due to expiring patents on high-revenue products is one of the most pressing issues in the pharma space. "The LOE wave will remain a critical industry topic through 2028 when the impact of the LOE is expected to reach 6.7% of revenue and an estimated US$300 billion lost," said Arda Ural, life sciences sector leader at EY Americas.

Patent cliff or hill, call it what you will, it is set to drive M&A; 77% of executives in a Deloitte survey expect M&A to increase in 2025. "With the pending patent cliff, portfolio reshaping and deal-making have been key topics over the past year," said Greg Rotz, pharmaceutical and life sciences advisory leader at PwC US.

The motive is simple: Big Pharma is hungry to fuel pipelines. In 2024, total R&D expenditure increased through acquisitions and organic growth, reaching 16.3% in absolute terms, and exceeding 25% as a percentage of sales for the first time, revealed IQVIA. Joa-

quin Duato, chairman and CEO of Johnson & Johnson, succinctly summarized this in his JPM presentation: "M&A and R&D are the ways we create significant value and build our pipeline."

Albert Bourla, chairman and CEO of Pfizer, reiterated the sentiment in his JPM presentation: "If 2024 was a year where commercial execution was the forefront... in 2025, R&D and the advance of our pipeline is taking number one priority."

However, increased investment does not guarantee increased returns. A study in Drug Discovery Today analyzing the 200 largest pharmaceutical firms, novel drug approvals, and over 80,000 clinical trials between 2012 and 2023 found that though investment in internal R&D continues to grow, currently exceeding US$3.5 billion per novel drug, there has been a five-decade decline in pharmaceutical R&D efficiency. "While in-house pipelines are necessary, they are not sufficient at current levels, forcing firms to buy innovation," said Ural.

The heart delivering the life blood to the industry is, of course, biotech: "Historically, 70% of the top 10 best-selling products originated from external sources, highlighting pharma's heavy reliance on biotech," Ural continued.

**Biotech: The industry's heart beats again**

David Schaffer, executive director of QB3, a company with several incubators in the Bay Area, put the state of biotech bluntly: "We are currently in the longest biotech bear market in history."

While 2022 and 2023 were a biotech heart attack (perhaps causing a few real ones), 2024 delivered a much-needed AED. It appears that 2025, albeit with some continued caution, could see the biotech heart beating more healthily again.

The preceding 'sugar high' of 2021-2022 caused the Initial Public Offering (IPO) artery to clog considerably. While 2024 saw a slight uptick in the number of US biotech IPOs (23 compared to 20 in 2023), performance remained mixed. "There were more IPOs in 2024 than in 2023, but some companies failed due to unsuccessful clinical trials. Others had distant milestones or were too early in development and struggled," Christiana Bardon, managing partner of MPM BioImpact elaborated.

The cautious optimism residue from 2024 seems to have stuck for 2025. The first cohort of 2025 IPOs has shown relatively better performance compared to 2024 deals. Investors are showing appetite for companies with strong clinical data. Companies with de-risked, later-stage assets seem better positioned for successful debuts. A significant pipeline of private biotech companies has been stored in the atria for a more oxygenated market before being pumped out into the public markets. Many raised private funds, allowing flexibility to choose the right window. "The best biotech companies do not want or need to go public. The mezzanine financing environment has been strong and healthy. If companies can get great valuations and raise enough capital privately, there is no reason to go public, especially since public markets are more critical of valuations," said Bardon.

Expected interest rate cuts could encourage more companies to test the public markets. "Over the past two decades, we observed an inverse correlation between Fed rates and IPO activity," said Ural. "If Fed rates continue to decline throughout 2025, historical patterns suggest a rebound in the IPO activity."

**Venture capital: increasing Industry oxygen**

Venture capital (VC) investment mirrors the broader market trends: a shift from the 'growth-at-all-costs' mentality of the pandemic era towards more selective, value-focused funding. The narrative for 2024 and into 2025 is strategic realignment, and deep breaths.

Investors are favoring fewer but larger deals, concentrating on companies with assets in later stages of development (phase two and beyond) that have clearer paths to commercialization and are somewhat de-risked. The median venture round size remained high in 2024 and early 2025, often exceeding the US$100 million mega round threshold. "Mega rounds dominated in 2024, with 106 deals far surpassing 2023 totals. These rounds involved large syndicates, where investors not only wrote big checks but also reserved capital for future support. This approach minimized next-round risk but inflated post-money valuations, making future returns uncertain," explained Norris.

Though early-stage (Seed, Series A) deal volume decreased from pandemic highs, it stabilized through 2024. The average deal size, particularly for Series A, increased in 2024. January 2025 saw a strong start with US$3.4 billion in VC funding, up 76% year-over-year.

There is growing optimism for increased exit opportunities in 2025. This provides VCs with needed liquidity and delivers oxygen back to the body. Big Pharma's appetite for innovation is expected to drive M&A, particularly for earlier-stage assets, as buyers navigate premiums for later-stage companies.

While the body is recovering, a healthy heartbeat will be the only way for to survive. It is less about a closed door and more about finding the right key – strong data and a compelling value proposition – to unlock it, said Donna LaVoie, founder and CEO of LaVoieHealthScience, a communications company helping biotechs convey their stories to the market: "Biotech firms often struggle with making their innovations accessible to a wider audience, including investors and policymakers. While specialized investors understand the technical details, most do not have that level of expertise. This is why pharmaceutical companies with broader market appeal attract more investor interest. Biotech firms need to shift from focusing solely on complex science to showing the tangible, real-world impact of their work."

Securing funding is undoubtedly more competitive, demanding strong science, clear milestones, and operational efficiency. However, substantial capital is still flowing into biotech, particularly towards companies demonstrating significant therapeutic potential and addressing unmet needs. This focus on fundamental value, rather than market froth, underscores the sector's enduring health. ■





## Jonathan Norris

Managing Director
**HSBC INNOVATION BANKING**

**What is HSBC Innovation Banking's role in the life sciences?**
We focus on the innovation ecosystem and support early-stage, venture-backed companies in healthcare, technology, and climate tech — from seed stage to public. We offer commercial banking services like deposit accounts, cash management, and foreign exchange, and provide venture debt to help extend companies' equity runway. In addition, we offer expert perspective on the market.

**How has the investment landscape evolved recently?**
In 2024, investors began making new investments, but remained very cautious. Biopharma investment was up, but US$100 million + mega rounds raised most of the capital. Smaller Series A and Series B companies struggled to find new investors, and that trend will likely continue. However, new investment activity picked up in January, especially in biopharma.

Many companies that raised rounds in 2021–2022 turned to insider add-on rounds in 2023–2024. These rounds were smaller and created time pressure to hit value inflection points for future fundraising. In 2025, many of these insider rounds will come to a head. Companies will either bring in new investors or face consolidation and M&A, often under unfavorable terms. Early-stage companies raising smaller rounds will likely continue to face significant fundraising challenges.

**What will it take to restore optimism in the sector?**
Healthy industry activity would include pre-clinical and phase 1 private M&A making up at least 50% of deals. Big pharma and biotech remain eager for early-stage assets and are willing to pay for them. Strong phase 2 data give companies the option to go public or pursue M&A.

Uncertainty remains with a new administration, but the industry's core strengths are intact. The market has normalized compared to the record-setting pace of 2021, and investment is still higher than in 2019. Early 2025 IPOs are performing well, and while "cautiously optimistic" is often overused, it fits the current sentiment. ■

## Arda Ural

Life Sciences Sector Leader
**EY**

**What impact will the 2024 election have on the Life Sciences industry?**
There will be a multi-layered impact of the elections starting with tariffs. Currently at 3%, tariffs could rise to 26% or more. These rates could go higher for China, Mexico and Canada. This would directly impact costs of goods sold for life sciences companies and at a macro level will contribute to inflation in the US. Each company will need to reevaluate the supply chain network. On the regulatory side, the bipartisan BIOSECURE ACT may soon be approved by the Senate with potential modifications in early 2025. This act will increase risks when working with sanctioned companies. While pharma has until 2032 to adjust, this will complicate relationships with CROs and CDMOs, requiring pivots to compliant partners.

**How will macroeconomic trends impact IPO activity and valuations in 2025?**
If Fed rates continue to decline throughout 2025, historical patterns suggest a rebound in the IPO activity.
The Biotech and Pharma ETF indexes reflect pent-up valuation potential influenced by election outcomes and anticipated Fed rate cuts. A sustained high-valuation environment will likely attract more IPOs. The macro picture includes tailwinds such as declining rates, a peaceful transition of power, and evolving FTC policies.

**How will artificial intelligence help the industry overcome the patent cliff?**
Artificial intelligence (AI) and machine learning could be the industry's next breakthrough opportunity. R&D expenses rose from 11.8% of revenue 20 years ago to 18% today, eating into margins. SG&A expenses have remained stagnant at 28% over the past decade, highlighting inefficiencies. AI offers opportunities to reduce costs and enhance productivity through AI-enabled drug discovery and development, potentially driving both top-line growth and bottom-line efficiency. Whether AI can fully address the pipeline imbalance remains to be seen, but it represents the industry's best shot at innovation and recovery. ■

# Disrupting the Dragon Dance

Image courtesy of Clarence E. Hsu at Unsplash

## Decoupling, BIOSECURE and China

The dragon dance is a traditional Chinese dance performed during celebrations like Chinese New Year to ward off evil spirits and bring good fortune. In the pharmaceutical world, the relationship between the US and China is a dragon dance: intricate, occasionally fiery, and requiring immense coordination. It wards off the evil of sickness and this complex choreography has delivered affordable medicines to American shores for years. Recently, the music changed, the tempo is frantic, and President Trump is shouting to cut off the dragon's head.

The US imported US$10.2 billion while exporting US$9.3 billion to China in 2023, according to the Atlantic Council. "Given the interdependence between the US and China for pharma ingredients, services and innovation, a full decoupling would be challenging and could cause disruptions to the US drug supply, especially for generic drugs, the APIs for which are predominantly sourced from China," explained Gil Roth, president of the Pharma and Biopharma Outsourcing Association (PBOA), a trade association representing the contract manufacturing sector.

Roth is right. According to the US-China Economic and Security Review Commission, the US sources 80% of its APIs from overseas either directly from China or countries like India, who rely on China for 80% of its APIs. Chinese manufacturers supply 90 to 95% of the ibuprofen imported by the US and EU, 70% of the global paracetamol supply, and over 80% of key antibiotic APIs.

**Policy Interventions: Tariffs and the BIOSECURE Act**

A March 2025 survey from the Biotechnology Innovation Organization (BIO) found that around 90% of US biotech companies rely on imported components for at least half of their FDA-approved products. While reliance is distributed amongst China and other regions like the EU, the imposition of broad tariffs will delay the pipeline of treatments and reduce access to affordable medicines; 70% of surveyed companies anticipate higher manufacturing costs due to tariffs on China.

While pharmaceutical products were initially spared from the highest reciprocal tariff rates imposed on some Chinese goods in early April 2025 (with rates reaching up to 145% for certain items), a baseline 10% universal tariff remained, and the possibility of future, sector-specific levies persist. Even the threat of tariffs can disrupt planning and increase costs; one earlier analysis estimated that potential tariffs could raise costs for the pharmaceutical, life sciences and medical device sectors by billions annually.

Further complicating the relationship is the BIOSECURE Act. In September 2024, the House of Representatives passed the bill with a 306-81 majority. The act has stalled in the Senate. However, all executives questioned on the matter agree that the bill will be passed in some form, bearing the name BIOSECURE or not. BIOSECURE aims to prevent US federal funding from being used by American companies that contract with designated Chinese 'biotechnology companies of concern', explicitly defined as BGI, MGI, Complete Genomics, WuXi AppTec, and WuXi Biologics.

Companies like WuXi AppTec have been involved in the development of a significant portion—perhaps as much as one-quarter—of drugs approved in the US. WuXi AppTec supported 27% of all FDA small molecule drug approvals from 2023, and 10% of biologics approvals from 2022, according to Jefferies. This does not account for other drugs currently in development. "WuXi's scale and reach create uncertainty, particularly for companies in critical development phases. For early-stage companies still preparing for clinical trials, pivoting from WuXi is possible but costly. Those nearing product filing need to secure approvals while preparing





Jim Donovan
Contract Manufacturing Business Leader
**PFIZER CENTREONE**

> "WuXi's scale and reach create uncertainty, particularly for companies in critical development phases. The greatest risk lies with companies between phase one and three."

was chilling. Early-year inquiries were strong, but then fell silent. The uncertainty spilled into Europe. Potential clients confessed to avoiding China for CDMO services and being offered higher costs and longer delivery times from alternative suppliers while some of our capacity remained idle."

Denying US manufacturers access to Chinese and APAC capabilities would be a major drawback, and many US-based CMOs pivot to China to offset the high US manufacturing costs. "When larger capacity is needed, we can shift production to China, where facilities are built quickly and cost-effectively," said Robert Lee, senior vice president of business development at Particle Sciences.

"Early-phase trials in APAC have given our clients access to faster regulatory timelines and study start-up, large treatment-naïve patient populations, the ability to generate early human data—often even before submitting an IND in the US, and cost advantages that stretch every dollar further," said Rick Farris, managing director of North America for Novotech, a contract research organization with deep roots in APAC.

**A new choreography, not a new dance**

Establishing or expanding domestic pharmaceutical manufacturing capacity requires substantial capital investment. While some large pharmaceutical companies like Johnson & Johnson and Eli Lilly announced investments in US facilities, partly in response to policy pressures, many firms, especially generic drug manufacturers operating with lower profit margins, may find the costs prohibitive. Higher labor costs and regulatory compliance expenses in the US compared to China also contribute to the financial challenge. Increased costs, whether from tariffs or more expensive domestic production, may ultimately be passed on to consumers.

Studies examining the impact of previous tariffs suggest that they did not lead to a large-scale return of manufacturing to the US. Instead, trade patterns shifted, with imports increasing from other countries that themselves maintain significant supply chain links with China. Achieving supply chain independence from China is complex and will result in diversification rather than complete decoupling.

While enhancing domestic manufacturing capabilities and diversifying supply chains are prudent goals for improving resilience and security, a complete decoupling from China would impact millions of lives. Increased costs, delays in drug availability, disruptions to innovation, and the sheer complexity of reconfiguring deeply integrated global supply networks suggest that such a move could be detrimental. A more pragmatic approach involves strategic diversification to reduce over-reliance on any single source, targeted security measures like those outlined in the BIOSECURE Act (implemented with consideration for transition periods), continued investment in domestic capacity, and maintaining collaboration where feasible and appropriate. ■

# Gil Roth

President

**PHARMA AND BIOPHARMA OUTSOURCING ASSOCIATION (PBOA)**

> A lack of investment in R&D over the past two years has already created a gap, delaying projects that might have advanced if funding had been available. This lag will likely disrupt pipelines for years.

**Can you provide an overview of funding trends affecting the CDMO sector?**
Capital continues to favor quicker returns, driving interest toward later-stage assets more likely to be acquired by larger pharma companies or reach commercialization. Early-stage R&D projects face longer timelines, making them less attractive when inflation remains high. If interest rates continue to decline, there could be increased investment in earlier-stage assets, since the potential for long-term gains would improve, but the shift has not materialized yet. A lack of investment in R&D over the past two years has already created a gap, delaying projects that might have advanced if funding had been available. This lag will likely disrupt pipelines for years.

While the Inflation Reduction Act (IRA) does not directly target CDMOs, it influences how pharma companies approach R&D decisions. Under the IRA, Medicare price negotiations start on a fixed timeline post-approval, incentivizing companies to aim for broad initial approvals through large-scale trials. This shift could steer pharma companies away from developing niche drugs or conducting phased clinical trials, opting instead for potential blockbuster products with large patient populations. The long-term effect on CDMOs remains uncertain.

**What are the potential impacts of the Biosecure Act?**
Since the bill has not — and may never — become law, most CDMOs seem hesitant to make major capital expenditures. Pharma sponsors sent out numerous requests for proposals (RFPs) in 2024, but it appears few made definitive moves to shift work from China-based CDMOs to those in other regions.

**How might the Trump administration impact the CDMO space?**
During the previous Trump administration, tariffs targeted many sectors, but pharma ingredients were exempt. To date, this administration will not enact similar waivers, though that may change. Given the interdependence between the US and China for pharma ingredients, services, and innovation, a full decoupling would be challenging and could cause disruptions to the U.S. drug supply, especially for generic drugs, the APIs for which are predominantly sourced from China.

**How have GLP-1s transformed the industry?**
The rise of GLP-1 therapies created a massive market for prefilled syringes and related services like packaging and sterile fill-finish production. Following Novo Holdings' proposed acquisition of Catalent, many CDMOs in the sterile fill-finish sector announced expansions, new capacity, and increased capabilities, signaling a broader industry response. The infrastructure and equipment needed for prefilled syringe production were committed long before the current boom, leaving little room for new entrants.

However, this growth is not just about direct contracts with GLP-1 sponsors. As these products consume significant production capacity at major facilities, other therapies may get displaced, opening opportunities for smaller CDMOs to absorb that business. GLP-1 development continues, with potential monthly-dose formulations. Oral versions remain in the R&D pipeline. If GLP-1 manufacturers shift from prefilled syringes to vials, it could lower device production needs while still requiring GMP compliance. The halo effect of GLP-1 expansion creates new opportunities throughout the industry, making the prefilled syringe market especially lucrative for CDMOs ready to scale.

**What is the potential of AI in the manufacturing space?**
The challenge lies in the need for extensive existing data to train these systems effectively. That data exists for oral solid dosage forms more than it does for other modalities, and since many OSDs are commodity generics, where margins are too thin to justify massive AI investments, this makes AI-driven automation unfeasible. The idea of dark factories—fully automated, human-free facilities—makes sense in reducing contamination risks for aseptic production but remains impractical for advanced therapies like cell and gene treatments. AI could play a larger role in automating manufacturing, though it will likely take years before it significantly impacts high-end pharma production.

**What is PBOA's mission and look-ahead for 2025?**
A focus will be the reauthorization of major user fee acts (UFAs) like PDUFA, GDUFA, BSUFA, and MDUFA, covering pharmaceuticals, generics, biosimilars, and medical devices. Negotiations between the FDA and industry will shape the next five-year UFA agreements, determining industry commitments and funding priorities.

We engage with Congress on supply chain policies, including onshoring, friend-shoring, and reshoring initiatives. Ensuring lawmakers have realistic expectations about the CDMO sector's capacity will be essential. As Congress revisits the 2017 tax bill, we aim to advocate for incentives that support greater domestic investment in pharma infrastructure. ■





> Biotech firms need to shift from focusing solely on complex science to showing the tangible, real-world impact of their work.

# Donna LaVoie

Founder and CEO

**LAVOIEHEALTHSCIENCE**

**What were some key developments for LaVoieHealthScience in 2024?**
Developing and communicating a strong narrative became more important during this time as key issues, including drug pricing, the change in administration and its impact as well as the ongoing impact of Medicare drug price negotiations, were top of the agenda.

A standout success this year came from an important client who achieved significant clinical progress in treatment-resistant schizophrenia. Our client completed a late-stage pivotal program, which the market received positively. Results from a R&D Investor/Partner day in NYC on clinical results helped to deliver on the signing of global licensing partnerships and future growth opportunities.

**How does advancing data affect companies' market success?**
Having a strategic roadmap to how to advance data and technology has become a critical point in company story telling. Having years of the right study data provides a solid foundation for discussions with investors and potential partners. While gathering valuable data is a key step, securing regulatory acceptance and marketing authorization as well as preparing for successful commercial launches remain crucial next steps in the journey. The market can be competitive, and not all drugs that clear regulatory hurdles achieve commercial success. Companies must be ready for these complexities and prepare to navigate them as they move toward full commercialization. It's as much about execution as data itself.

**What is your view on the current market for going public?**
In the past, venture capital firms encouraged companies to go public early in strong market periods to secure quick exits. However, this led to many companies entering the public market without being fully prepared to handle the responsibilities of being publicly traded. Many companies have now become more cautious, delaying their IPOs until they are genuinely ready for the complexities involved. The IPO market in 2025 seems like that of 2024, largely driven by investor sentiment. Without a strong appetite from investors, IPOs in complex sectors, like biotech, will remain subdued until companies in our sector effectively communicate their stories to a broader audience.

**How do strategic communications influence biotech valuations?**
Biotech firms often struggle with making their innovations accessible to a wider audience, including investors and policymakers. While specialized investors understand the technical details, most do not have that level of expertise. This is why pharmaceutical companies with broader market appeal attract more investor interest. Biotech firms need to shift from focusing solely on complex science to showing the tangible, real-world impact of their work.

Strategic communications will be key in shaping biotech valuations, achieving reimbursement and acceptance. Finding the balance between appealing to the public and institutional investors will be a challenge, much like trying to balance a recipe with the right mix of ingredients for the perfect dish.

**How has AI impacted the biotech industry, and how are companies adopting it?**
AI has begun to make a significant impact across several areas of the biotech industry, from drug discovery to precision medicine and diagnostics. We are seeing how AI can help identify targets for treatment and personalization therapies in the field of precision medicine. In business operations, AI tools also play a supportive role by summarizing meetings and information. While these tools are becoming more widely used for research purposes, strategy development and interpretation will remain the highest value on the chain. Many of our clients started exploring collaborations with pharmaceutical companies to integrate AI technologies. The full impact of AI adoption in biotech remains to be seen and we will have many learnings in years to come.

