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# UNITED STATES LIFE SCIENCES 2024

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# Dear Readers,

Welcome to the 2024 edition of GBR's ***United States Life Sciences*** industry report.

Cautious optimism. These two