**What is your outlook for the healthcare industry in the coming years?**
The healthcare industry is undergoing significant transformation, particularly with the new administration in the United States. While systemic challenges are being addressed, the demand for healthcare and medicines remains constant, ensuring that healthcare innovation continues to be a priority.

At LaVoieHealthScience, our strategy for the coming years focuses on leveraging current market conditions and bringing in the right talent to drive business growth. Talent is essential to delivering high-quality advisory services and effectively solving client challenges. Recruiting and retaining top-tier talent will remain central to our approach, enabling us to support our clients' success while navigating the evolving healthcare landscape. By staying focused on these core objectives, we remain positioned to help our clients grow and succeed. ■

# Amazonification Effect

## How patient centricity is changing pharma logistics

Precision medicine is precisely the future of healthcare. By stratifying patients based on genomic and phenotypic variations, it addresses the diverse ways individuals respond to treatments. Personalized medicines accounted for 38% of new FDA drug approvals in 2023, with oncology leading the charge. Unlike traditional mass-market drugs, personalized therapies require patient-specific formulations, dosages, packaging and delivery. They are high-value, temperature-sensitive products that are transforming the industry from the lab up. "These therapies are driving direct-to-X models, including direct to patients, hospitals and pharmacies", explained Raphaël Chin-Fo-Sieeuw, vice president of life sciences and healthcare Americas at DHL.

This evolution demands a radical shift in supply chain design. Logistics must now accommodate not only the stringent cold chain requirements of these advanced therapies but also the increasingly consumer-like expectations of patients. The convergence of personalization and patient centricity is creating unprecedented demands—but also unprecedented innovation—in pharma logistics.

**Delivering Precision**

For many years, pharma followed a one-size-fits-all approach to medication. Today, that paradigm is shifting rapidly toward specialty pharmaceuticals and biologics, said Chin-Fo-Sieeuw: "Pharmaceutical companies are increasing their focus on biopharma and specialty pharma, with many divesting from consumer healthcare and generics businesses."

In the US, the market for personalized medicine is expected to expand from US$179.66 billion in 2024 to US$400.46 billion by 2034. Biologics and cell and gene therapies underpin the personalization market. "Cell and gene therapies are having a significant impact on traditional pharma logistics," said Fabrice Panza, manager of global cool chain solutions at Etihad Cargo. "These therapies influence packaging requirements, physical and documentation flows, and the capacity needed to track highly valuable products," Panza continued.

They also require cold storage solutions, which has led to the growth of the segment: "The cold chain logistics industry is growing at over 25% per year due to the increasing number of temperature-sensitive products coming to market," explained Richard Etll, CEO and co-founder of Skycell.

Regulations are tightening, and efficacy standards are becoming more demanding. This adds further pressure to logistics providers to deliver at higher standards—faster, safer and smarter. "The industry must invest in specialized infrastructure to handle the evolving supply chain needs, especially for small, time-sensitive shipments like personalized medicine with short shelf lives," said Trevor Caswell, chair of Pharma.Aero, a collaboration platform bringing together cargo firms and life sciences companies.

To address these challenges, logistics companies are deploying digital technologies and artificial intelligence at scale. Both Etihad Cargo and SkyCell partnered with Validaide, an advanced digital platform for pharma lane management, to enhance the transparency and efficiency of their pharmaceutical supply chains. Etihad Cargo aimed to streamline its cold chain operations, while SkyCell leveraged the partnership to further validate its container solutions and ensure compliance with global pharma logistics standards.

SkyCell is also launching an AI-driven monitoring tool in partnership with Microsoft to oversee shipments in real time. "Our AI agent monitors shipments automatically, using machine learning to help prevent damage that could affect shelf life or efficacy," explained Etll.

This innovation is vital as personalized medicine rises in prominence. Every lost or damaged pallet can mean millions of dollars in loss—not to mention potential delays in treatment for patients with life-threatening conditions.

**Fusing personalized medicine and patient centricity**

In the traditional model, the patient is at the end of the supply chain, following discovery, development, production and distribution of prescription drugs. That model is rapidly being upended. Today's patients expect more—and they are getting it. 71% of consumers expect companies to deliver personalized interactions, research from McKinsey showed. While this insight applies broadly to consumer markets, it increasingly applies in healthcare too. An Accenture survey revealed that patients want to be valued as consumers and receive the same level of responsiveness, attention and convenience from healthcare providers that they receive from prominent consumer brands.

One company has arguably set the standard for this kind of responsiveness: Amazon. Now, Amazon is turning its attention to healthcare. "Amazon is not just acquiring companies, but entire ecosystems—buying hospitals, pharmacies, logistics and even aircraft. This model of integration and patient-centeredness is the future of healthcare, and Amazon's expertise in this approach is reshaping the industry," said Frank Van Gelder, secretary general of Pharma.Aero.

Amazon's foray into healthcare started in 2018 in a partnership with Berkshire Hathaway and JPMorgan Chase to create a nonprofit company to examine ways to improve US employee satisfaction in healthcare while reducing costs. "The healthcare system is complex, and we enter into this challenge open-eyed about the degree of difficulty," Jeff Bezos, Amazon founder and ex-CEO stated in the 2018 press release. "Hard as it might be, reducing healthcare's burden on the economy while improving outcomes for employees and their families would be worth the effort. Success is going to require talented experts, a beginner's mind, and a long-term orientation."

The Amazonification of healthcare is not just about speed and convenience—it is about placing the patient at the heart of every decision. As personalized medicine continues to grow, logistics will become an even more strategic function within the pharmaceutical industry. ■





## Frank Van Gelder

Secretary General
**PHARMA.AERO**

**How can the healthcare industry ensure a more resilient supply chain?**

The industry must invest in specialized infrastructure to handle the evolving supply chain needs, especially for small, time-sensitive shipments like personalized medicine with short shelf lives. It is not just about what can be done today, but how to adapt and improve processes, SOPs, and resources to support new requirements. Companies must accept the inevitability of digital transformation and invest in specialized facilities to sustain the future of healthcare logistics.

**How are e-commerce models changing pharmaceutical logistics?**

The term "Amazonization" captures the shift to e-commerce where the customer, or in healthcare's case, the patient, is at the center and has a voice in their therapy and how it is delivered. The key difference with Amazon is that it is not just acquiring companies, but entire ecosystems—buying hospitals, pharmacies, logistics and even aircraft. This model of integration and patient-centeredness is the future of healthcare, and Amazon is reshaping the industry. ■

## Raphaël Chin-Fo-Sieeuw

VP Life Sciences and Healthcare Americas
**DHL GROUP**

**How is the life sciences industry evolving, and how will DHL remain relevant amid changes?**

Patient centricity is reshaping the logistics supply chain and the life sciences industry. Advanced therapies, biopharma growth and the rise of digital healthcare are driving major changes. Pharma companies are increasingly focused on direct patient engagement through digitalization, while predictive analytics and evolving ecosystems are transforming the landscape. New players are entering the space, including tech companies becoming medical device providers through wearables. Two other key forces shaping the industry are sustainability and resilience. The pandemic highlighted the critical need for supply chain resilience, making it a boardroom priority. This is driving strategic decisions around nearshoring, capacity expansion, and innovation.

**What is the focus for 2025 for DHL?**

With Strategy 2030 released last year, identifying capability gaps and investment opportunities is now the priority. The company is closely tracking market trends and the evolving logistics and trade landscape. Life sciences will be a major focus and is an area where we expect growth. ■

## Fabrice Panza

Global Cool Chain Solutions Head, GDP Pharma Responsible Person
**ETIHAD CARGO**

**What are highlights from 2024 for Etihad Cargo, and PharmaLife specifically?**

2024 was a record-breaking year, marking the fifth consecutive year of double-digit growth. PharmaLife has been the strongest-growing segment of Etihad Cargo's special products since 2020. Two factors are driving this growth: the overall expansion of the healthcare and life sciences industries, and our targeted investments in this sector. In 2024, we introduced cool dollies, completing our product offering.

**How does Etihad use technology to optimize flights and PharmaLife workflows?**

We are also partnering with Validaide, an advanced digital platform for pharma lane management that supports our risk assessment capabilities, while Envirotainer provides cutting-edge ULD technology. Their ULDs are equipped with the latest generation of sensors, including RelEye, which collect data on location, temperature and humidity. We use this data for predictive analysis and to validate the sustainability of our processes. Other partners, such as Csafe and Skycell, are also investing significantly in IoT to enhance real-time visibility. ■

# HUBS

> Competition is good. More great life sciences clusters mean more innovation reaching those who need it most.

Ben Bradford
Head of External Affairs
**MASSBIO**

GBR Series
UNITED STATES LIFE SCIENCES 2025

Image courtesy of Tierneyat Adobe Stock

# The Birthplace of Biotech

## A spotlight on California's innovative clusters

For many, the name California conjures images of agriculture, Hollywood filmmaking, wine making, or tourism, yet, according to Tim Scott, the new president and CEO of Biocom California: "Even combined, the output of these four well-known industries does not match the massive, vital industry that is the California life sciences sector… From the cross-pollination opportunities between tech and biotech companies in the Bay Area, to the unsung med-tech sector in Orange County and the highly collaborative San Diego ecosystem that spawns hundreds of new companies each year, all are found here."

**The Bay Area: A golden bridge between biotech and tech**

The San Francisco Bay Area stands as a pivotal nexus where biotechnology and technology converge. Being at the heart of both biotech and tech, San Francisco makes it near impossible for the two industries not to rub against each other, and when they do, a spark ignites, setting fire to the pharmaceutical landscape. Over 40% of life science startups in the region incorporated AI or machine learning in their core technology in 2023, according to Foothold America.

Proximity to world-class research institutions like UCSF, Stanford and UC Berkeley ensures a steady flow of cutting-edge discoveries and collaborations. These institutions collectively filed over 600 biotech-related patents and received US$2.4 billion in NIH funding in 2023 alone. South San Francisco hosts over 250 biotech companies within 12 million square feet of dedicated space, making it one of the largest biotech clusters globally. This interconnected network fosters partnerships between startups, established firms and academic research centers, driving innovation in areas like synthetic biology, gene editing and software as medical devices.

QB3, one of four California Institutes for Science and Innovation, currently runs the Bakar Bio Labs incubator, and will launch an additional two in the coming years. "Computation, data science, machine learning and artificial intelligence are increasingly playing a larger role in biotech," said David Schaffer, director of QB3. "Within our first incubator, we have seen an increasing number of companies working at the interface of machine learning and biotechnology."

Venture capital plays a pivotal role in sustaining this growth. In 2024, life sciences companies in the Bay Area raised US$7.7 billion in venture capital across 79 deals, reflecting a slight increase from US$7.5 billion in 2023.Investors in the Bay Area are known for their risk tolerance and long-term vision, enabling early-stage companies to secure 40% more seed funding than the national average in 2023. This financial ecosystem supports the rapid adoption of AI/ML technologies across drug development stages—from patient stratification in clinical trials to optimizing pharmaceutical manufacturing processes.

The Bay Area's culture of innovation is further exemplified by initiatives like Biocom California's 'Converge,' which connects leaders from tech and life sciences to accelerate breakthroughs in healthcare solutions. Companies such as NVIDIA, Insitro and Tempus AI are spearheading efforts to harness big data for drug discovery, wearable diagnostics, telehealth improvements and implantable technologies. As biotech firms continue to integrate Silicon Valley's computational expertise into their operations, they are reshaping traditional paradigms of drug development while addressing global healthcare challenges.

**Orange County: An unsung medtech leader**

The county employs over 65,000 individuals across more than 2,000 life sciences and biotechnology establishments. Notably, it is recognized as the 'Medical Device Capital of the World,' with over 20,000 professionals in the field. The region leads in optical instruments manufacturing, employing nearly 3,300 people, nearly twice that of the next largest region.

Orange County's life sciences sector directly contributes US$46.4 billion to the regional economy, reported in Biocom California's 2024 Life Science Economic Impact Report.

**San Diego: A biotech spawning ground**

San Diego's life sciences sector is renowned for its collaborative ecosystem, fostering the growth of numerous startups. The region is home to nearly 2,000 life science-related companies, providing approximately 76,000 direct jobs and generating an annual economic output of US$56 billion. "The local environment is rich with startups and innovation, allowing Wacker Biotech to engage with early-stage companies and foster collaboration. The political emphasis on local manufacturing benefits our growth in the region," said Philippe Cronet, general manager at Wacker Biotech, a CDMO based in the city.

The proximity to Tijuana, Mexico's medical device manufacturing hub, further enhances San Diego's manufacturing capabilities, offering a highly skilled workforce and additional resources. At 12.3% annually, San Diego also boasts the nation's strongest life sciences employment growth in the US, according to CBRE's 2025 US Life Sciences Outlook.

**Los Angeles: Overcoming biotech homelessness**

Los Angeles has experienced significant growth in its life sciences sector, with the number of establishments in LA and Ventura counties increasing from 1,238 in the first three quarters of 2019 to 3,442 in the same period of 2023, more than doubling over five years. The region's life sciences sector generated an economic output of US$66.9 billion in 2023 and employed more than 95,913 people. As testament to biotech's continued growth, demand for life science real estate outstripped supply in 2024. While rents in Boston and San Francisco dropped 8% and 2% in the past year, driven by high availability rates, demand for life science in LA was more than double supply, contributing to a 6% rent increase in the first half of 2024. LA led the nation in converting office spaces to lab and R&D facilities, with over 667,000 square feet repurposed in Q1 2022, a 339% increase from the previous year.

With unmatched diversity, deep talent pools, and serious investment, the Golden State is not just part of the biotech conversation—it is setting the pace. ■

> We have recognized the synergies between the life science and tech industries, and have worked to foster relationships that can accelerate therapeutic, medical device and diagnostic development.

# Tim Scott

President and CEO

**BIOCOM CALIFORNIA**

**How does Biocom California support industry growth?**
We have developed programs in five key areas that support our industry: advocacy in our local communities, Sacramento and Washington DC; cost-saving through our purchasing group; workforce development; fundraising; and networking.

We organize a number of events focusing on connecting earlier stage companies with potential large pharmaceutical partners and investors. Biocom's annual Global Partnering and Investor Conference draws 500 attendees and more than 200 VCs and pharma business development leaders looking for opportunities.

Another example of a member benefit is the work done through our Biocom California Institute to meet the workforce needs of life science companies. We have fostered the development of innovative curricula at the community college level that are designed to teach individuals the skills needed to enter the biomanufacturing workforce. With recent trends pointing to onshoring many life science jobs that had been taken offshore, a ready workforce will be essential to meeting the hiring needs of our members.

Finally, we recognize the synergies that exist between the life science and tech industries and have worked to foster relationships that can enable the acceleration of therapeutic, medical device and diagnostic development. This work led to Biocom's Converge Summit, which focuses on the intersection of life science and technology – much of it driven by AI/ML.

**What makes California a powerhouse in the life sciences industry?**
California is the birthplace of biotech, and the state's industry has continued to evolve and grow in its main clusters: Los Angeles, Orange County, the Bay Area, and San Diego. Each of these clusters has distinct strengths, from the cross-pollination opportunities between tech and biotech companies in the Bay Area, to the unsung med-tech sector in Orange County, to the highly collaborative San Diego ecosystem that spawns hundreds of new companies each year.

Funding for California institutions from the National Institutes of Health and the National Science Foundation creates a launchpad for innovation, enabling the basic research discoveries that become the new technologies that drive California life sciences growth. In 2023, California received more than US$6 billion in NIH and NSF funding, the highest amount of any state in the US.

Also important to California's success is the state's mature venture capital community, which is investing billions of dollars every year - US$34 billion in 2023.

Today, the industry's total economic output exceeds US$400 billion and supports 500,000 high paying direct jobs. California leads the nation in agriculture, Hollywood filmmaking, and wine production, and is third in tourism. Even combined, the output of these four well-known industries does not match the massive, vital industry that is the California life sciences sector.

**How did JPM set the tone for 2025's M&A activity?**
The mood at this year's JP Morgan conference M&A activity was electric. Three major deals were announced on just the first day: Johnson & Johnson's purchase of Intra-Cellular Therapies, Eli Lilly's acquisition of Scorpio Therapeutics, and GSK's purchase of IDRK, setting the tone for a potentially big year for M&A. These deals highlight how important the entrepreneurial life science sector is to providing large pharmaceutical with innovative therapies and technologies to fill their pipeline. With an upcoming patent cliff – the top 10 drugs expected to go off patent in 2025 represent over US$25 billion in 2024 sales, and another US$400 billion over the next decade —companies will seek new technologies, driving even more M&A activity.

**How does the IRA impact drug pricing and development strategies?**
The IRA is prompting pharma companies to find ways to raise efficiencies during the drug development process, resulting in reduced costs. For example, in clinical trials, which are the most expensive part of drug development, companies are utilizing AI-driven platforms and other technologies to accelerate trial enrollment and identify patients faster.

**Is the new administration in Washington DC going to adversely affect biotech?**
Certainly tariffs, NIH funding cuts and reduction in FDA staff can have a negative effect on biotechnology, pharma and medical device development. Appropriately staffed and well-resourced federal agencies are needed to support the life science ecosystem. Tariffs on imported goods may increase manufacturing costs, disrupt supply chains, and increase prices for consumers and patients. ■






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# Life, Liberty, and the Pursuit of Innovation

## The Northeast leads a new American revolution in life sciences

In the spirit of the original 13 colonies, a new revolution is underway, this one fought not with muskets, but with molecules. The life sciences industry has become the battleground for global innovation, and the Northeastern states—Massachusetts, New Jersey and Pennsylvania—are the patriots defending their turf. While challengers from across the globe rally for a foothold, these states are doubling down on what made them powerful in the first place: World-class institutions, public-private alliances and a relentless pursuit of scientific advancement. These are not just states; they are the founding fathers of America's life sciences dominance, proving that the birthplace of American independence is still where the future is forged.

**Massachusetts: The first to fight**
In the Commonwealth of Massachusetts, the common derived wealth is from the state's burgeoning life sciences sector—every dollar invested in research returns US$2 to US$3 in economic activity for the state. A commonwealth is defined as a political community founded for the common good; Massachusetts, therefore, is a commonwealth of the global life sciences industry. Massachusetts companies comprise 15.2% of the national drug development pipeline and 6.4% of the global pipeline.

In 2023, the state's biopharma industry added nearly 3,000 net new jobs, accounting for approximately 17% of the state's overall job growth, despite representing only 3.7% of the workforce. Massachusetts only lags California by 900 R&D jobs, despite being six times smaller.

Massachusetts is the bosom of biotech. Two Massachusetts-headquartered biotechs—Rapport Therapeutics and Fractyl Health—went public in 2024, matching the total for all of 2023, despite the total number of IPOs dropping from 19 to 17. R&D programs of companies receiving VC funding were focused on oncology (34%), central nervous system (12%) and anti-infectives (11%). In H1 2024, 95 Massachusetts companies received 95 rounds of funding. The average Series A round was US$57.8 million – up from US$50.9 million in 2023. "With just 2% of the nation's population, the state pulled in nearly 30% of the country's venture capital funding in 2024, second only to California, which is six times its size," emphasized Ben Bradford, head of external affairs at MassBio.

In November, Governor Healey signed the Mass Leads Act into law, further strengthening the state's position. Massachusetts committed US$500 million over 10 years to its life sciences sector through the Act, boosting annual tax incentives from US$30 million to US$40 million to attract companies and create jobs. In December 2024, the state launched the third iteration of the Life Sciences Initiative (LSI), that will inject the industry with a US$500 million capital investment over the next decade. When LSI was originally passed in 2008, seven out of the top 20 pharma companies had a physical presence in the state; now 18 out of 20 do. "The innovation is here. Industry, academia and government collaborate," said Bradford.

**New Jersey: The crossroads of the revolution**
Historically named the Garden State, New Jersey is blossoming into the 'Garden of Eden' State in the life sciences, offering a fertile ecosystem for the industry to thrive and flourish. "New Jersey is home to eight of the top 10 global biopharmaceutical companies, nine of the top 10 R&D firms, and over 5,600 life sciences establishments. With nearly 120,000 jobs and a US$121 billion economic output, these assets drive scientific progress and groundbreaking healthcare technologies. The state accounted for 43% of all novel FDA approvals in the past two years," summarized Debbie Hart, president and CEO of BionNJ.

Walk the streets of Newark or Princeton and odds are every person you meet either works in the life sciences industry or knows someone who does. The state has the highest concentration of engineers and scientist per square mile in the country. New Jersey also boasts more biomanufacturing facilities than any other state and has 22 million square feet of lab space, which, in total floor area, is roughly the size of nine Empire State Buildings. There are millions more square feet for purchase and the ongoing and planned construction of life sciences campuses and hubs puts that number on pace to increase 27% by 2026.

New Jersey has become a cell and gene therapy hub, with 40% of all therapies in development taking place in the region. Cellares, a San-Francisco-born cell therapy manufacturer, elected in January 2024 Somerset County for its new 118,000 square foot manufacturing site in Bridgewater. The state is committed to continuing its lead in cell and gene therapies with the launch of NJBioFutures

in February 2025. The public-private workforce development coalition, launched by Johnson & Johnson and the New Jersey Council of County Colleges, aims to develop a skilled talent pipeline that meets the evolving needs of the cell and gene therapeutics sector. Novartis, Quva Pharmaceuticals and Tevogen are all part of the initiative.

In February 2025, the New Jersey Economic Development Authority and the Coriell Institute for Medical Research announced a US$41 million investment to create a Strategic Innovation Center to support biomedical research and innovation with an incubator and laboratory spaces for emerging biotech companies. "My Administration has been laser-focused on advancing New Jersey's innovation economy through targeted investments in our most crucial industries and sectors," stated Governor Phil Murphy.

**Pennsylvania: The liberty lab**

Pennsylvania's life sciences industry is primed for major growth and cutting-edge innovation. Leading institutions like the University of Pennsylvania, the University of Pittsburgh and Penn State each invest more than US$1 billion annually in research and development. Collectively, the state's colleges and universities rank fourth nationwide in life sciences R&D spending. More than 100,000 Pennsylvanians are employed in the sector, at standout companies such as Krystal Biotech in Western PA, Spark Therapeutics in Philadelphia, GSK in Lancaster County, and many others.

To build on momentum, Governor Shapiro's proposed 2025 to 2026 budget includes a US$65 million boost in innovation funding, with an additional US$30 million earmarked for life sciences. These investments are designed to accelerate data sharing, support the commercialization of scientific discoveries and attract new business to the state. The funding would also help match private venture capital, making Pennsylvania a competitive hub for biotech while increasing support for entrepreneurs.

Improving infrastructure and fostering collaboration between academia, pharmaceutical companies, governments and incubators will be essential. States like Texas and Massachusetts heavily invested in life sciences, and Pennsylvania has the potential to follow suit under its Governor Shapiro, who prioritizes the sector, according to Louis Kassa III, CEO of the Pennsylvania Biotechnology Center, a non-profit incubator in the state: "With greater infrastructure investment, Pennsylvania could become a top-three state in the field. Pennsylvania's strong academic institutions and research organizations position it to lead in biotech."

From Boston's biotech boom to Jersey's gene therapy renaissance and Philly's pharma-powered resurgence, the Northeast has planted its flag. These states are not content to watch the life sciences revolution unfold—they are leading it. With strategic investments, robust ecosystems and unwavering civic support, the patriots of the industry are holding their ground. And just like the tea that once spilled into Boston Harbor, the ripple effects of their innovation are being felt around the world. ■







# Debbie Hart

President and CEO
**BIONJ**

> New Jersey is home to eight of the top 10 global biopharmaceutical companies, nine of the top 10 R&D firms, and over 5,600 life sciences establishments.

**How have trends and regulatory changes impacted life sciences investments and priorities?**

In 2024, the life sciences industry faced challenges, particularly around funding, largely due to the closed IPO window. The Inflation Reduction Act (IRA) notably impacted small molecules and rare diseases, leading companies to reassess investment strategies. A particular concern has been the reduction of patent life for small molecules, which is now nine years compared to the 13 years for large molecules. This shift discouraged investment in small molecule therapeutics, delaying or even halting the development of vital therapies.

Companies are adapting their investment portfolios to align with the new frameworks, especially given the high cost of drug development and regulatory uncertainty. This environment is leading many to refocus their investments on therapeutic areas with clearer regulatory pathways or those less impacted by the IRA. Companies are shifting operational priorities toward areas with higher confidence in regulatory approval. New Jersey continues to support these shifts with initiatives that foster growth, such as its US$16 million investment in innovation hubs like the HELIX and SciTech Scity, and the collaboration with Princeton University on AI, reinforcing the State's commitment to maintaining a strong, innovation-driven life sciences sector.

**What is New Jersey's market share in emerging technologies?**

New Jersey is a leader in gene therapy, driving 40% of all cell and gene therapies currently in development. The State is home to pioneering companies such as Celularity, specializing in cell-based therapies, and Legend Biotech, advancing CAR-T cell therapies for cancer treatment. With these innovations, New Jersey is playing a pivotal role in shaping the future of gene therapy.

Additionally, New Jersey boasts more biomanufacturing facilities than any other state. Companies like Cellares, an innovative leader in cell therapy manufacturing, are expanding the State's capabilities with their new 118,000-square-foot "Smart Factory" in Bridgewater.

The launch of an AI hub, announced by Governor Phil Murphy in partnership with Princeton University, positions New Jersey as a leader in leveraging AI to fuel scientific and industrial innovation. Notably, CoreWeave, a leading AI company, recently joined as a founding member of the new AI hub, alongside Microsoft.

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**What factors drive New Jersey's life sciences leadership?**

New Jersey has firmly established itself as a powerhouse in the life sciences industry, fueled by substantial investments from both the state government and the private sector. With world-renowned universities and research institutions producing a highly skilled workforce, the State offers an unmatched ecosystem for innovation and growth.

The State's investment in ResearchWithNJ.com connects companies with cutting-edge research at New Jersey universities, fostering partnerships and driving innovation to accelerate scientific and technological progress.

The New Jersey Economic Development Authority also plays a vital role in supporting this dynamic sector, offering essential financial incentives, tax credits and resources that encourage expansion. For example, the New Jersey Commission on Science, Innovation and Technology has delivered 400 awards totaling close to US$20 million since 2020 — resulting in investment in 274 start-ups supporting 558 new jobs.

This along with the creation of cutting-edge innovation hubs such as HELIX, NEST, SciTech Scity and ON3 underscore the State's unwavering commitment to advancing the life sciences.

**What are BioNJ's priorities for the next 24 months?**

We remain adaptable and proactive, particularly as we anticipate potential shifts in government policies. A key focus is the ongoing impact of the IRA, which we are actively monitoring. We are committed to enhancing transparency around Pharmacy Benefit Managers (PBMs) and advocating for reforms that promote fairness. Additionally, we are addressing the complexities of the 340B Drug Pricing Program to ensure that funds are allocated to Patients and that therapies are delivered efficiently.

BioNJ is dedicated to keeping New Jersey at the forefront of the biopharma industry, ensuring it remains an ideal hub for growth, collaboration and success. ■

# Ben Bradford

Head of External Affairs

**MASSBIO**

> It is the Massachusetts story — early-stage companies developing great science, commercial giants with a local presence, and financial partnerships that turn ideas into treatments.

**How has the life sciences ecosystem in Massachusetts evolved over the past year?**

The funding environment was slow. We saw an uptick in venture capital funding for Massachusetts companies throughout 2024. This momentum has carried into 2025, with a strong start for venture funding in the state.

MassBio released the Vision 2030 report — a five-year strategic plan to ensure Massachusetts remains the global leader in life sciences. We continued to support early-stage innovation through MassBioDrive, our accelerator program. We hosted our second annual Align Summit. Massachusetts remains the best place in the world for research and development, and MassBio stands committed to supporting it.

**What is the current state of venture funding in Massachusetts?**

2024 venture capital funding exceeded 2023. We saw many mega rounds, with 48% of all VC funding for Massachusetts companies concentrated in the top 20 rounds of the year. We saw six IPOs in 2024, up from two in 2023. In 2025, I am encouraged by IPOs and M&A. My hope is exits will free up capital for investors to reinvest in early-stage science — seed, pre-seed, and Series A — where funding is most needed.

**What makes Massachusetts a life sciences leader?**

With just 2% of the nation's population, the state pulled in nearly 30% of the country's venture capital funding in 2024 — second only to California, which is seven times its size. Massachusetts also holds 15% of the nation's drug pipeline, which does not account for the large, non-Massachusetts companies developing here. International companies come here to set up a physical presence or partner with early-stage research for licensing and acquisitions.

When the first Life Sciences Initiative passed, only seven of the world's top 20 pharma companies had a presence. Now, 18 have physical offices. Industry, academia, and government collaborate. Early-stage and commercial companies partner to turn ideas into treatments. Without that collaborative spirit, Massachusetts would not lead the way it does today — and patients would not benefit from the life-changing advancements happening here.

Take the story of Bristol Myers Squibb and Karuna Therapeutics. Bristol Myers Squibb came to Massachusetts and acquired Karuna. That partnership led to the first major advancement in schizophrenia treatment in decades. It is the Massachusetts story — early-stage companies developing great science, commercial giants with a local presence, and financial partnerships that turn ideas into treatments.

**As competing states work to attract biotech companies with generous incentive programs, how will the State stay a leader?**

In 2024, the state approved the third reauthorization of the Life Sciences Initiative, securing continued funding for the industry. That includes grants for non-profits, tax incentives for hiring companies, and early-stage capital to help de-risk companies and attract venture funding.

Competition is good — especially for patients. I am confident Massachusetts will remain the leader, but the stronger the competition behind us, the better it is for everyone.

**What impact do you see the new administration having on Massachusetts?**

A strong, predictable business climate will help companies and investors understand what to expect — and that will drive more investment. Additional rate cuts would help. A new FTC with more flexibility on M&A could also spark growth. If these changes happen, I expect the industry to pick up quickly.

Massachusetts relies on NIH funding more than almost any other state. While cuts do not immediately impact industry, long-term reductions in research funding slow the creation of new companies. Fewer companies mean less innovation and fewer clinical trials —delaying life-changing treatments for patients. Protecting research funding is critical for the future of life sciences.

**How is MassBio preparing its members for the industry of the future?**

We cannot take our eye off where the future is going — and that future includes AI for drug discovery. AI has the potential to speed time to market and personalize medicine in powerful ways. MassBio ensures our member companies get the education they need to use AI in drug development. We are also backing early-stage companies with AI at their core, including a dedicated MassBioDrive cohort for AI-driven drug development.

As international relationships grow more complex, we want Massachusetts to be a place where companies feel confident producing medicine. It may not always be large-scale, but for small-batch or clinical-scale manufacturing — especially for cell and gene therapy (CGT) and advanced modalities — Massachusetts has the infrastructure and expertise. ■

> Better alignment between institutions and industry can drive innovation, scientific progress, and economic growth in the coming years.

# Louis P. Kassa III

CEO

**PENNSYLVANIA BIOTECHNOLOGY CENTER (PABC)**

**What are recent developments at PABC and what sets your incubator apart?**
We are collaborating with the Blumberg Institute on a yellow fever therapeutic in partnership with the NIH, leading to the establishment of a drug development division. Our labs are operating at full capacity, and as larger companies graduate, we are filling vacancies at B+labs with early-stage companies. Another milestone is our involvement in the Biogenesis Research Park, a new campus on Long Island, NY, that would be the largest government-supported cell and gene therapy initiative in the US. This project is set to become a major biotech hub, featuring an on-site CDMO, a robust incubator, and space for company growth.

This incubator is part of our broader strategy to expand our network, with plans to establish more incubators over the next few years, strengthening connections between Pennsylvania and New York. Unlike typical incubators that push companies out after a few years, we maintain ongoing connections. Many biotech companies in our incubator reach IPOs or acquisitions in an average of 3.5 to 4 years, faster than the industry average of 8.5 years.

**How have recent biotech trends affected operations?**
The surge in VC investment from 2021 has not been matched by returns, leaving many companies to focus on just one or two technologies to extend their runway. In the lab space, vacancy rates have been concerning. It is a sign of less abundant VC funding. There is optimism that by mid to late 2025, things will pick up.

**What role do incubators play in the industry?**
Incubators are crucial in supporting biotech companies, especially during slower phases. We provide nonprofit support, programming services and assistance in securing funding through a network of venture capitalists, angel investors and state funds. Most venture capital is directed towards larger, more established biotech firms, leaving early-stage companies struggling to secure investment. While the science has always been present, the investment has not followed due to concerns about scaling labs and interest rates. There needs to be more investment from venture capitalists or targeted state funding to support smaller companies.

**What projects at your center show promise in biotechnology?**
Our scientists are developing what could become the world's first yellow fever therapeutic. Hepatitis B remains our primary mission, and we are determined to find a cure. There is promising news from local biotech companies like Arbutus, which we have supported from its early days, and Virion Therapeutics, a company developing new treatments using CRISPR technology. Even though big pharma companies are scaling back their investments in hepatitis B after the success with hepatitis C, smaller companies and our research continue to push forward.

**How do you see Philadelphia's biotech future and the evolution of technology?**
The Philadelphia region, and Pennsylvania, are at a crossroads in biotechnology, transitioning from small molecule drug development to advanced cell and gene therapies. At our Doylestown facility, we focus on small molecules, while our Philadelphia labs are deeply involved in CAR-T therapies and CRISPR-based gene editing. AI has become a game-changer in biotechnology. We launched an AI company which helps those unable to afford the large AI contracts that big pharma can access.

**How can Pennsylvania enhance its biotech profile?**
Improving infrastructure and fostering collaboration between academia, pharmaceutical companies, governments and incubators is essential. States like Texas and Massachusetts have heavily invested in life sciences, and Pennsylvania has the potential to follow suit under its new governor, who prioritizes the sector. Investments in infrastructure should reduce lab vacancy rates and create growth opportunities. With greater infrastructure investment, Pennsylvania could become a top-three state in the field. Pennsylvania's strong academic institutions and research organizations position it to lead in biotech. Better alignment between institutions and industry can drive innovation, scientific progress, and economic growth in the coming years.

**What are PABC's growth plans?**
We are expanding beyond Pennsylvania into biotech hubs like California, New York and New Jersey to foster collaboration, strengthen our brand, and support hepatitis B research. Partnerships with institutions such as UCLA, Caltech, USC, Rockefeller, and NYU drive innovation. Our academic foundation sets us apart, with programs for high school, masters and fellowship students engaging 100 students each summer in Doylestown and expanding in Philadelphia. ■





# Mitochondrial Hubs

## Emerging powerhouses of the US

In the body, mitochondria produce energy to power the body; across the US, a new wave of cities is doing the same for life sciences innovation. As the sector expands beyond legacy markets like Boston and San Francisco, regions like North Carolina, Ohio, Texas and Colorado are emerging as vital hubs of discovery and development. For areas to put their names on the life sciences map, three key factors will come into play in 2025: Access to a talent pool, funding that allows commercialization potential, and a strong real estate infrastructure to support growth.

**North Carolina: That Research Triangle Park spark and beyond**
North Carolina (NC) ranks as the fourth largest biotech hub in the US, with over 830 life sciences companies employing more than 75,000 people. The industry generates US$88 billion annually in economic impact and contributes US$2.4 billion in state and local tax revenue, according to Brookings.

The state secured more than US$10 billion in life sciences investments in 2024. Novo Nordisk announced a US$4.1 billion expansion in Johnston County to enhance production of semaglutide, the active ingredient in its weight-loss drugs Ozempic and Wegovy. Amgen committed to a US$1 billion expansion in Holly Springs, establishing a second drug substance manufacturing facility. Johnson & Johnson invested over US$2 billion in Wilson County to build a new pharmaceutical manufacturing campus. FUJIFILM Diosynth Biotechnologies will invest US$1.2 billion to expand its contract manufacturing facility in Holly Springs. As testament to the business-friendly environment, Japanese pharmaceutical company Kyowa Kirin, selected North Carolina as the site of its first North American pharmaceutical manufacturing operation.

NC is working to ensure its talent pipeline progresses alongside its drug pipeline. Wilson Community College is opening a biotechnology workforce training center in June 2026. The state also received US$25 million through the federal Build Back Better Regional Challenge (BBBRC), which supports the Accelerate NC – Life Sciences Manufacturing coalition's efforts to build a more inclusive, homegrown biotech workforce by expanding access and awareness in historically underserved communities.

**Ohio: Innovation corridor**
As of November 2024, Central Ohio experienced a 29% increase in life sciences businesses over five years, totaling nearly 1,200 companies. Employment in the sector grew by 7% to 18,000 jobs. The industry overall grew by 13-14%, compared to a 1% growth in other sectors.

Behind much of Ohio's success is the Ohio Discovery Corridor. "Stretching from Cincinnati to Columbus to Cleveland, the Ohio Discovery Corridor is a unique concentration of research expertise. When combining the expertise, capabilities and assets, Ohio is competitive with the top biotech hubs in the country" explained Eddie Pauline, president and CEO of Ohio Life Sciences, Ohio's industry association, representing 4,900 life science establishments across the state.

This corridor makes Ohio one of only four states with three or more leading life sciences talent clusters a CBRE report highlighted. Cincinnati, Cleveland and Columbus were recognized for their robust talent pools in research and development, medtech and medical devices, respectively. Central Ohio's universities and colleges have collectively granted over 8,700 degrees in relevant fields over the past five years. This talent is leading to expertise. Nationwide Children's Hospital in Columbus, for example, developed two of the first eight FDA-approved gene therapies. The state's expertise drew companies like Sarepta Therapeutics to relocate their R&D center of excellence from Boston to Columbus, recognizing the wealth of gene and cell therapy on offer.

**Texas: Bigger in bio**
The Lone Star state has become a star in the life sciences industry recently. As of 2024, the state housed over 7,462 life sciences businesses, employing more than 116,000 individuals. The biopharmaceutical sector alone contributes over US$95 billion to the state's economy. Between 2018 and 2021, Texas brought 5,300 patents to market, which included 2,709 for surgical and medical devices, 1,014 for pharmaceuticals and 508 for biochemicals. According to the National Institute of Health, Texas ranks second in the nation in the number of clinical trials. There are 15 medical universities and 18,000 industry-related graduates annually, of which, 900 receive biotech-related doctorates. The state also houses four National Cancer Institute designated cancer centers.

Texas is home to three of the top emerging life sciences clusters in the US: Houston, Austin and Dallas-Fort Worth. Houston saw the second-largest growth in life sciences employment in the country from 2022 to 2023, accordingly to CBRE's 2025 life sciences outlook. In 2023, Dallas was selected as one of the three main sites for the Advanced Research Projects Agency for Health, a US$2.5 billion federal agency aimed at advancing research in critical diseases. Austin is among the top 10 cities nationally for bio and health funding, with US$3.5 billion in VC funding raised between 2019 and 2024.

Outside these clusters, in August 2024, Plano City Council approved an economic development agreement between NexPoint and the city for a forthcoming life sciences hub, dubbed the Texas Research Quarter. The first phase of construction of the 91-acre campus will be complete in 2026.

**Colorado: High altitude accelerator**
Located in the Rocky Mountains, the road into the life sciences has been anything but rocky for the Boulder/Denver research cluster. In 2024, Colorado's life sciences ecosystem raised US$2.15 billion, marking a 46% increase compared to 2023. Ambrosia Biosciences, headquartered in Boulder, secured US$25 million in Series A funding in early 2025, with US$6 million contributed by Merck. In Q3 2024, construction was completed at Flatiron Park, a 1,000,000 square foot speculative purpose-built life sciences campus consisting of 23 buildings. The Denver-Boulder area ranked 11th nationally for R&D talent, 16th for manufacturing talent, and 18th for medtech talent.

These 'mitochondrial hubs' are not just expanding biotech's geographic footprint, they are energizing the research leading to tomorrow's treatments. ■

> Ohio is increasingly competitive in attracting larger, well-known life science brands, plus our institutions continue to spin out new biotech companies; people across the country are starting to notice.

# Eddie Pauline

President and CEO

**OHIO LIFE SCIENCES**

**How does Ohio Life Sciences support the state's life sciences industry?**

The Ohio Life Sciences Association (OLS) is Ohio's industry association, representing 4,900 life science establishments and we focus on growing the market by ensuring our companies have the talent, funding, infrastructure, and business friendly policy they need to thrive.

**How is OLS helping address the talent gap?**

The life sciences industry is growing fast in Ohio. Our recent industry study shows 13% growth compared to 1% in all other industries. In response to this, we have secured new investments from the state government to launch new programs like BioPathways, which are focused on helping young students figure out how to navigate opportunities within the life sciences industry. We have also helped fund pharmaceutical manufacturing and biotech bootcamps at our community colleges around the state. We have also launched a new career matchmaking service, which is helping employers find quality candidates for new opportunities at their firms. Simultaneously our research institutions—places like the Ohio State University, Nationwide Children's Hospital, Cleveland Clinic, and Cincinnati Children's—are continuing to bring in more STEM focused students and researchers. Nationwide Children's Hospital for example developed two of the first eight FDA-approved gene therapies: One for spinal muscular atrophy (Zolgensma) and one for Duchenne muscular dystrophy (Elevidys). This work has drawn companies like Sarepta Therapeutics to relocate their R&D center of excellence from Boston to Columbus, recognizing the wealth of gene and cell therapy talent here.

**How would you assess the innovation landscape in Ohio?**

We have attracted over US$1 billion in NIH funding. Cincinnati Children's is ranked as the top children's hospital in the country, and Nationwide Children's is ranked sixth. The Ohio Discovery Corridor, stretching from Cincinnati to Columbus to Cleveland, is a unique concentration of research expertise. When combining the expertise, capabilities, and assets across these three cities, Ohio is competitive with the top biotech hubs in the country. JobsOhio, our privatized economic development organization, allows for faster responses in attracting and incentivizing businesses compared to other states. Ohio offers a low cost of doing business, including lower taxes and living costs.

**Can you outline a few economic impacts of the life sciences sector on Ohio?**

The pharmaceutical manufacturing sector alone created 3,000 new jobs in the past two years. The industry directly employs over 60,000 people. More than 200,000 jobs are connected to the state's life sciences industry, generating US$2.2 billion in tax revenue. The industry offers high-paying positions with an average salary of US$105,000, which is 67% above the state's private sector average.

**How is OLS supporting biotechs during the capital drought?**

I have heard everything from "biotech nuclear winter" to "biotech is in the penalty box." However, there is a lot of patient capital ready to be invested. Through Ohio Third Frontier, we have a network of entrepreneurial support programs with funds available for pre-seed and seed investments. Efforts are also underway to create a Series A fund. The US$500 million O.H.I.O fund has launched and will be announcing its first biotech investment soon. JobsOhio has also made a nine-figure investment to attract health and life sciences companies so our challenge will be to match that level of investment in biotech capital.

**What is your outlook on the life sciences industry and OLS' role in that?**

Ohio is increasingly competitive in attracting larger, well-known life science brands, plus our institutions continue to spin out new biotech companies; people across the country are starting to notice. Examples like Amgen investing in Ohio to build one of its most sophisticated facilities and Canon Healthcare establishing its headquarters in Cleveland are becoming more common. The Ohio Discovery Corridor connects our three-life science themed innovation districts, seeded with a US$100 million investment from JobsOhio, with institutions contributing even more funding. In 2025, we will open a life science industry hub and training center in Columbus. Our momentum is strong.

Our goal is to advocate for more resources for the industry. We aim to activate our resource development programs, such as BioPathways and a new career portal that will vet candidates and match them with life science companies. OLS will be aggressive in our efforts to drive attention and resources toward the industry. ■

# DRUG DISCOVERY AND DEVELOPMENT

> The US leads the world in biomedical innovation — it is a national treasure.

Christiana Bardon
Managing Partner
**MPM BIOIMPACT**

GBR Series
UNITED STATES LIFE SCIENCES 2025

Image courtesy of National Cancer Institute at Unsplash

Image courtesy of Novo Nordisk

# Metabolic Disease and the Three Bears of Drug Development

## Discovering Goldilocks treatments in oncology, immunology and neurology

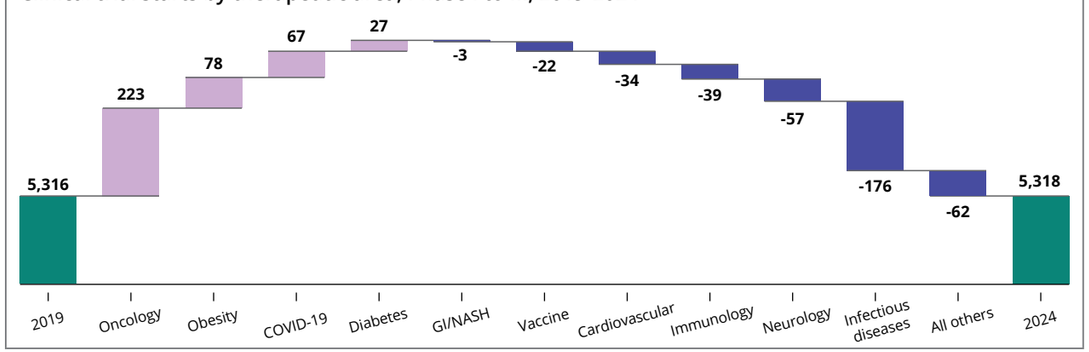
In 2024, the top three disease areas — oncology, immunology, and neurology —accounted for 66% of clinical trial starts, according to IQVIA. Oncology led the way with a 41% share, while immunology (14%) and neurology (11%) experienced a decline in clinical trial starts since 2019, dropping by 39 and 57 trials, respectively. Increases in oncology and obesity related trials made up the difference, increasing by 223 and 78 respectively. The number of clinical trial starts reached 5,318 in 2024, a number near identical to 2019's 5,316, indicating a return to pre-pandemic levels. US headquartered companies accounted for 35% of these.

The loss of exclusivity (LoE) due to expiring patents on high-revenue products will translate to losses of more than US$300 billion in sales through 2030. The patent cliff will drive M&A; 77% of executives in a Deloitte survey expect M&A to increase in 2025. M&A reveal which indications Big Pharma expects to see the greatest returns. "We are focused on high growth markets with high unmet medical needs. In innovative medicine, we are focused in oncology, immunology and neuroscience," acknowledged Joaquin Duato, chairman and CEO of J&J at the JPMorgan Healthcare conference in January.

27 deals were announced in 2024 with values above US$2 billion, including nine in oncology and three in neurology. Assessing the top 10 pharma companies shows oncology as the clear favorite, representing 28% of total M&A deal value from 2019 to H1 2024, according to Larka. The largest deal, Novo Holding's US$16.5 million acquisition of Catalent, shows the dramatic increase in interest in metabolic disease. M&A investments in metabolic disease accounted for 19% of total deal value in 2023, versus only 0.3% in 2022.

### Total 2024 Trial Starts Returned to 2019 Level Increases in Oncology and Obesity Offset Other Declines

**Clinical trial starts by therapeutic area, Phase I to III, 2019-2024**




Sources: IQVIA Institute





**Oncology: approvals are too cold!**

One in five people will develop cancer in their lifetime, according to the World Health Organization (WHO). There is a 77% expected increase in cases from 2022 to 2050, attributed to changing population demographics and increased exposure to risk factors. In the US, the American Cancer Society projects over 2 million new diagnosed cancer cases in 2025 and over 618,000 deaths, equivalent to 1,700 per day. In countries with real GDP per capita above US$33,000, the US leads in percentage of patients achieving five-year survival, at 65%. The US oncology spend represented 45% of global oncology spending in 2023 and is expected to grow at a CAGR of 11-14% from 2024 to 2028, when it is projected to reach US$180 billion.

Treatment of women's cancers, prostate cancer and late-stage multiple myeloma advanced in recent years as novel modalities, including antibody-drug conjugates, radiopharmaceuticals, bispecifc antibodies and CAR T-cell therapies, provide better outcomes. The first CAR T approved by the FDA was Novartis' tisagenlecleucel in 2017 for acute lymphoblastic leukemia, leading to commercial availability of CAR T. Arcellx, a biotech advancing anitocabtagene autoleucel for relapsed or refractory multiple myeloma, is advancing CAR T in partnership with Gilead, with a hopeful 2026 launch. Aileen Fernandes, chief business officer, is excited for the future of the therapy: "At the macro level, academic centers and physicians are excited about CAR-T because they have seen the impact of this therapy in lymphoma and now in multiple myeloma. We are also seeing hospitals investing in CAR-T infrastructure, expanding access and exploring outpatient administration of CAR-T."

There is a lot of momentum in the space, as evidenced by Roche's acquisition of Poseida Therapeutics in January to expand Roche's cell therapy capabilities, particularly in developing CAR-T cell therapies for hematological malignancies. In March, AstraZeneca announced its agreement to acquire EsoBiotec for their in vivo CAR-T.

Despite receiving the most funding dollars, oncology has the third lowest likelihood of all therapy areas of getting approval from Phase I. According to Andrew Feinberg, president and CEO of BostonGene, a biotech using AI-driven analysis of tumor genomics, the tumor microenvironment, and digital twin models to personalize cancer treatment, this will change: "We simulate clinical trials before they begin, modeling patient responses and optimizing drug development strategies. This dramatically increases the probability of technical success (PTS), accelerates trial timelines and reduces costs."

**Immunology: major indications are too hot!**

For the past two decades, immunology was a major growth engine in the biopharmaceutical space, sustaining 12-23% growth each year, which was three to five times that of the industry. Reaching US$166 billion by the end of 2024, immunology was the second largest therapy area by value. While growth continues, IQVIA predicts a slowdown from 15% CAGR over the past five years to 3-5% for the next five. This is due to patent expirations of autoimmune blockbusters, like Humira and Stelara. There is intense competition in major immunology indications like rheumatoid arthritis, psoriasis and ulcerative colitis. There will likely be at least six mechanisms of action and 12 brands for each of these indications, IQVIA found.

Innovators are looking to small immunology indications like lupus, hidradenitis suppurativa and alopecia areata as a hedge against overcrowding. Four first in class therapies were launched in the space in 2024, in indications like prurigo nodularis and WHIM syndrome. Three of 2024's largest acquisitions further support this trend. In April, Vertex Pharmaceuticals beat four companies to acquire Alpine Immune Sciences for US$4.9 billion. Alpine is testing its flagship drug in patients with lupus and autoimmune cytopenias. Eli Lilly and Biogen also strengthened their immunology portfolios acquiring Morphic Therapeutics and Human Immunology Biosciences, respectively.

Marinomed, an Austrian-based biotech, divested its medical device business to focus on Marinosolv, a drug delivery platform enhancing the solubility of poorly soluble drugs. "Marinosolv has greater long-term commercial potential, particularly in immunology and ophthalmology," said Andreas Grassauer, the CEO.

**Neurology: target selection is (almost) too hard!**

According to the Lancet, one in three people worldwide will experience a neurological disorder during their lifetime. Disability, illness and premature death caused by neurological conditions increased 18% since 1990. Globally, disorders affecting the nervous system are the leading cause of overall disease burden.

The focus on such conditions is well founded, and 2024 saw great advances. The FDA approved four first in class molecules. Within this, Cobenfy was the first new mechanism of action launched for schizophrenia treatment in over 30 years. From IQVIA data, there were 605 neurology trial starts. Alzheimer's, depression and Parkinson's are the focus, each seeing more than 200 trials over the past five years. Phase I and II trial starts increased in 2024, with growth elevated by multiple sclerosis, depression, muscular dystrophy and amyotrophic lateral sclerosis.

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# Liping Liu

Founder, CEO and Chairwoman

**HIGHTIDE THERAPEUTICS**

**What are recent milestones progressing HighTide Therapeutics towards its mission?**
HighTide develops innovative therapeutics for metabolic diseases, including diabetes, MASH, and obesity. We focus on the patient's health as a whole—rather than just treating the disease. We aim to improve patient total health outcomes by developing multi-target, multi-mechanism therapeutics. We are in late-stage clinical development. We plan to file our first NDA for type 2 diabetes in China in H2 2025.

In 2024, we launched three pivotal phase 3 trials for type 2 diabetes in China and completed enrollment. We also finished enrollment for a global phase 2b MASH study, primarily in the US, with some patients from Hong Kong and China as well. In early discovery, we identified several lead candidates targeting weight loss and neurodegenerative diseases. In Dec 2023, we went public on the Hong Kong stock exchange. Our first year as a public company boosted visibility.

We moved into a 35,000-square-foot space in Hetao Shenzhen-Hong Kong Science and Technology Innovation Cooperation Zone, a key region for our next decade of growth. We are building a foundation for worldwide expansion.

**How do recent results support berberine ursodeoxycholate (HTD1801)'s potential to be a blockbuster drug?**
We have strong data proving HTD1801 is an innovative, first-in-class dual-mechanism molecule. It activates AMPK and inhibits NLRP3 inflammasome—two key metabolic disease targets. While others develop drugs that target AMPK or NLRP3 separately, HTD1801 is the first to target both simultaneously. This approach delivers metabolic and anti-inflammatory benefits, addressing chronic inflammation—the root cause of cardiovascular and neurodegenerative diseases. It also opens doors for anti-aging applications.

Pharma seeks rare mega-blockbuster drugs. PD-1 inhibitors and GLP-1s changed the industry. HTD1801 has similar potential. Success requires a balance of safety, tolerability, efficacy, and broad impact. Addressing disease at its root enables multiple indications. This is how a drug becomes a blockbuster. ■

# Andrew Feinberg

President and CEO

**BOSTONGENE**

**What is the BostonGene's mandate?**
BostonGene leverages AI and biocomputing to redefine precision medicine. Our proprietary AI-powered multimodal platform integrates vast biological data to revolutionize treatment decisions. We are not just analyzing cancer—we are decoding its biology to personalize treatment for every patient.

The reality is stark: Developing cancer drugs is expensive, slow and inefficient. Only 5% of clinical trials succeed, resulting in over $50 billion in failed trials every year. Despite major advancements in technology, biology, and science, therapeutic development has remained unchanged for decades. BostonGene is changing the paradigm with AI.

**How does BostonGene's holistic approach to data integration change precision medicine?**
You cannot identify what a symphony is playing by just looking at the instruments. Similarly, you cannot understand disease by studying isolated biological components. Traditional research examines proteins, transcriptomics, immune system responses and genetic mutations in silos. BostonGene breaks these silos.

Our AI-powered multimodal platform integrates data at four critical levels. On the molecular level, genomic, transcriptomic and proteomic insights uncover the underlying drivers of cancer and power drug and target discovery.

Our fusion neural network and proprietary AI model process this multimodal data, reconstructing missing insights and simulating patient responses to therapies. By creating a comprehensive Tumor PortraitTM and a Digital Twin of each patient, we deliver truly personalized treatment strategies.

**How will AI transform oncology?**
BostonGene's AI model is proactive. We simulate clinical trials before they begin, modeling patient responses and optimizing drug development strategies. This dramatically increases the probability of technical success, accelerates trial timelines and reduces costs. We optimize patient selection, ensuring that only those likely to respond are enrolled. We model drug mechanisms of action, designing smarter trials that require fewer patients. We unlock drug repurposing opportunities, rescuing failed assets and bringing them back to market. ■





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Neurological conditions only have a 5.9% chance of FDA approval from phase I and average 11.1 years development, according to BIO analysis. Neurological disease treatments come with challenges such as understanding the underlying pathophysiology of a disease, which in many cases is multifactorial. The genetic aetiology of many CNS disorders is ambiguous, leading to difficulty in target selection.

If the challenge of target selection is surmounted, drug delivery becomes the next obstacle. The blood brain barrier (BBB)— a protective, selective and semi-permeable membrane between the blood and the interstitium of the brain—blocks 95% of small molecules and nearly all biologics. At Aphios, a biotech company focusing on CNS disorders, the lipid-based composition of nanoparticles hurdles this barrier. "For active transport we enhance delivery by attaching ligands, such as sugar moieties, to the nanoparticle surface. There are many receptors for sugar at the blood-brain barrier, so these ligands help transport the nanoparticle material across the BBB," explained Trevor Castor, the founder, president and CEO.

Camden Cutright, president US at Micropore—a company building more efficient processes to formulate injectable drug products—elaborated on the benefits: "Lipid nanoparticles protect RNA payload from the body's natural immunity defenses, increasingly they are also being tuned to facilitate targeted delivery."

## Metabolic Disease: Goldilocks conditions

One in eight people globally live with obesity, a figure that has doubled since 1990. The percentage of children with obesity has quadrupled over the same period. In 1997, the WHO declared obesity a global epidemic. Since then, it has only gotten worse. A recent study from CU Boulder estimates one in six deaths in the US are related to excess weight or obesity. Obesity goes hand in hand with noncommunicable diseases such as cardiovascular diseases, diabetes, cancers, neurological disorders, chronic respiratory diseases and NASH. In 2019, higher-than-optimal BMI caused 5 million deaths, according to the WHO.

Unsurprisingly, all bets were on the metabolic space in 2024. The largest acquisition, Novo Holding's takeover of Catalent, added momentum. There was a 77% increase in obesity trial starts in 2024 compared to 2023, and a nearly five-fold increase over the past five years, found IQVIA. Morgan Stanley Research predicts the global market for obesity to reach US$105 billion in 2030, and as high as US$144 billion for 2050. Eli Lilly is the world's most valuable pharmaceutical company, in part because of its glucagon-like peptide-1 agonist (GLP-1), Mounjaro/Zepbound. McKinsey identified drugs for obesity and related conditions as one of eighteen future arenas—along with semiconductors and AI— that could reshape the global economy and generate US$29 trillion to US$48 trillion in revenues by 2040. "The metabolic disease space is entering its golden era," summarized Liping Liu, founder, CEO and chairwoman at HighTide Therapeutics.

42% of the obesity pipeline are GLP-1s. These come with a slurry of side effects like muscle loss, osteopenia and reduced effectiveness over time. Over 60% of GLP-1 users stopped within a year due to side effects, tolerability issues, or reaching their target weight, found a UK government report. Hightide's berberine ursodeoxycholate (HTD1801) has potential to be creamer for the GLP-1 coffee, said Liu: "GLP-1 side effects often stem from high doses. Combining HTD1801 with a lower GLP-1RAs dose enhances weight loss while preserving muscle mass."

HTD1801 is also being tested in type II diabetes phase 3 and MASH phase 2b trials. The FDA approved the first MASH drug in 2024, an area with high unmet need.

## Prevention: the 'just right' treatment

There is an epilogue page to the story. A study in an American Cancer Society Journal found an estimated 44% of all cancer deaths in US adults were attributable to modifiable risk factors— like cigarette smoking, second-hand smoke, excess body weight, alcohol use, poor diet, physical inactivity, UV exposure, and certain infections. In a word: preventable.

The WHO's obesity factsheet states: "Overweight and obesity, as well as their related noncommunicable diseases, are largely preventable and manageable."

The Lancet revealed that 84% of stroke disability-adjusted life years (DALYs) could be prevented through reduced exposure to identified risk factors. Reducing high fasting plasma glucose could reduce the burden of Alzheimer's disease and other dementias by 14%.

Research in a peer reviewed journal suggests environmental factors, such as pollutants, medications, toxins and viral infections, and lifestyle factors including diet, sleep deprivation, stress and lack of physical activity all contribute to the rise in autoimmune diseases.

Antinuclear antibodies (biomarkers of autoimmunity) increased 30% since 1988 and obesity by 50% since 1990. Our genes have not changed; our environment has. A study in Nature Reviews Drug Discovery found global pharmaceutical R&D expenditures is US$276 billion annually. If even half of that money was directed towards lessening known risk factors, we would live in a healthier world. ■

# In the Lab

## Beyond dealmaking, a dive into the science

For decades, the fight against neurodegenerative diseases like Alzheimer's, Parkinson's and Multiple Sclerosis was waged against pathologies visible under the microscope: the plaques and tangles in Alzheimer's, the loss of dopamine-producing neurons in Parkinson's, and the damaged myelin sheaths in Multiple Sclerosis.

Though traditionally viewed as a bystander, evidence suggests that chronic inflammation within the central nervous system (neuroinflammation) is a crucial driver of disease onset and progression. New therapeutics are increasingly targeting inflammation as a core pathology, which could change the narrative of neurogenerative disease moving forward.

**The inflammatory cycle**

Neuroinflammation involves the activation of the brain's resident immune cells, microglia and astrocytes. While this response is protective in the short term against injury or infection, chronic activation becomes detrimental. In neurodegenerative diseases, factors like misfolded protein aggregates (amyloid-beta, tau, alpha-synuclein) trigger persistent immune activation. Activated microglia and astrocytes release a cascade of pro-inflammatory molecules, including cytokines like Tumor Necrosis Factor-alpha (TNF-α), Interleukin-1 beta (IL-1β), and Interleukin-6 (IL-6). These molecules, particularly TNF-α, perpetuate neuronal dysfunction, damage, and cell death, creating a vicious cycle where inflammation drives further neurodegeneration, which in turn fuels more inflammation.

**Alzheimer's Disease: Beyond plaques and tangles**

While Alzheimer's disease (AD) pathogenesis is not completely understood, there are patterns shared amongst all Alzheimer's patients, which led to the treatments we have today. AD progresses in a loop. A protein called amyloid-beta, which normally plays a helpful role in memory and the brain's immune defense, starts to build up and form sticky clumps, or plaques. These plaques interfere with how brain cells (neurons) communicate and can overstimulate them to the point of damage or death. Another protein called tau, which normally helps keep the structure inside neurons stable, becomes overactive and twists into tangles. These tangles block important transport systems in the cell and eventually cause the cells to die, a driver of memory loss. As damage builds, the brain's immune cells—microglia—detect something is awry and release proteins to clean up the mess. Over time, their response becomes chronic and overactive, triggering long-lasting inflammation in the brain.

Traditional AD treatments focus on amyloid plaques and tau tangles. However, "despite recent approvals of lecananab and donanemab, their 30% slowing of cognition vs. placebo suggests that plaques and tangles are not the true drivers of Alzheimer's," emphasized Cuong Do, president and CEO of Biovie.

The true driver? Inflammation. Inflammation activates signaling pathways like ERK and NF-κB, which lead to the release of TNF-alpha, the master regulator of inflammation. High levels of TNF-alpha cause insulin resistance in neurons and promote further cell death. This stress on brain cells leads to increased production of amyloid precursor protein (APP) and more amyloid beta. Inflammation accelerates AD. The cycle of inflammation creating plaques and tangles is seen as a central mechanism of AD, and it is shaping the direction of new treatments that aim to break the loop by targeting inflammation. Biovie's Bezisterim targets neuroinflammation: "In a six-month trial, patients on Bezisterim experienced a 68% slowing of cognitive decline versus placebo," demonstrated Do.

Aphios, another biotech, focuses on mitigating neuroinflammation in AD but using a different target. "In aging brains, the CCR5 gene becomes increasingly active, contributing significantly to inflammation that disrupts synaptic connectivity and accelerates cognitive decline," explained Trevor Castor, founder, president and CEO of Aphios.

By repurposing Maraviroc, an HIV drug that blocks CCR5 by encapsulating it in nanoparticles designed to cross the blood-brain barrier, Aphios aims to reduce neuroinflammation and slow AD progression.

**Multiple Sclerosis: long- term treatments**

Inflammation is the cornerstone of Multiple Sclerosis (MS), a disorder where the immune system attacks the myelin sheath (protective outer coating) that insulates nerve fibers. This effectively 'unwraps' the outer coating of neurons and leads to progressive disability. Existing treatments primarily target the inflammatory relapses, but significant unmet needs remain in preventing long-term disability progression.

Immunic is developing Vidofludimus Calcium, an oral therapy currently in phase 3 trials for relapsing MS (RMS) and phase 2 for progressive MS (PMS). According to CEO Daniel Vitt, the drug possesses a unique dual mechanism: "It was initially developed as a DHODH inhibitor, which is excellent for treating inflammation and reducing brain lesions and relapses."

**The path forward**

The growing understanding of neuroinflammation's central role across diverse neurodegenerative diseases is paving the way for a new generation of therapies. By addressing inflammation – a common thread linking AD, MS and PD – these approaches hold the potential to move beyond symptom management and tackle the underlying drivers of neurodegeneration. As these therapies progress through clinical trials, the coming years will be critical in determining if targeting inflammation can truly change the trajectory for patients living with these devastating conditions. ■





## Daniel Vitt

CEO

**IMMUNIC THERAPEUTICS**

**What is Immunic Therapeutics' core focus?**

Immunic is focused on developing oral drugs for chronic autoimmune and inflammatory diseases. Our lead asset, vidofludimus calcium, is currently being tested for multiple sclerosis (MS).

**Can you describe the phase 2 trial results for vidofludimus calcium?**

We treated 268 patients with relapsing-remitting MS, the drug significantly slowed relapses and reduced brain lesions over six months. We observed a dose-dependent reduction in neurofilament light chain (NfL), a key biomarker for neurodegeneration. The drug halved confirmed disability progression, so we continued with an open-label extension, where 254 patients were enrolled. After two years, 94.2% of patients were free of 12-week confirmed disability worsening.

Vidofludimus calcium was initially developed as a DHODH inhibitor, which is excellent for treating inflammation and reducing brain lesions and relapses. During clinical trials, we discovered it is also a potent activator of Nurr1, a target linked to neuroprotection. Our drug's potential ability to activate Nurr1 could explain its neuroprotective effects, making it particularly exciting for treating neurodegenerative conditions. ■

## Cuong Do

President and CEO

**BIOVIE**

**How is targeting neuroinflammation a new approach to treating Alzheimer's?**

Biovie believes neuroinflammation is the real driver of neurodegeneration. Inflammatory signals activate ERK and NFkB, triggering TNFα production. TNFα increases APP production, leading to more amyloid and activate kinases that phosphorylate tau, creating tangles. In a six-month trial, patients on Bezisterim experienced a 68% slowing of cognitive decline versus placebo. Biovie is preparing for a Phase 3 trial to further validate its impact.

**Why is inflammation the silver bullet for treating Alzheimer's, Parkinson's and long COVID?**

By targeting inflammation at its core, Bezisterim can alleviate downstream processes that contribute to Alzheimer's, Parkinson's, and other neurodegenerative disease pathology.

Research on long COVID suggests that brain fog, malaise, and fatigue are driven by TLR4 activation. By blocking TLR4, Biovie hopes to disrupt this cycle. We received a US$13 million grant—the only therapeutic awarded funding—to explore Bezisterim's potential for long COVID, offering hope for the 17 million Americans currently suffering from long COVID. ■

## Trevor Castor

Founder, President and CEO

**APHIOS**

**Where is Aphios focusing its research in treatments for Alzheimer's?**

Our research on Alzheimer's disease focuses on mitigating neuroinflammation – a key driver of disease progression. In aging brains, the CCR5 gene becomes increasingly active, contributing significantly to inflammation that disrupts synaptic connectivity and accelerates cognitive decline. Evidence from the HIV field, where individuals lacking CCR5 exhibit resistance to infection, underscores the receptor's role in immune modulation.

We are repurposing maraviroc – a molecule used in HIV treatment to block CCR5 – by encapsulating it in nanoparticles. This formulation enables effective crossing of the blood-brain barrier, reducing neuroinflammation while potentially lessening the side effects, such as brain bleeding. By blocking CCR5, our strategy aims to preserve synaptic function and slow the progression of Alzheimer's disease.

**How do nanoparticles assist in drug delivery for central nervous system (CNS) disorders?**

Nanoparticles offer a promising means to traverse the blood-brain barrier due to their lipid-based composition, which is very biosimilar to this barrier. Once inside, the nanoparticle can deliver its therapeutic cargo directly to the brain. ■

# CONTRACT MANUFACTURING, SERVICES AND CHEMICALS

> Many large pharma companies are restructuring, and plant divestitures will create growth opportunities for CDMOs. The industry landscape will resemble a checkerboard for a while.

Jim Donovan,
Contract Manufacturing Business Leader,
**PFIZER CENTREONE**

GBR Series
UNITED STATES LIFE SCIENCES 2025

Image courtesy of Dipharma Francis

# Bolstering the Burgeoning Biologics Boom and Beyond

Image courtesy of Novartis

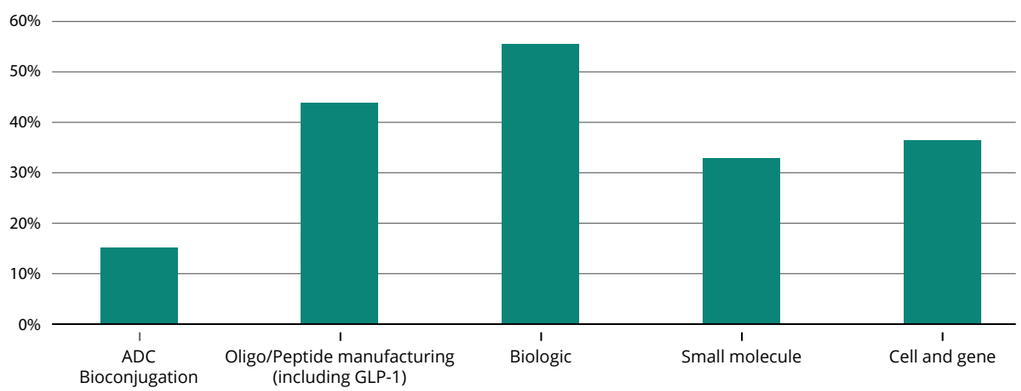
## CDMOs expand and innovate to meet industry demand

Noncommunicable diseases—which include conditions like heart disease, stroke, cancer and diabetes—account for 74% of all worldwide deaths, according to the World Health Organization. Biologics are designed to target specific biological pathways and have proven effective in managing these conditions. It then comes as no surprise that the biologics industry expects spectacular growth, namely a compounded annual growth rate (CAGR) of 9.96% from 2025 to 2034, when the market is expected to reach US$1.14 trillion. "This growth is driven by the increasing number of programs at various stages of development. Within biologics, bispecifics and ADCs are seeing the most growth," explained Adam Pietruszkiewicz, chief commercial officer at Mabion.

In 2024, 18 of the 50 FDA approved drugs were pure play biologics, representing 36% of total approvals. This number is up from 2023's 29%. Biologics are compounds derived from organic, rather than chemical, origin. They include monoclonal and bispecific antibodies, along with cell and gene therapies and ADCs. 11 out of the 13 top modalities that most interest investors are biologics, according to the Oppenheimer 2025 Annual Biopharma Outlook Survey, which surveys 49 institutional life sciences investors. Bispecifics and monoclonal antibodies took the first and third spots on the list, with small molecules sandwiched in second.

According to the 2024 CPHI Annual Report, 54% of executives believe investments in biologics will deliver the best marginal and overall returns for CDMOs over the next five years. The contract manufacturing space is aware of this potential, and many have already began expanding to help meet demand.

### What Will Be CDMOs Most Lucrative Modality Over the Next 5 Years? (Executive Survey)




Sources: CPHI 2024 Annual Report

Of the 31 CDMOs and CMOs interviewed for GBR's report, 18 recently completed, are undergoing, or announced plans to expand capabilities, either organically or inorganically. Companies expanding capabilities with new technologies are also included in this total. Of these expansions, 50% are centered around biologics. Put simply, "Biological drugs represent the future," said Marianne Späne, chief business officer of drug substances and drug products at Siegfried.

Siegfried is bringing the future to the present with recent moves in the biologics space. In November 2024, to strengthen its offering in biologics, specifically in cell and gene therapy (CGT), DINAMIQS, a 2023 acquisition, inaugurated laboratories in Zurich's Bio-Technopark. "Siegfried DINAMIQS bridges drug design and process development in the CGT space," continued Späne.

Across the pond, Thermo Fisher Scientific launched Accelerator Drug Development in October 2024. It combines contract development, manufacturing and clinical research services into a unified solution across major therapeutic modalities—including biologics, viral vector, CGT— reducing trial-and-error, eliminating redundancies and preserving know-how, intellectual property, time and resources explained Anil Kane, executive director and global head of technical and scientific affairs. In 2023, the firm expanded in St. Louis, doubling the company's biologics manufacturing capacity, growing from 2,000 L to 5,000 L to produce complex biologic treatments for diseases including cancer, autoimmune conditions and rare disorders. "Large-molecule biologics remain a key focus, with services ranging from cell line development to process evaluation, scale-up, and sterile fill-finish production," said Kane.

With CRISPR-Cas9 becoming a tool in 2012, CGT has a lot of potential. "The progress over the last 15 years has been incredible, and I am excited to take all of our learnings into the next decade of gene therapy drug development – the future is bright," emphasized Steve Favaloro, chairman and CEO of Genezen, a US-based CGT CDMO.

In Kentucky, India-based Piramal invested US$80 million to expand its sterile injectables facility, giving the firm the ability to provide fill-finish services for ADCs. It will include a high-speed line to double annual production capacity and increase fill-finish capabilities. Peter DeYoung, CEO of Piramal Pharma, explained: "The expansion was driven by the demand for differentiated capabilities, including expertise in ADCs, sterile fill-finish, high potency APIs and peptides."

Also in the South, Alcami added a new sterile fill/finish line with isolator and two lyophilizers in its Charleston, South Carolina manufacturing site in 2024. The expansion meets growing industry demands for onshore sterile fill/finish capabilities amidst tightening capacity as the pipeline of biologics grows, according to the press release. Alcami opened a pharma storage facility near Research Triangle Park, offering LN2 storage to walk-in -80, -40, -20, and CRT ambient pallet storage. "The long-term goal is to expand further into the biologics space, building on our existing services while adding additional redundancies and scale," highlighted Timothy Compton, chief strategy officer at Alcami.

Expansions to the Pace Life Sciences' facilities in New Hampshire and Minnesota will add sterile fill-finish capacity and enhanced analytical capabilities to support clients developing biologics, gene therapies and other novel molecules. "Biologics and gene therapies hold enormous potential," said Dean Bornilla, head of commercial. "The new sites

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## Anil Kane

Executive Director and Global Head of Technical & Scientific Affairs

**THERMO FISHER SCIENTIFIC**

**Can you provide key advancements from 2024?**

In 2024, Thermo Fisher Scientific launched Accelerator™ Drug Development, our comprehensive, 360-degree Contract Development and Manufacturing Organization (CDMO) and Contract Research Organization (CRO) drug development solution. This platform streamlines services for clinical research, manufacturing and supply chain support across all modalities under one provider, reducing complexity and accelerating time-to-market.

We also extended our existing collaboration with the Stevanato Group to advance drug delivery innovations, including on-body delivery systems. Their Vertiva® platform, now capable of subcutaneous large-volume drug delivery up to 10 mL, offers a comprehensive solution for partners developing molecules suited for large-volume subcutaneous delivery across various indications.

Additionally, Thermo Fisher's acquisition of Olink Holding is a part of our growth strategy and long-term vision for proteomics and personalized medicine. Olink Holding has been on the forefront of proteomics for years. Their proprietary technology enables biopharmaceutical companies and academic researchers to understand disease efficiently at the protein level. These discoveries support the development of new treatments to improve the quality of life of patients in need.

**What expansions has the company undergone?**

We invested over US$22 million to expand our oral solid dose facilities in Cincinnati, Ohio, and Bend, Oregon, enhancing early-stage drug development and manufacturing capabilities.

Recent expansions in clinical trials include a new European clinical supply solutions facility in Basel, Switzerland; a new GMP-compliant facility in Bleiswijk, Netherlands; and a clinical supply site in Buenos Aires, Argentina, to improve regional support for clinical research clients.

We also established a 4,000-square-foot Innovation Lab in Allentown, Pennsylvania, and a new aseptic training center in Monza, Italy, providing hands-on training in simulated Good Manufacturing Practice (GMP) environments, leveraging augmented and virtual reality (AR/VR) to enhance sterile drug manufacturing expertise. ■

## Marianne Späne

Chief Business Officer Drug Substances and Drug Products

**SIEGFRIED**

**How has Siegfried expanded capabilities through M&A?**

We acquired two Novartis manufacturing sites in Spain, enhancing our drug product footprint with innovative oral, inhalative and sterile forms. In 2023, we acquired DINAMIQS, entering preclinical activities in biological active ingredient production. In November 2024, we opened a 4,500 m² R&D center in Evionnaz, Switzerland, strengthening our development capabilities. Two years prior, we launched a drug product development center at our Barberà del Vallès site in Barcelona.

In June 2024 we acquired Curia Global's site in Grafton, Wisconsin. It is specialized in early-phase development and manufacturing services. The facility further reinforces our early development entry point and speed to clinical capabilities, which is why we call it the Siegfried Acceleration Hub.

**How does Siegfried advance cell and gene therapies (CGT)?**

CGT are a young modality with great momentum. More products are reaching commercial stage. Biotech and pharma companies face significant safety and CMC challenges during clinical trials. Siegfried, bolstered by our DINAMIQS division, plays a crucial role in overcoming these challenges, especially in early clinical phases. For example, Siegfried DINAMIQS experts optimized viral vector cassettes to enhance gene expression in the body and developed processes for novel capsids to improve targeted tissue delivery. We also develop comprehensive analytical strategies and provide in-house analytical services, ensuring that insights gained inform subsequent steps towards GMP. This approach helps improve GMP batch success rates and yields, keeping manufacturing costs competitive. Siegfried DINAMIQS bridges drug design and process development in the CGT space. In CGT, we are truly a CRDMO standing at the forefront of science, technology, and state-of-the-art GMP practices.

**What are Siegfried's growth plans and general objectives in 2025?**

We will continue to broaden our technology offerings, such as in spray drying and pre-filled syringes, and will focus on further strengthening our development, commercial, and operational excellence. ■





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strengthen our ability to support analytical testing needs from early development through commercialization."

Grand River Aseptic Manufacturing announced the construction of a 150,000 square foot syringe and cartridge filling center. The firm also expanded its inspection, finishing and warehouse center. "These expansions enable us to handle longer production runs, accommodate more specialized devices, and meet the increasing demand in biologics," said Derek Hennecke, GRAM's CEO.

Lifecore Biomedical recently installed a five-head isolator filler which doubled manufacturing capacity. "This new five-head filler allows us to expand in a fast-growing market in water-based biologics like GLP-1s and monoclonal antibodies," said Paul Josephs, president and CEO.

Biologics manufacturing capacity increased significantly over the last two decades from nearly 600 kL in 2000 to just over 6,700 kL in 2024. Capacity is projected to increase to 9,000 kL by 2028. However, biologics CDMOs were seen by the industry as the most likely to see capacity shortfalls in the next year, according to the CPHI Annual Report. Biologics manufacturing is also expensive. Luckily, firms are innovating to meet these challenges.

### One step for CDMO, one giant leap for biologics

US$260 billion of the US's US$568 billion spent on pharmaceuticals in 2021 went toward biologics. Biologics demand 46% of the nation's annual drug spend but represent only 2% of prescriptions.

Executives in CPHI's Annual Report identified continuous biologics manufacturing as the most likely technology to lower biological production costs over the next five years. Only two contract manufacturers operate continuous biologics set-ups: Enzene Biosciences and Just Evotec.

Enzene is in the final stages of launching its US manufacturing site in New Jersey, housing two production lines powered by EnzeneX™ platform, a continuous manufacturing technology. The platform, originally scaled at 200-500 L, expanded to 1,000 L and delivers up to 40 kg per batch. The technology offers 10x increase in productivity, though a client achieved a 30x increase, and 50% reduction in carbon emissions, explained Himanshu Gadgil, the CEO. The firm's 2025 goal is unprecedented— "breaking the US$40/gram cost barrier for production of mAbs."

The technology is a worthwhile capital expenditure. "Our initial US$50 million investment in the US facility enables nearly one ton of production capacity per year. In contrast, a traditional batch manufacturing setup would require US$200-US$300 million for the same output," Gadgil continued.

### Beyond biologics: The GLP-1 wave reshapes manufacturing

The contract manufacturing landscape is being reshaped by demand surges for novel drug classes, none more so than GLP-1 receptor agonists. Though not biologics themselves, the meteoric rise of these peptide-based therapies for diabetes and weight management has sent shockwaves through the CDMO industry, forcing rapid strategic and operational adjustments. The sheer scale of demand created unprecedented pressure on specific manufacturing capabilities, particularly sterile fill-finish for injectables like prefilled syringes and autoinjectors. As Martin Meeson, CEO of Axplora noted: "If there was an acronym to characterize the industry today it would be GLP-1."

This intense demand formed a crucial backdrop to the most significant M&A event in the CDMO history, and the largest deal of 2024: Novo Holdings' US$16.5 billion acquisition of Catalent. Novo Holdings simultaneously struck a deal to sell three of Catalent's fill-finish sites (in Italy, Belgium and Indiana, USA) to Novo Nordisk, the maker of blockbuster GLP-1 drugs Ozempic and Wegovy. This move was widely interpreted as an effort by Novo Nordisk to secure dedicated manufacturing capacity for its high-demand products, effectively taking significant fill-finish capacity off the open market for other drug developers.

Analyzing the deal a year later reveals profound ripple effects. For competitors and smaller biotech firms, the acquisition intensified existing capacity constraints. "One immediate consequence has been a reduction in available manufacturing capacity, par-

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> The preference for European manufacturers in the US has grown over the past five or six years, driven by the push for geopolitical risk mitigation.

# Saurabh Gurnurkar

Managing Director
**UQUIFA GROUP**

**How does Uquifa's customer-centric approach drive growth and loyalty?**
We are a B2B business, developing and manufacturing APIs and advanced intermediates, as a CDMO for our innovator customers. The customer is key for us and, we aim to follow them closely because a satisfied customer becomes the best ambassador. Our project management and transparent communication, we believe, makes the customer´s experience smooth. Our teams take pride in being nimble and being able to respond to projects' needs in an agile manner. Our renewed focus on customer centricity is a reminder to everyone that we come to work each day because there is a customer behind it. Multi-year relationships with existing customers and the addition of new logos across both the CDMO and Off-Patent API segments demonstrate the value our enterprise is able to create for them.

**What is driving Uquifa's push to expand its presence in the US?**
The US has for many years been a key market for our products and service offering. We keep getting asked by newer customers regarding a potential outpost in the US for delivery of early chemistry capability. While we are a European manufacturer and service provider, we see a synergy in expanding our US presence, with some toolbox capability to complement the same. The US is already our largest market for the services and products we offer. We aim to establish early-stage synthesis or development capabilities there—fitting into our one-stop shop value chain which could eventually lead to large-scale production options for the project in Europe.

**How is supply chain resilience evolving in the current market?**
Supply chain resilience remains critical. Even though we are beyond COVID the industry is still grappling with challenges, such as delayed shipments through the Red Sea. To secure reliable delivery, we have made strategic decisions like maintaining higher inventory levels and working with shipping companies that take alternative routes. We have also leaned on our partners, building a network of strategic vendors.

The preference for European manufacturers in the US has grown over the past 5–6 years, driven by COVID and the push for geopolitical risk mitigation. While customers will always demand competitiveness, chemistry expertise, manufacturing excellence, and compliance, the fact of being in Europe will remain an advantage. If you can tick those boxes, you have a strong chance of winning business.

**How is Uquifa driving innovation in small molecule development and manufacturing?**
One of our key strengths lies in our extensive toolbox of chemistry for small molecule synthesis and development. We specialize in early-phase development, offering comprehensive end-to-end solutions in API development with unmatched flexibility and exceptional turnaround times. Our discovery chemistry team of highly skilled chemists offers extensive services, such as lead optimization, asymmetric synthesis and specialized chemistries.

In particular, our advanced particle sizing capabilities stand out as a significant asset. We offer a diverse range of particle sizing techniques, including lyophilization and milling, with a wide variety of state-of-the-art equipment. These techniques not only enhance the stability and bioavailability of drugs but also ensure optimal performance and product quality. We also focus on introducing proprietary expertise to the market, for the benefit of our customers and, will continue this over the next 2–3 years.

**How does Uquifa demonstrate its commitment to ESG principles?**
In 2024, we were awarded an EcoVadis Silver Medal, improving our score by 10 points from the previous year. This places us among the top 15% of companies evaluated worldwide.

We are actively working to lower greenhouse gas emissions. Our facilities are committed to reducing waste generation, increasing recycling rates, and minimizing water consumption.

We foster a safe and inclusive workplace, ensuring rigorous health and safety standards, continuous employee training, and diversity and inclusion initiatives. Uquifa actively supports local community projects.

We uphold strict ethical guidelines, ensuring compliance with anti-corruption policies, fair labor practices, and responsible corporate governance. We work closely with our suppliers to ensure adherence to ESG criteria, promoting responsible sourcing and ethical business conduct throughout our value chain.
Furthermore, the group aligns its strategy with the United Nations Sustainable Development Goals (SDGs), reinforcing our commitment to global sustainability objectives. Our ongoing ESG efforts are not just about compliance but about creating a positive, lasting impact on the environment, society, and the industry. ■





Adam Pietruszkiewicz
Chief Commercial Officer
**MABION**

> Biologics are growing at 10–12% annually, driven by the increasing number of programs at various stages of development. Within biologics, bispecifics and ADCs are seeing the most growth.

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ticularly for injectables, forcing many clients to seek alternative partners," said Dirk Lange, CEO of Pyramid Labs.

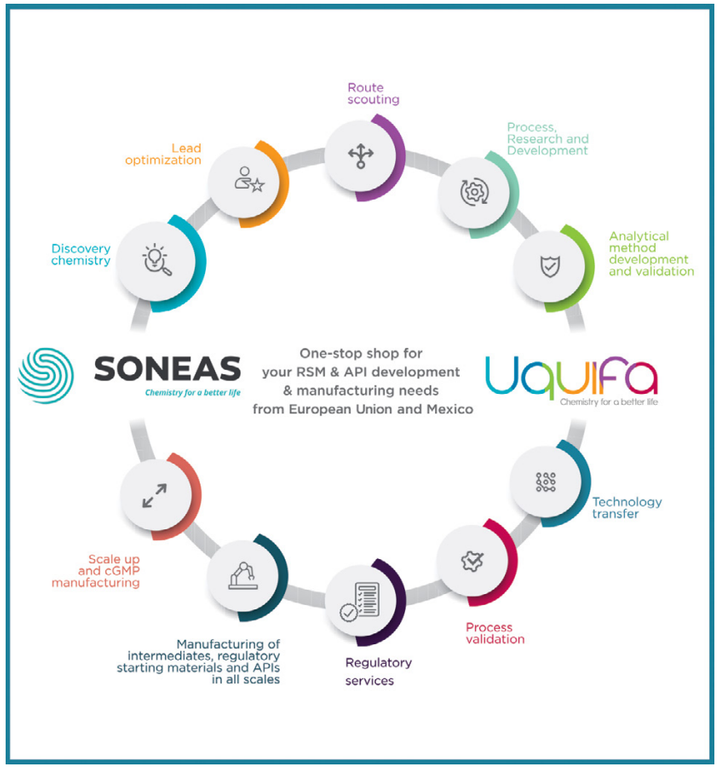
"The ripple effects of the Catalent acquisition and the surging demand for GLP-1 drugs are reshaping the market. Companies need stable, reliable CDMO partners, and we are strategically positioned to fill that gap," Dirk added.

This sentiment reflects a broader industry scramble as companies reassess their manufacturing partnerships in the wake of the capacity squeeze. Paul Josephs, president and CEO of Lifecore Biomedical noted the favorable impact for remaining CDMOs: As giants like Novo Nordisk and Eli Lilly bolster internal capacity or acquire external sites for GLP-1s, multinationals' other blockbuster products could be pushed to outsourced manufacturers, along with others going into pre-filled syringes or cartridges."

However, the acquisition poses challenge for smaller players. "A single pharma company absorbing so much CMO capacity has significant implications... Smaller biotechs, smaller pharma, and smaller commercial production are underserved in a market where everyone is rushing to service ultra-blockbuster drugs... Many companies struggle to secure CMO capacity because they are not large enough to compete," said Colleen Dixon, president and CEO of Selkirk Pharma.

The void of capacity in the market led to a slurry of expansions across the country. One such was Afton Scientific's US$200 million plant expansion in Albemarle County. "The facility can support six to eight lines of Vial, syringe/cartridge, and lyophilization capacity. We are adding pre-filled syringe capacity to our Avon I building to respond to demand from our existing customers and add options for new customers," said Thomas Thorpe, CEO and founder of Afton Scientific. "We anticipate continued growth in prefilled syringe demand, especially driven by the surge in GLP-1 drug demand, which has significantly impacted the CDMO industry. Afton's expansion comes at a pivotal time to help meet this demand, particularly for sterile fill/finish services."

Pharmaceutical companies are increasingly seeking secure and reliable capacity, often prioritizing domestic supply chains to mitigate geopolitical risks. The search for stability, combined with the specific technical demands of new drugs is driving investment, expansions and strategic positioning among CDMOs eager to capture the displaced demand and serve the next wave of innovative therapies, whether they are biologics, peptides or other complex modalities. The ability to offer specialized capabilities and demonstrate long-term reliability has become paramount in this dynamic manufacturing environment. ■



> Investors are finding it difficult to balance early-phase success with the commercialization hurdles ahead.

# Steve Favaloro

Chairman and CEO

**GENEZEN**

**How has Genezen's acquisition of uniQure's manufacturing operation helped the business evolve?**
Genezen needed commercial capability in order to compete in the market and deliver a high level of service to our customers. While we could have chosen to build a new plant and attempt to fill it with customers, market conditions made that approach nearly impossible. Acquiring uniQure's manufacturing operation and hiring its staff transformed us into an end-to-end gene therapy CDMO. We now offer commercial products, including our role as the supplier of Hemgenix, as well as commercial-scale adeno-associated virus (AAV), lentivirus, and retrovirus vectors. This enables phase-appropriate manufacturing and differentiates us from the market.

**How does Genezen connect with patients?**
As the contract manufacturer and one step away from patient advocacy, CDMOs can often feel removed from the patient, so we make an effort to stay connected. We bring in parents from foundations we support, and our customers share stories about our impact. Our culture balances keeping employees motivated and ensuring that this is a great place to work.

**In what ways has cell and gene therapy developed in recent years?**
While there are certainly headwinds in the financing/capital markets, gene therapy as a modality has never been stronger. The progress over the last 15 years has been incredible, and I am excited to take all of our learnings into the next decade of gene therapy drug development – the future is bright. For therapeutic innovators, AAV in rare disease and neural applications remains very attractive as a way to address unmet patient needs. Genezen is here as a development and manufacturing expert to support them.

**What challenges do companies face in this space?**
The cell and gene market has evolved significantly over the past decade. Today, it presents more challenges. Although there are some green shoots, capital markets are struggling to determine how to reward biotech companies for early-phase clinical data. Investors are finding it difficult to balance early-phase success with the commercialization hurdles ahead.

When it comes to partnering with our customers, we are learning more about where we need to "skill-up" versus "skill-out" to work most effectively with them. We have found that helping customers identify the right fit for the capacity they need is critical. It requires a lot of planning during the early years post-launch to fully understand the true demand for a product.

One challenge on the technology side is that cell therapies are typically tailored one-to-one for each patient. There are companies working to address this through automation, aiming to treat tens or even hundreds of patients at a time. Solutions like synthetic plasmids or other alternative raw materials could also play a role in scaling up production.

**Could you tell us about Genezen's partnership with CSL?**
Genezen has partnered with CSL to use the CytegrityTM cell producer line for lentivirus production. This is a great example of us leveraging a partnership to pass benefits on to customers. It is a win-win for us and CSL. We get to use this technology without having to develop it ourselves, and CSL gets a partner producing clinical material with their product. We also manufacture Hemgenix, an AAV gene therapy for Hemophilia B, globally for CSL.

**How do you see the future for cell and gene therapy, and Genezen?**
I am an optimist in this space, bullish on the modality and potential patient impact, and fascinated by the science. Just 10+ years ago, there were no commercial products in this field at all – imagine what it will look like after another 10 years. It is crucial to choose the right partners, with the right expertise and best practices, as we continue to grow.

For Genezen, we aim to bring more commercial products to market in the coming years alongside our partners. We are working on getting our Indianapolis site approved for commercial operations, to align with our Lexington site, and we will expand further when the opportunity arises.

At the same time, we want to maintain our flexibility across different development scales. The small, parent-founded foundations raising funds to try to cure their child's rare disease are just as important to us as the multinational companies. We show up every day to produce medicine, impact healthcare, and provide excellent service. ■





> From an innovation point of view, breaking the US$40/gram cost barrier for production of mAbs is a key objective this year.

# Himanshu Gadgil

CEO

**ENZENE BIOSCIENCES**

**What are recent developments and milestones at Enzene Biosciences?**
Our CDMO setup in India has matured, and we are in the final stages of launching our US manufacturing site in New Jersey. This facility will house two production lines powered by our EnzeneX™ platform, which utilizes our fully connected continuous manufacturing™ technology. Several partners have already signed up, and we anticipate going live in the coming months. By March 2025, our New Jersey site is expected to be fully staffed with 50 employees and well on track to meet operational goals.

Our discovery labs in India are now fully commissioned, supporting major clients in protein reagents, assay development, and immunogenicity testing.

**What are the advantages of fully-connected continuous manufacturing™?**
Fully connected continuous manufacturing™ offers unmatched efficiency, reducing both cost of goods and capital expenditure. Our initial US$50 million investment in the US facility enables nearly 1 t/y of production capacity. In contrast, a traditional batch manufacturing setup would require US$200-US$300 million for the same output. Our EnzeneX™ platform, originally scaled at 200-500 L, has expanded to 1000 L, delivering up to 40 kg per batch. The cost efficiency and sustainability advantages are attracting growing industry interest, with over 10 integrated projects executed. In addition to cost benefits, the technology offers 10x increase in productivity and ~50% reduction in carbon emission, while maintaining high quality standards. Regulatory agencies like the USFDA have also provided draft guidelines, signaling increased adoption of this technology in the coming years.

**What sustainability initiatives does Enzene implement?**
The EnzeneX™ platform itself has a much lower carbon footprint due to its compact design and high efficiency. Our manufacturing suite occupies less than 1,500 square feet while producing up to 40 kg per batch per month. We are focusing on optimizing media usage. Many nutrients are recycled but not reused, so we are leveraging process analytics and spent media analysis to fine-tune nutrient supply. We are exploring media recycling in our perfusion process. There is significant plastic usage in biomanufacturing, and we are actively seeking partnerships to develop solutions in this area.

**What major trends are shaping the CDMO industry?**
A significant trend post-COVID is the shift toward localized manufacturing, with governments and companies prioritizing regional production. This aligns well with our compact, scalable manufacturing model. We also see evolving dynamics in advanced therapy areas such as gene therapy, mRNA, and antibody-drug conjugates (ADCs). Enzene is actively exploring expansion into these domains to remain a modality-agnostic biologics CDMO.

**What role does Enzene play in the growing biosimilars market?**
With many biologics coming off patent, biosimilars are becoming increasingly important. The cost pressures that once drove the rise of generics are now influencing biosimilars, and our India-based manufacturing hub provides a cost-effective solution for biosimilar production. Our discovery labs are designed to support early-stage research, focusing on protein reagent synthesis, AI-assisted therapeutic discovery, and rapid turnaround times. AI-generated sequences have great potential, but there's a gap in validating these leads. We aim to bridge that gap with high-throughput screening platforms that generate lab data in days rather than weeks.

**Where do you see the CDMO industry heading, and how is Enzene positioned for growth?**
The biotech investment cycle is rebounding after a dry spell in 2024. The CDMO sector typically lags biotech investment by about a year. Now that funding is flowing back into biotech, we anticipate a surge in early-stage deals where CDMOs will play a critical role. Enzene is well-positioned. The biotech pipeline remains strong, and commercial CDMO deals are increasing. New modalities such as CGT, mRNA, and ADCs will continue to expand. Companies that provide end-to-end solutions and innovative technology, like Enzene, will be well-placed to capitalize on these trends.

**What are Enzene's key objectives for 2025?**
Our priority is execution. We have a strong deal funnel, and many of these are now being signed and converted into active projects. For 2025, our focus is to ensure we provide top-tier service to our clients, delivering projects on time, maintaining high-quality standards, and expanding industry knowledge on the advantages of fully-connected continuous manufacturing™ over fed-batch or modular-based definitions of continuous manufacturing. From an innovation point of view, breaking the US$40/gram cost barrier for production of mAbs is a key objective this year. ■

# Dirk Lange

CEO

**PYRAMID LABS**

> Alignment on business strategy, culture and operational philosophy is now a critical factor in vendor selection.

**Can you detail Pyramid Labs' growth?**
Growth was largely organic, driven by quality performance and word-of-mouth referrals. In 2023, Audax Private Equity acquired the company, bringing in an experienced management team and investing in expansion initiatives. This includes the launch of a high-speed fill line for pre-filled syringes, cartridges and vials—enhancing Pyramid's ability to support large-scale commercial programs.

**How is Novo Nordisk's acquisition of Catalent reshaping the CDMO landscape?**
One immediate consequence has been a reduction in available manufacturing capacity, particularly for injectables, forcing many clients to seek alternative partners.

The ripple effects of the Catalent acquisition and the surging demand for GLP-1 drugs are reshaping the market. Companies need stable, reliable CDMO partners, and we are strategically positioned to fill that gap.

**How is Pyramid Labs adapting to industry trends and emerging drug modalities?**
The pharmaceutical landscape is rapidly evolving, with biologics, peptides and oligonucleotides gaining prominence. While monoclonal antibodies have long dominated the field, more complex modalities such as bispecific antibodies and fusion proteins are becoming increasingly common. The success of GLP-1 receptor agonists has fueled further investment in peptides, solidifying their place as a viable drug class.

Beyond technical capabilities, the nature of CDMO-client relationships is changing. Pharmaceutical companies are moving away from transactional engagements and seeking long-term strategic partnerships. Alignment on business strategy, culture and operational philosophy is now a critical factor in vendor selection.

**How is Pyramid Labs expanding capabilities in device assembly and testing?**
Pyramid Labs is launching device assembly and testing capabilities in 2025. The company already provides labeling and packaging services and will now support the assembly of auto-injectors and other drug delivery devices.

The integration of device assembly and testing aligns with industry trends toward self-administration and combination products. By offering these services alongside our existing fill-finish and packaging capabilities, we are ensuring clients have a seamless path from drug manufacturing to patient-ready products.

**How is the shift toward self-administration driving changes in fill-finish demand and capabilities?**
A major trend shaping the industry is the increasing emphasis on patient-centric drug delivery. Self-administration is becoming the norm, driving demand for pre-filled syringes and autoinjectors. However, higher drug concentrations and increased viscosity present unique formulation and manufacturing challenges.

Moving from a 20 mg/mL antibody solution in a vial to a 200–250 mg/mL concentration for a pre-filled syringe requires advanced formulation expertise to maintain stability. This complexity extends to the fill-finish process, necessitating specialized equipment and knowledge.

To address these needs, Pyramid Labs has expanded its capabilities in pre-filled syringes, supporting both clinical and commercial production.

**What has been the focus of the firm's R&D efforts?**
Pyramid Labs is making significant investments in product stability and advanced formulation development. A key area of focus is the interface between drug manufacturing, fill-finish processing, and medical device assembly and the unique challenges associated with pre-filled syringes—such as interactions with siliconized glass barrels—require specialized analytical expertise to mitigate stability risks.

We are investing heavily in technology and infrastructure to address these challenges. This includes strengthening our development capabilities to support high-concentration formulations and combination product integration.

Regulatory expectations for combination products continue to evolve, further underscoring the need for expertise in quality control and operational execution.

**What are Pyramid Labs' goals for 2025 and beyond?**
As Pyramid Labs enters 2025, the company is focused on executing its strategic growth plan. The launch of its high-speed fill line in Q3 will expand its ability to meet the increasing demand for injectable drug products. Additionally, the company is onboarding new programs, particularly for late-stage clinical and commercial production.

Our goal is to be the CDMO of choice for clients seeking agility, technical expertise and long-term partnership. With strong backing from Audax and a clear strategic vision, we are well-positioned to drive continued growth and innovation in the years ahead.

As the industry continues to evolve, Pyramid Labs stands out as a stable, reliable and forward-thinking partner in an increasingly complex pharmaceutical landscape. ■





Image courtesy of Contract Pharmacal Corp

# Small Molecule, Big Impact

## CDMOs going with the flow (Chemistry)

While biologics and advanced therapies receive much of the hype, small molecules remain the backbone of pharmaceutical treatments. Small molecule drugs can reach targets that biologics cannot access and can be formulated as an oral dose, a choice many patients prefer. "Solid oral dose products remain essential due to their simplicity and ease of use," emphasized Jim Donovan, VP, contract manufacturing business leader at Pfizer CentreOne. "This demand will not fade because convenience for patients is critical."

Keith Dodson
Executive Director, Business Development and Head US Marketing
**PORTON PHARMA**

> Small molecules remain the backbone of the pharmaceutical pipeline. Even as they evolve, with more complex structures like PROTACs and high-potency APIs, they continue to play a crucial role in drug development.

ACG, the world's largest supplier to solid dosage manufacturers with a presence in 138 countries and six continents, sees it much the same way. "The industry is heavily investing in biologics and injectables, with many companies expanding their portfolios in this space. We believe this trend will be short-lived. Injectable products are expensive and difficult to store, distribute and administer. That limits accessibility and affordability. The industry will return to oral solid dosage forms for their cost-efficiency and scalability," reflected Karan Singh, managing director at ACG.

During 2023-2024, small molecules led biopharma technology venture funding, raising US$13.1 billion across 236 rounds, according to DealForma. Of 2024's 50 FDA drug approvals, 64% were of small molecules. The small molecule API market is expected to grow at a CAGR of 5.45% until 2034, reaching US$331.6 billion. "Even as they evolve, with more complex structures like PROTACs and HPAPIs, small molecules play a crucial role in drug development," emphasized Keith Dodson, executive director of business development and head of US marketing at Porton Pharma.

Many pharma companies lack in-house API manufacturing capabilities and prefer outsourcing to CDMOs, which feeds small molecule CDMO market growth, expected to rise from US$56.49 billion in 2024 to US$60.88 billion in 2025, reflecting a 7.8% CAGR. "Small and mid-sized companies increasingly outsource to CDMOs to streamline drug development, reduce costs and increase flexibility," listed Andrea Confetti, exclusive synthesis BU leader at Dipharma Francis. Even large pharma companies outsource API production to focus on R&D and commercialization.

Many of the small molecule CDMOs that spoke with GBR are increasing capacity as demand increases. Many are evaluating ways to expand capacity to support US API market growth. In the short term, there will be a

scale up in existing manufacturing assets. Longer term, new construction will likely add more capacity.

High-potency (HPAPI) and specialty APIs in the US are driving small molecule API growth. This trend has already trickled down to CDMOs. "We see rising demand for high-potency API capabilities, and we are expanding those at our New Jersey and Shanghai sites," mentioned Dodson.

Italy-based PROCOS is opening a new manufacturing facility by 2026 to support growth of the small molecule sector, increasing overall manufacturing capacity by 25%. "This new facility will significantly enhance our small-scale production capacity, enabling us to meet the growing demand for high-quality, specialized APIs in the US market," said David Short, senior manager of business development in the US and Canada.

Producing high-quality APIs requires compliance with Good Manufacturing Practices (GMP), FDA and EMA regulations. "Regulatory scrutiny by the FDA has intensified, particularly for foreign manufacturers, whose facilities are inspected every 2-3 years under rigorous standards. Domestic manufacturers face unannounced inspections at any time," warned Jay Shukla, president and CEO of Nivagen Pharmaceuticals.

A large driver of small molecule CDMO market growth is the increasing complexity of drug development. As compounds become more intricate, the number of synthetic steps required for production has risen by approximately two-thirds over the past two decades and is accelerating. "In the past three years, complexity in the industry increased, even in synthetic chemistry APIs. This impacts regulations and critical process parameters, even at the intermediate stage," detailed Martin Meeson, the CEO of Axplora.

Increased complexity means longer syntheses that challenge innovators' timely readiness for the clinic. With many new molecular entities being approved via some form of expedited approval pathway, there is continued high demand for CDMO services to meet ever-shorter timelines. "In the innovator space, time is more valuable than money," emphasized Dodson.

**Moving at high distance over time**

After the COVID-19 pandemic, speed-to-market requirements have heightened. "There was once one mega-blockbuster drug that dominated for years, with no competitors. Today, when a blockbuster hits, other companies quickly enter the space," explained Colleen Dixon, president and CEO of Selkirk Pharma.

Drug makers are starting to seek out contract research development manufacturing organizations (CRDMOs) to accelerate the time it takes to bring new therapies to market. CRDMOs eliminate phase-to-phase handoffs and minimize time spent onboarding new partners. According to Krishna Kanumuri, CEO and managing director of Sai Life Sciences, an India-based CRMDO: "While drug development once took eight–10 years, the industry now aims to achieve it in just 1,000 days. As a result, manufacturing and testing cycles are accelerating rapidly."

The Indian CRMDO market is poised for significant growth and is ranked second globally for established small molecule capabilities with 262 FDA approved sites.

**Over the hill and picking up speed**

The FDA released guidance for applying continuous manufacturing to pharmaceuticals in 2004 and approved the first drug manufactured using continuous manufacturing in 2015. A decade later, despite its merit, continuous manufacturing is not the norm. Takahiro Ueda, CEO of CMIC CMO USA, explained: "Continuous manufac-

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AC

RF

> "Small molecule drugs dominate pharmaceutical development, holding almost 60% of the market in 2024, and FDA approvals for small molecules are expected to stay strong."

# Andrea Confetti and Roberto Fanelli

## AC: Exclusive Synthesis BU Leader
## RF: Catalogue APIs BU Leader
## DIPHARMA FRANCIS

**What is driving growth in APIs and how is Dipharma positioned within this landscape?**

RF: The API market is projected to reach US$350 billion by 2029, reflecting a 6% annual growth rate. Within this broader market, generic APIs—a key segment where Dipharma operates—play a crucial role. Several factors contribute to market expansion, i.e., chronic diseases like diabetes and cardiovascular conditions, together with an aging global population, driving the demand for cost-effective treatments, fueling generic API production. Small molecule drugs dominate pharmaceutical development, holding almost 60% of the market in 2024, and FDA approvals for small molecules are expected to stay strong.

By leveraging well-established yet innovative manufacturing processes, Dipharma ensures the production of affordable generics while remaining nonetheless competitive. Dipharma is well-positioned for growth in the API market, backed again by strong regulatory achievements in 2024, including five CEP submissions and four DMF approvals. Since 1970, our Italian facilities have maintained a flawless record of positive inspections from global agencies like the FDA, AIFA, PMDA, KFDA, and more recently, ANVISA. Strengthening its presence in South America, the company strategically expanded in Brazil, where it received CADIFA for UDCA. With investments in facility upgrades and a dedicated unit for new generic APIs.

**How does Dipharma support its clients in the evolving CDMO environment?**

AC: Small and mid-sized companies increasingly outsource to CDMOs to streamline drug development, reduce costs, and increase flexibility. The CDMO market for small molecules, which represents Dipharma's core segment, is growing at nearly 8% CAGR, projected to reach US$55 billion in 2025. This growth is driven by the increasing complexity of drug development and industry consolidation, with a need to focus on core competencies.

We support clients throughout the entire lifecycle of their molecule, from preclinical studies to commercialization, providing tailored solutions to accelerate development. A clear example of our adaptability is a project started in 2021, with a pilot-scale batch for phase 2 clinical trials. The molecule's clinical path advanced faster than expected, leading to back-to-back production campaigns up to 2024. We scaled up from a single 15 kg batch in 2021 to a full industrial campaign sizing 4 tons in just three years.

**How does the US market shape Dipharma's business strategy?**

AC: The US market is a key driver for Dipharma's business, contributing over 40% of total revenues. We strongly focus on this region, where one of our facilities is located. Dipharma acquired the Kalamazoo site in 2018 and transformed it into a GMP-compliant facility, successfully inspected by FDA in 2024.

In recent years, in the US there has been a strong trend of bolt-on acquisitions, as well as a frequent in-licensing of early projects designed for lab scale, not fit for commercial production. To strengthen our position as the partner of choice, we excel in managing these processes by enhancing purification techniques, developing innovative analytical methods, and streamlining synthesis to efficiently scale up to commercial production.

**How is Dipharma strengthening its commitment to ESG and sustainability?**

AC: We evaluate our entire value chain and launch initiatives to control and reduce environmental impact, optimize chemical processes, and support employees' safety and health. Over the past five years, we implemented technical and management solutions to cut hazardous waste by over 20%, surpassing our 15% reduction target. We tripled the ratio of hazardous waste sent for recycling or recovery instead of disposal and we reduced GHG emissions by 20%.

**How is Dipharma advancing continuous manufacturing?**

RF: Flow chemistry has always been a key part of Dipharma's identity, since its foundation on continuous processes for the manufacture of nitroglycerin. This expertise remains a cornerstone of our daily operations, and we advance our flow chemistry capabilities at both lab and pilot scale. A recent implementation is the continuous synthesis of a Nitro-alkyl reagent, where we optimized reaction conditions using a flow reactor and a real-time monitoring system, improving reliability and safety while reducing waste and ensuring yield and process control. Dipharma is also planning ahead by investing in a dedicated skid designed for industrial use. Continuous processing is not just a shift in design — it is a foundation of Dipharma's sustainable, cutting-edge manufacturing approach. ■

> Supporting companies while managing the uncertainties in funding and timelines is key to fostering long-term, successful partnerships.

# David Short

## Sr. Manager, Business Development - US & Canada

## PROCOS SPA

**How will the new R11 manufacturing facility enhance production capacity and meet growing market demands?**
With its building shell complete and equipment installation underway, the facility will feature 20 reactors across four multi-purpose production lines, offering capacities from 1,000 to 6,000 L. This expansion will add 73 cubic meters of production capacity, targeting high-value, complex molecules, particularly in clinical development stages. Scheduled for full qualification by late 2025 or early 2026, the R11 facility will increase overall manufacturing capacity by 25%. For US clients, it will provide flexible mid-scale production tailored to smaller volumes, and specialized therapeutics, ensuring a more robust, diversified and geographically redundant supply chain.

**How does Procos differentiate itself from other API manufacturers?**
We specialize in custom synthesis, offering tailored solutions for emerging therapies that require highly specialized APIs. Our advanced R&D capabilities, combined with a strong manufacturing capacity and a collaborative approach, enable us to meet client demands efficiently and cost-effectively. This flexibility allows us to support clients in diversifying their supply chains while maintaining high-quality standards.

**What strategies does the firm deploy to ensure supply chain reliability?**
Procos ensures supply chain reliability through a comprehensive business continuity plan that proactively identifies potential risks and mitigates disruptions, enabling seamless operations and timely deliveries. We maintain long-term, trusted partnerships with key suppliers and continuously optimize our procurement and production processes. Our established global supplier network supports both generic API production and custom synthesis projects, enhancing flexibility and resilience.

**How does Procos navigate regulatory challenges as an API manufacturer?**
We adhere to the highest compliance standards in North America, Europe and Japan by working closely with regulatory agencies to anticipate and adapt to evolving industry requirements. Our in-depth expertise in generic APIs allows us to navigate complex regulatory landscapes, ensuring full compliance while fostering productive collaborations with authorities. This dual focus on operational efficiency and regulatory excellence empowers Procos to deliver consistent, high-quality products to clients worldwide.

We continually invest in state-of-the-art facilities and ensure they meet or exceed regulatory expectations. This commitment to quality enhances our reputation as a trusted partner, especially in North America, where regulatory oversight is tightening. By prioritizing quality, we open opportunities for collaborations with leading pharmaceutical companies, positioning us to remain competitive in a rapidly changing regulatory environment.

**What steps is Procos taking to minimize its environmental footprint?**
We are committed to reducing our environmental impact through investments in energy-efficient technologies, waste reduction, and sustainable sourcing practices. Our R&D team plays a vital role in optimizing manufacturing processes for maximum efficiency, which not only ensures high production standards but also contributes to a greener future. We are preparing our first sustainability report, scheduled for release in 2026.

**How does Procos adapt to the evolving needs of biotech firms?**
Biotech firms are often at the forefront of cutting-edge medicine, requiring specialized manufacturing processes for complex molecules. Procos supports these companies by developing tailored processes to meet their unique needs. We work closely with smaller biotech firms, offering flexibility in adapting our services to their specific requirements. Our expertise enables us to assist in the development of critical components for advanced therapies, ensuring we meet the increasing demands of the specialized drug market.

**What are the challenges of partnering with smaller biotech companies in today's capital environment?**
Smaller biotech firms often experience more fluid and rapidly changing dynamics compared to larger pharmaceutical companies, with their needs frequently shifting due to changes in the capital environment. Procos emphasizes flexibility and adaptability, adjusting timelines and being ready to scale production quickly as projects progress. Supporting these companies while managing the uncertainties in funding and timelines is key to fostering long-term, successful partnerships.

**What are Procos' objectives for the upcoming year?**
Procos is poised for transformative growth in 2025, driven in part by the commissioning of our R11 facility. This new facility will significantly enhance our small-scale production capacity, enabling us to meet the growing demand for high-quality, specialized APIs in the US market. We will continue to invest in cutting-edge technology and talent development to ensure we stay at the forefront of the API manufacturing industry and support our clients' evolving needs. ■





> CMIC CMO USA is leading and exploring the global implementation of continuous manufacturing.

# Takahiro Ueda

## CEO

## CMIC CMO USA

**Can you introduce CMIC CMO USA?**
CMIC CMO USA is a CDMO company launched in 2007 in the US running a plant in Cranbury, New Jersey. CMIC was the first company that started CRO business in Japan, and currently offers a full range of pharmaceutical functions, but not owning products (except several Orphan drugs). This ensures CMIC never compete with its clients, so clients will comfortably outsource to CMIC. While some companies rival CMIC in specific areas, no competitor offers the full suite of services which CMIC provides.

CMIC CMO USA brings high-quality Japanese pharmaceutical manufacturing to the US, while also helping US companies enter the Japan market. CMIC's full pharmaceutical capabilities give US pharma companies a one-stop shop for registration and PMDA approval.

**How is business continuity planning informing CMIC's business strategy?**
When it comes to business continuity planning (BCP), location is critical. The two major disruption risks are natural disasters and political instability. Ideally, companies would have manufacturing plants across regions to reduce risks. However, this is easier said than done. Most pharmaceutical companies lack the financial muscle to operate their own plants globally. In practice, it is a challenge involving expensive and time demanding tech transfers between sites. At the same time, for companies to sell the same products worldwide, approval from multiple regulatory authorities which often requires international inspections are necessary.

CMIC CMO USA is leading and exploring the global implementation of continuous manufacturing in GMP environment as a CDMO. This enhances agility and helps our clients pivot efficiently under market or regulatory pressures. We will pursue this and aim to contribute to the industry BCP.

**Why is continuous manufacturing the keystone piece of BCP?**
While the concept of global BCP makes sense, it is far from being widely adopted. For example, Batch manufacturing has multiple implementation stages, starting from bench (1 Kg) and scaling up to pilot (>40 Kg), commercial (>250 Kg). At each implementation scale, the process must be characterized. At each scale-up event, there is increased risk of failure, and this development process takes time. On the other hand, continuous manufacturing operates on time rather than scale, and development is performed directly at the commercial scale. It enables the company to examine many product compositions and process parameter choices in a very short time.

Moreover, critical quality data can be obtained and analyzed in real time and used to control the process. Faulty product units can be diverted to scrap without compromising the entire lot, while in batch, humans usually handle testing manually. Continuous manufacturing drastically cuts errors, speeds up changeovers, and lowers waste.

Companies that have implemented mirror Continuous Manufacturing lines can quickly switch locations during natural disasters, ensuring uninterrupted production. This will encourage the industry to expedite having secondary and tertiary manufacturing sites as backup which directly connects to the BCP concept.

**What are the greatest challenges in continuous manufacturing?**
Broad implementation requires overcoming three challenges: equipment is expensive, few know how continuous manufacturing works, and implementing new lines can take several years. Leaders such as J&J, Pfizer, Vertex and Eli Lilly keep their expertise in-house, leaving the rest of the market in the dark. Without serious human capital and the right equipment, implementation often fails.

CMIC CMO USA is working to ease these issues. We partnered with Rutgers University in October 2023, supported by the State of New Jersey. To spread continuous manufacturing worldwide, the industry needs standardized equipment. We've aligned with Fette Compacting who developed continuous manufacturing equipment, which we believe can be standardized ensuring reliability, superior quality, and accelerated development. With standardized manufacturing systems, regulatory approval would become easier and faster.

**What is CMIC CMO USA's market differentiator and goals for the next 24 months?**
Our goal for 2025-2026 is bringing our concept to market, executing for our customers who are counting on this strategical focus of continuous manufacturing.

We established the conceptual base through a MOU with Rutgers and a strategic alliance with Fette. Rutgers brings deep technical expertise and proven research capabilities with academic resources in continuous processes, helping us refine formulations, validate new methodologies, and streamline scale-up bringing more robust, cost-efficient processes in a shorter time. Fette supplies state of the art advanced equipment, the FE CPS makes high-throughput, consistent production viable. ■

> The demand for seamless phase transitions is growing, with integrated CRDMOs enabling better knowledge transfer and faster development.

# Krishna Kanumuri

CEO and Managing Director

**SAI LIFE SCIENCES**

**What are recent developments at Sai and key trends you have observed in the CRDMO space?**

The CRDMO market, particularly in India, has seen significant growth in the recent times. A clear trend has emerged where innovator companies prefer to work with integrated partners. As the only true end-to-end CRDMO in India, we are positioned to meet this need. The demand for seamless phase transitions is growing, with integrated CRDMOs enabling better knowledge transfer and faster development.

Companies are also working to reduce reliance on China and expand their global footprint. With a smaller market share compared to China, India stands to gain from this shift.

Sai Life Sciences' recent successful listing on the Indian Stock Exchanges provides us an opportunity to plan for the long-term.

**What is driving the need for more integrated end-to-end services, or CRDMOs, in the market?**

Speed is the biggest theme in the pharmaceutical space. Without the CRDMO model, each phase—whether from discovery to early development or development to commercial manufacturing—requires a handoff. Companies want to minimize the time spent onboarding new partners. With many companies pursuing the same targets, being first to market offers a significant advantage. While drug development once took eight–10 years, the industry now aims to achieve it in just 1,000 days. As a result, manufacturing and testing cycles are accelerating rapidly.

The integrated CRDMO model is well established. Our strength lies in our ability to excel across the entire spectrum of discovery, development, and manufacturing.

**What factors have allowed Sai to accelerate its growth?**

Five years ago, we launched SaiNxt, an organization transformation initiative, which redefined our ambition and the pace at which we aimed to grow.

We expanded globally, establishing a development site in Manchester and a discovery site in Cambridge, Massachusetts, while also building a new campus and facility in Hyderabad. Above all, we prioritize culture. We didn't acquire companies but grew from within.

**What is Sai's perspective on technology?**

We are a technology-centric company and were one of the first to digitalize our manufacturing facility. We have made aggressive investments in digital platforms across the company, ensuring the full integration of systems from development to commercial manufacturing. We also invest in cutting-edge technologies like flow chemistry and high-throughput experimentation.

**What are the company's expansion plans?**

The US and Europe remain the largest markets for innovation in the pharmaceutical industry, with a consistent demand for genuine partners who can accelerate drug development. This is particularly true for US-based companies, and therefore the US will continue to be a significant market for the foreseeable future.

In 2024, we successfully passed two FDA inspections, each resulting in Establishment Inspection Reports (EIRs). Achieving EIRs is a critical milestone and serves as a 'ticket to play' in the global pharmaceutical landscape.

We also recently acquired a partially built facility in Hyderabad, a key step in our ongoing expansion plans.

**How can the pharma industry enhance supply chain resilience, and what is Sai's approach?**

There is no one-size-fits-all strategy for building a more resilient supply chain. It requires a thorough analysis of each region's unique dynamics and the identification of key choke points. Resilience is developed on a product-by-product, service-by-service basis.

Collaborating closely with our partners to pinpoint and address high-risk areas will be crucial—not only for us but for the entire industry. When bottlenecks are identified, we take proactive measures to either develop in-house solutions or collaborate with local partners to mitigate risks. Whenever a supply constraint or potential disruption arises, we work to backward integrate and regain control over critical processes.

**What is Sai's role in the industry as demand evolves?**

We are committed to delivering high-quality service, investing in new technologies, and adapting as our customers' needs evolve. The key to success as a CRDMO is being where your customers want to be.

The CRDMO sector is poised for growth. While companies initially planned to invest more heavily in internal capabilities post-COVID, there remains a strong demand for flexibility. Businesses are scaling back internal operations and increasingly seeking to expand their external partnerships.

Geographic diversification will play a critical role in building more resilient supply chains. Whether in regulated or unregulated markets, the shift away from over-reliance on China will benefit regions like the US, Europe and India. ■





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turing hit the market before, but most big pharma companies gave up after failed attempts. J&J and Pfizer, however, invested heavily, perfected it, and made it work. Without serious capital and the right equipment, it fails."

Today, CDMOs must adapt production processes to accommodate varying product types, volumes, and customer demands, ensure quality without sacrificing speed, and meet stricter regulations. These constricts make the higher capital investment of continuous manufacturing more reasonable. "There are three key factors driving the uptake of flow chemistry: process safety, manufacturing efficiency, and better yields with less waste," said Saurabh Gurnurkar, the managing director of the Uquifa Group.

CDMOs are investing in continuous manufacturing and starting to see success. "CordenPharma starts with proof-of-concept studies, and scales where we see success" explained CEO and president Michael Quirmbach. "One example of this was our move into Flow Chemistry, for which we have now installed a manufacturing plant."

Dipharma Francis, a CDMO founded on the continuous manufacture of nitroglycerin, consistently thrives using continuous processes. "A recent implementation is the continuous synthesis of a Nitro-alkyl reagent, where we optimized reaction conditions using a flow reactor and a real-time monitoring system, improving reliability and safety while reducing waste and ensuring yield and process control," said Roberto Fanelli, catalogue APIs BU leader.

Continuous flow chemistry is becoming essential in pharmaceutical manufacturing, as North America localizes supply chains. Gamil Alhakimi, president of GL Chemtec International, said: "While not all synthesis can shift back, flow chemistry offers major advantages over batch processes, including improved safety, efficiency, cost reduction, and scalability. It also minimizes impurities, enhances process control, and speeds up production."

Supply chain resilience is one of the greatest selling points of continuous manufacturing, especially from the perspective of business continuity practices (BCP). "Continuous manufacturing uses the same equipment across multiple regions. Only parameter settings need adjustment, making tech transfers faster and cheaper. With identical equipment at multiple sites, companies can quickly switch locations during natural disasters, ensuring uninterrupted production," Ueda elaborated.

Even with its growing capacity, the US must be cautious in its approach to cutting off foreign small molecule API providers. The proposed Biosecure Act could devastate the segment. WuXi AppTec's small molecule unit is involved in around 62 FDA approved drugs. The company is responsible for manufacturing the API, intermediate or finished dose of these drugs and, likely, all aspects of the drug manufacturing. WuXi AppTec supported 27% of all FDA small molecule drug approvals from 2023. Cutting off this capacity could be catastrophic for patients.

The potential disruption caused by limiting access to established API manufacturers like WuXi AppTec underscores the delicate balance in global pharmaceutical supply chains. While bolstering domestic manufacturing capacity is a long-term goal, abruptly severing ties with key international partners could lead to significant drug shortages and hinder patient access to vital therapies. This highlights the need for nuanced policy approaches that consider both national security interests and the immediate realities of drug development and patient care. Companies may need to proactively diversify their supplier base and invest further in domestic capabilities to navigate this evolving landscape effectively. ■

# Fortifying the Flow

Image courtesy of CMC Pharmaceuticals

## Chemical suppliers, distributors and CMC firms formulating supply chain resilience

Sibu Varghese
VP Pharmaceuticals
**IMCD**

> The first consideration for a pharmaceutical company when bringing a new product to market is the API. If we can be in the process from that API stage, we become the customer's solution provider.

The fragility of global supply chains has never been more apparent. Events like the COVID-19 pandemic, geopolitical instability, and climate-related disruptions underscore the critical need for resilience, particularly within the pharmaceutical sector where interruptions can directly impact patient health. "After the Covid-19 pandemic, supply chains suffered from a lack of raw materials, excipients, packaging and high energy costs. Lead times were up to a year," highlighted Maurizio Silvestri, executive president at DMX.

Drug shortages, often stemming from manufacturing quality issues or raw material problems, remain a significant concern. "2024 saw a record 323 drug shortages, with average durations reaching three years—nearly double the timeframe from five years ago. This trend signals a worsening market with a slower recovery. Essential medicine discontinuations have risen by 40%, creating permanent supply gaps as manufacturers exit the market," said Laura Bray, founder of Angels for Change, a non-profit working to end drug shortages.

In response, chemical suppliers, distributors, and Chemistry, Manufacturing, and Controls (CMC) service firms in the US are implementing strategies to mitigate risks, ensure consistency, and bolster the reliability of the nation's medicine supply.

**Tackling variability at the source: The supplier role**

Building a truly resilient supply chain requires addressing potential failure points across the entire value chain. A foundational element, and often a primary source of disruption, lies at the very beginning: the sourcing and consistency of raw materials. Issues with the quality, purity, or reliable availability of these essential inputs can cascade downstream, leading to production delays, batch failures, and ultimately, the drug shortages highlighted previously. Therefore, the proactive measures taken by chemical and material suppliers to manage inherent variability and ensure quality are fundamental to fortifying the pharmaceutical supply network.

Raw material variability represents a fundamental challenge in pharmaceutical manufacturing, especially bioprocessing. Marion Kuhn, vice president at BASF Pharma Solutions, noted: "Raw material variability has been a challenge in bioprocessing since its inception. This variability can not only impact cell performance but also alter the final composition of the drug product, leading to compliance issues and regulatory challenges."

Inconsistencies impact yields, process efficiency, and final product quality, potentially affecting safety and efficacy. Suppliers combat this through rigorous quality control, advanced manufacturing and innovation. BASF, for instance, developed products like Kolliphor® P188 Bio and Kolliphor® P188 Cell Culture to provide consistent performance and address lot-to-lot variability in critical components. "We are employing advanced manufacturing practices and rigorous release testing protocols to ensure consistency," said Kuhn.

Evonik addresses supply risks and sustainability by offering plant-derived alternatives. "Squalene, a lipid used as an adjuvant in parenteral drug delivery, is typically extracted from shark liver, which threatens ecosystems, increases the risk of contamination from methylmercury, varies in quality, and is prone to inconsistency in raw material supply," said Yann d'Hervé, Head of the Health Care Business Line at Evonik

In response, Evonik introduced PhytoSquene, avoiding variability, ecological concerns, and inconsistent supply.

Partnering with suppliers who prioritize strict raw material characterization, quality management, traceability, and global sourcing redundancy is crucial for manufacturers seeking to minimize variability.

**Distributors: Ensuring flexibility**

Pharmaceutical distributors are essential nodes in the supply chain, increasingly acting as more than just intermediaries. "Customers nowadays expect distributors to be no longer just logistics and supply chain facilitators," said Neil Houston, director of pharmaceuticals Americas at IMCD.

Now, distributors are logistics experts who enhance stability and efficiency, saving the healthcare system billions annually. Brenntag Specialties emphasizes the importance of a global footprint and market intelligence. "With boots on the ground worldwide, we spot supply chain fluctuations early and react quickly," said John Lampariello, president of pharma North America. "This allows us to offer multiple manufacturers, giving customers flexibility and simplifying their supply chains. They remain dual-sourced without the burden of managing multiple relationships," continued Lampariello.

Distributors play a key role in managing inventory across extensive networks, ensuring medications are available where needed while adhering to stringent storage, handling and regulatory requirements like the Drug Supply Chain Security Act (DSCSA).

**CMC: Building reliability in**

CMC firms contribute significantly to supply chain reliability by ensuring robust product development and stable manufacturing processes. "CMC Pharmaceuticals focuses on creating a comprehensive CMC package from the start," said Mike Radomsky, the president, which ensures that formulation, stability and analytical methods are aligned for scalability and regulatory compliance.

Their work extending the operational shelf-life of a military prophylactic medicine demonstrates how CMC expertise can reduce waste and enhance supply stability.

While the push to reshore manufacturing to the US faces economic hurdles, particularly for generics, investments in domestic capacity, like BASF's new GMP plant, contribute to a more robust regional supply base.

**An integrated approach to resilience**

Ensuring a resilient pharmaceutical supply chain requires a multi-pronged approach, integrating the efforts of specialized suppliers, agile distributors and expert CMC/manufacturing partners. Strategies like diversifying suppliers, maintaining strategic inventory, enhancing process controls, ensuring regulatory compliance, and fostering strong partnerships are paramount. As the US life sciences industry navigates ongoing global uncertainties and prepares for the future, the collaborative efforts of these key players will be vital in safeguarding the consistent availability of essential medicines for patients nationwide. ■

# Mike Radomsky

President

**CMC PHARMACEUTICALS**

> We balance the need for speed in drug development with strict regulatory requirements by focusing on robust data, sound justifications and a well-structured technical package.

**How has business been for CMC Pharmaceuticals of late?**
We have had a productive year, particularly with our continued collaboration with the Department of Defense on Nerve Agent Defense programs.

**How does CMC Pharmaceuticals demonstrate its expertise in executing projects?**
We bring extensive chemistry and manufacturing expertise to many programs. Our team consists of chemists and chemical engineers with years of experience in pharmaceutical development, from early-stage formulation to stabilizing strategies and scale-up. We often start by producing small batches in the lab, then scale to larger quantities, and ultimately help clients transition to full-scale commercial manufacturing.

**Can you share an example of a project that highlights CMC's capabilities?**
A great example is a recent project where we extended the operational shelf life of prophylactic medicine for the military. Initially, the product had only a 30-day shelf life, leading to significant waste. The Department of Defense came to us for help in generating stability data to support an FDA filing for an extension. We conducted a multi-year stability study, developed the necessary analytical methods, and successfully extended the product's shelf life to over a year. This project not only highlights our technical expertise but also our ability to collaborate effectively with government agencies.

**What industry trends are shaping pharmaceutical development, and how is CMC adapting?**
One key trend we are seeing is the increasing focus on creating a comprehensive CMC package from the start. This means ensuring that formulation, stability work, and analytical methods are all aligned to support scalability and regulatory compliance. Many companies faced delays due to inadequate early-stage chemistry and manufacturing efforts, so we emphasize a science-driven approach. We balance the need for speed in drug development with strict regulatory requirements by focusing on robust data, sound justifications and a well-structured technical package.

**How does CMC Pharmaceuticals support a sustainable business model?**
We aim to deliver strong science and top-tier customer service, which helps us build trust and secure repeat business. A prime example of this is our ongoing work with the Department of Defense. We see sustainability as part of our long-term strategy to continue providing value to our customers while maintaining our environmental and operational standards.

**How has AI influenced the industry's drug development processes?**
AI has influenced the early stages of drug discovery, particularly in identifying excipients and stabilizing formulations. While we do not develop AI-driven models ourselves, some of our clients are leveraging AI for drug discovery. Once they have identified promising candidates, we come in to help with formulation and development, ensuring the stability, absorption, and solubility of the products. While AI helps speed up the initial discovery, the real work takes place in the lab, where we validate and refine these formulations for real-world applications.

**What sets CMC apart from competitors?**
Our deep expertise in drug chemistry, combined with our agility as a smaller company, allows us to respond quickly and effectively. We can initiate contracts and move to lab work faster than many mid-sized firms. Our team's decades of experience and specialized expertise in chemistry and manufacturing are key differentiators. Our focus on customer service—consistent communication, transparency, and project management—ensures that development stays on track, making us a trusted partner to our clients.

**How do you see CMC Pharmaceuticals evolving over the next decade?**
We are focused on significantly expanding our capabilities. We have been executing a growth plan that aims to double our size in terms of people, services, and facilities within the next four years. We will continue building on our core areas—formulation, analytical stability, process development, and scale-up—and further enhance our new service offering, contract manufacturing oversight. Our ability to help clients find and oversee commercial manufacturing sites has become an integral part of our strategy.

**What will CMC Pharmaceuticals focus on in 2025?**
In 2025, we will be focused on continuing to ramp up our expanded services. We are investing in new lab equipment, building out more lab space, and strengthening our quality unit to support manufacturing oversight. We will also be adding more chemists to our team to meet the growing demand. ■





# Yann d'Hervé

Head of Health Care Business Line

**EVONIK**

**How is Evonik leveraging its CDMO capabilities to accelerate drug development?**
In recent years, many new technologies have been scaled up and commercialized such as mRNA and siRNA-based drugs. Evonik's CDMO capabilities are being put to work to accelerate the development of these technologies.

Evonik leverages its Drug Substance CDMO expertise and capacities in organic synthesis and chromatographic purification in order to scale up and produce customized lipids in cGMP quality.

**How has Evonik strengthened its healthcare presence in North America?**
In Tippecanoe, Indiana, we operate one of the largest drug substance manufacturing sites in the US, which now grown into a world-class CDMO with small molecule and fermentation capabilities. In Vancouver, Canada, we acquired Transferra Nanosciences in 2016 to develop lipid nanoparticles (LNPs) and liposomal formulations. In Birmingham, Alabama, since the acquisition of SurModics Pharmaceuticals in 2011, we offer fully integrated complex drug product injectable capabilities. More recently, in 2024, Evonik opened a healthcare innovation satellite in Boston, Mass. to be closer to one of the world's largest biotech hubs. ■

# John Lampariello

President Pharma North America

**BRENNTAG**

**How will Brenntag pursue growth in pharma?**
M&A always plays a key role in expanding chemical distribution. We look for opportunities to scale, add new supply partners, and grow our value-added service capabilities. Organic growth comes from winning principal mandates in key areas. We identify gaps and show suppliers that Brenntag is the right channel for their business in the life sciences space. Lastly, we always push our existing principals in the market and work to expand market share for both our partners and Brenntag.

**What are current challenges in the market?**
One of the biggest challenges in the pharma market is rising regulatory demands and the need for stronger documentation. Many finished dose products are now global in nature and we are seeing increased requests for products that meet multiple pharmacopeias. In some cases, Brenntag is working with our supply partners to add additional testing and ensure the products meet the necessary regulatory requirements. ■

# Marion Kuhn

Vice President, Global Business Management

**BASF PHARMA SOLUTIONS**

**Can you detail advancements and milestones reached for BASF Pharma in 2024?**
With the launch of new products for biopharmaceutical applications, including Kolliphor® P 188 Cell Culture and Kollipro™ Urea Granules, we strengthen our commitment to providing the biologics market high quality raw materials that fit their manufacturing needs and reduce raw material variability.

Digitalization is a continuing focus to help our customers develop and manufacture drugs more efficiently. In 2024, we expanded our digital offer with the introduction of a new premium account option for our Virtual Pharma Assistants, which further enhances the user experience.

**How is BASF collaborating with industry partners to drive innovation in the pharmaceutical sector?**
BASF has established partnerships with Cytiva, the Bioprocessing Training and Education Center at North Carolina State University, and the National Cancer Institute. These collaborations drive biopharma innovation by developing new biopharmaceutical ingredients, optimizing existing products to better suit customer applications, and advancing scientific understanding of raw materials to enhance industry knowledge. ■

# NEW TECHNOLOGIES

“While AI adoption is still in the early stages in life sciences, we are seeing rapid growth, especially in pharma.”

Rohit Vashisht
CoFounder and CEO
**WHIZ.AI**

GBR Series
UNITED STATES LIFE SCIENCES 2025

Image courtesy of Skycell

# Beyond Drug Discovery

Image courtesy of GSK

## AI is sweet as pie

For pharma executives, citing artificial intelligence (AI) as a driver of growth is more contagious than measles in a room full of unvaccinated individuals—nearly all mentioned its benefits in their JPM Healthcare presentation. Roger Perlmutter, the CEO of Eikon Therapeutics and former R&D executive at Merck and Amgen, regards AI as "the defining tool of our era."

However, AI is a broad term and the avenues for growth in pharma are as wide and as numerous as those in New York City. While the orbit of AI is skewed by the gravity of drug discovery, its other use cases are gaining traction. "One of the magic bullets of AI is operational efficiency, so it does not take a decade to get from discovery to a marketed product," said Bari Kowal SVP of development operations at Regeneron at the Financial Times US Pharma and Biotech Summit.

Kowal has a point. At an average of 10 to 15 years, the US is the market leader in time taken to bring a drug to market. Given this timeline, efficiency in all stages of the drug development process becomes a necessity. "This means using AI to streamline the patient journey, minimize dropout rates, and ensure that patients stay in trials," said Paula Brown Stafford, CEO of Allucent, a contract research organization.



This also means utilizing AI for formulation development. "AI minimizes the number of required trials, improves production consistency, and enhances scalability from R&D to commercial manufacturing, all while reducing the operational footprint for long acting injectables compared to traditional methods," said Jay Shukla, president and CEO of Nivagen Pharmaceuticals, a sterile fill finish CDMO.

AI can also help unlock capital flow, said Saaurabh Shharma, partner and CEO at Agram Konnect, a strategic communication company: "AI-powered 3D visualization is revolutionizing how we communicate scientific concepts. For instance, a biotech firm launching a new molecule can use 3D animation to illustrate its mechanism of action for investors."

One of the most overlooked opportunities for efficiency lies in validation—the complex process of proving that everything in drug development works as intended. ValGenesis, a leader in digitizing the validation processes, integrated AI and machine learning into its Validation Lifecycle Management System (VLMS) across three key areas: protocol generation, validation execution, and review by exception. "Companies typically allocate 30% of their total costs to validation, and we are working to reduce this by at least half," Siva Samy, CEO and chief product strategist, stated.

Thanks to its AI-powered bots, ValGenesis can now generate validation protocols in five to eight minutes (a task that traditionally took two to three weeks) and reduce review and approval cycles from weeks to hours.

Ultimately, improving operational efficiency is not just about trimming budgets—it means getting therapies to patients faster, with greater precision and safety. Even regulators are adapting, as AI helps companies proactively manage quality and compliance in real time, an emerging shift from traditional reactive models.

### From the cherry on top to the filling

AI is becoming embedded in the industry's infrastructure. However you slice the AI pie, you will find it filled with efficiency, something baked into the DNA of technology firms operating in the pharma space.

One transformational avenue for pharma is generative AI (gen AI). McKinsey found gen AI could unlock between US$60 billion and US$110 billion a year in economic value for the pharmaceutical and medical products industries. While the recipe sounds promising, most companies are still in the prep phase. In a recent McKinsey survey of 100 executives leading gen AI efforts in pharma and medtech, 100% reported experimenting with the technology. However, when it came to realizing gen AI as a competitive differentiator generating consistent and significant financial value, only 5% of leaders fell into this category. GenAI budgets are forecasted to increase from 2024 to 2025, with 20% of McKinsey's surveyed leaders planning to allocate over US$10 million in 2025. Translating this investment into returns will be pivotal.

One reason for the suboptimal returns is the inability to apply it effectively. Scaling gen AI is not simply a matter of implementing a new technology; it is about rewiring the organization's operating model and culture to support new AI-driven ways of working. WhizAI, a company that developed a generative AI platform that allows companies to talk to their data like it is ChatGPT, highlighted that the industry has a lot of room to realize this potential. "We are just at the beginning stages of generative AI, much like the internet in the 90s. The true transformation will occur when AI is integrated into products that solve real business problems," said Rohit Vashisht, the company's cofounder and CEO.

Integration is key. 70% of digital transformations fail because leaders ignored change management, not because of technical issues. "For every dollar spent on a new technology, US$5 is required for change management to successfully drive capability building, adoption, buy-in, and value capture over time," according to McKinsey.

### Where is my AI?

Despite the benefits, many of AI's applications remain out of reach. The limiting factor? Siloed, inaccessible data. "We found that most customers—including big pharma—were not ready with their data, despite significant investments in cloud and analytics. Many are at an inflection point where they need applications but lack the necessary data foundation," underscored Rajiv Anand, founder and CEO of Quartic.ai.

In many companies, manual data processes persist, making any advanced analytics at scale or speed impossible. The solution is a DataOps approach which can enable pharmaceutical companies to extract more value from their data and more quickly advance and scale their digital and analytics initiatives. Companies like Quartic.ai recognized this drawback in the market and now offer an out-of-the-box DataOps solutions.

AI is not just a cherry on top—it is the filling. As pharma continues baking its digital transformation, one thing is clear: the recipe is changing, and efficiency is now the main ingredient. ■



## Rajiv Anand

Founder and CEO
**QUARTIC.AI**

**How did Quartic.ai's focus shift in 2024?**
Our key product developments in 2024 focused on DataOps. We found that most customers—including big pharma—were not ready with their data, despite significant investments in cloud and analytics. Many are at an inflection point where they need applications but lack the necessary data foundation.

Beyond DataOps, our focus has been on core multivariate analytics (MVDA, MSPC). We had MVDA and optimization solutions as standalone offerings, but now we evolved them into a comprehensive workbench for practitioners. Moving forward, our strategy is centered on three pillars: DataOps, advanced multivariate analytics, and opening our platform to integrate seamlessly with customers' existing ecosystems.

**Which market shifts are driving product development?**
Over the past 3-4 years, companies made significant investments in digital transformation. At the macro level, impatience is growing. Management expected a return on investment by now, whether from AI or digital transformation initiatives. This led to a pullback in funding for data platforms and digital capabilities. Internally, teams tried to build solutions in-house, but progress was slow. There was a push-pull dynamic between in-house IT teams and business leaders demanding faster results. This urgency drove our strategy. Customers can now use our out-of-the-box DataOps capabilities while integrating with their existing cloud infrastructure—AWS, Snowflake, or Databricks. They can layer our applications on top of their investments.

**What is the level of AI maturity across the life sciences industry?**
AI adoption is highest in two cases: early in the product lifecycle and when it impacts quality, throughput, or reliability. New molecules and processes create more openness to AI. Companies want to bring new products to market faster. Since these processes and equipment are untested, there is more flexibility to experiment before scaling to full production. The product development and qualification phase lends itself to experimentation, leading to higher AI adoption. ■

> With continued investments in AI and automation, we are accelerating the industry's shift to digital validation and data-driven decision-making.

# Siva Samy

CEO and Chief Product Strategist

**VALGENESIS**

**What are recent developments?**
We elevated our Validation Lifecycle Management System (VLMS) by integrating AI and machine learning, significantly reducing validation cycle times and costs. Our refined risk-based approach aligns seamlessly with evolving global regulatory expectations.

**Can you describe the three AI bots ValGenesis will release to market in 2025?**
Bot One streamlines protocol generation by digitalizing the validation process, eliminating manual tasks, and reducing effort up to 50%. Our intelligent scoring system automatically identifies the closest match for equipment, documents and content to auto-generate protocols. While traditional protocol generation takes two or three weeks, our bot completes it in just five to eight minutes, reducing effort by up to 80% while significantly improving content accuracy.

Bot Two optimizes validation execution by transitioning from paper-based to digital validation, cutting execution time by up to 50%. Using AI, the bot analyzes evidence, compares expected results, and auto-populates actual results, reducing the process from 15 minutes to just one minute. It ensures a Right First Time (RFT) approach, minimizing rework, discrepancies, and audit risks while enhancing quality, efficiency and regulatory confidence.

Bot Three focuses on review by exception, automatically parsing evidence at every step and comparing actual versus expected results. Any misalignment is flagged for action, allowing users to focus only on exceptions, reducing review and approval cycles from weeks to hours. These innovations can help companies lower validation budgets by at least 50%, translating into savings of hundreds of millions of dollars. With the launch of VLMS 5.0, we introduce the industry's first AI-powered digital validation platform.

**What case studies illustrate ValGenesis competitive advantage?**
NEXA uses our VLMS tool to enhance their equipment qualification processes and saved 1,500 hours in documentation efforts compared to paper-based methods. Project completion time decreased by four days.

Merck Millipore faced challenges in standardizing validation across global operations while maintaining regulatory compliance. With ValGenesis VLMS, they achieved a significant reduction in validation cycle time through automation and streamlined workflows, eliminated paper-based processes, and improved inspection outcomes.

Companies typically allocate 30% of their total costs to validation, and we are working to reduce this by at least 50%.

**What challenges does the industry face as it moves towards digitalization?**
Adopting digital solutions requires alignment with evolving regulatory expectations, as companies must ensure data integrity, auditability and risk-based validation. Many organizations rely on paper-based, manual systems. Transitioning to digital validation requires a cultural shift, user training and strong leadership buy-in. Seamless connectivity between QMS, MES, LIMS, ERP with digital validation platforms is essential but can be challenging due to disparate data sources and outdated infrastructure. Robust cybersecurity measures are needed to protect data, cloud environments and electronic records from breaches or manipulation. Ensuring that AI models remain trustworthy, explainable and validated within regulated environments is an ongoing focus.

We address these challenges by offering risk-based, AI-powered validation solutions that enhance compliance, efficiency, and seamless integration.

**How are pharma/biotech companies integrating AI into validation workflows?**
Pharma and biotech companies are rapidly integrating AI into their drug development and manufacturing workflows to enhance efficiency and data-driven decision-making. AI models analyze historical process data to predict deviations, optimize parameters, and ensure real-time process control for continuous manufacturing and CPV. AI-driven risk assessments enable companies to prioritize validation activities based on impact and compliance risk, aligning with evolving CSA (Computer Software Assurance) guidelines. AI enables organizations to stay proactive and compliant by scanning and analyzing regulatory updates and industry trends in real time.

**What are ValGenesis' primary objectives and market expansion strategies for 2025?**
ValGenesis is committed to accelerating digital transformation in drug product development, validation, and Continuous Process Verification (CPV) through AI-driven innovation, global expansion, and strategic industry partnerships within the Smart GMP platform. We will enhance our Quality by Design system to meet evolving CMC requirements, ensuring robust process control. Our platform will integrate AI and ML more deeply to reduce validation cycle times, increase efficiency, and improve compliance. We will strengthen our CPV capabilities to provide real-time process monitoring and insights, enabling continuous process optimization and regulatory adherence. ■





# How will the industry evolve?

Image courtesy of Skycell

"Therapies and modalities will continue to diversify because the patient-first approach focuses on developing therapies specific to disease states and rare diseases. For CMOs, this means dealing with more complex needs and requirements."

Colleen Dixon, President and CEO
**SELKIRK PHARMA**

"We supported over 1,000 oncology clinical trials, including innovative programs in cell and gene therapies and ADCs. While many of these technologies originated in oncology, we are now seeing them applied in non-oncology indications as well."

Rick Farris, Managing Director North America
**NOVOTECH**

"To succeed, we recognize that we cannot be all things to all people. Bringing in the right partners is key. Larger CDMOs struggle to support smaller clients due to inflexibility and longer lead times."

Marty Henehan, Vice President Business Development and Head, North America,
**MABION**

"The future of nucleic acid and genomic medicines is exceptionally promising. Within five to 10 years, traditional treatments like chemotherapy could become obsolete for certain cancers, replaced by precision therapies that are highly personalized."

Kate Broderick, Chief Innovation Officer
**MARAVAI LIFESCIENCES and TRILINK BIOTECHNOLOGIES**

"Companies must choose how they will win in an evolving landscape. Success requires better portfolio management, smarter capital allocation, AI-driven operations, risk management, and cost control. Now is the time to rethink strategic choices and build the capabilities to break the cycle of lagging returns."

Greg Rotz, Pharmaceutical and Life Sciences Advisory Leader
**PWC US**

"At the CES convention, one of the biggest trends across industries was personalization — delivering tailored experiences to consumers. Pharma is a step behind but following suit."

Karan Singh, Managing Director
**ACG**

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## *Thank you!*

We would like to thank all the authorities and executives that took the time to share their valuable insights for this report, as well as our partners, Biocom California, MassBio, BioNJ and Ohio Life Sciences.

Image courtesy of MJH Shikder at Unsplash

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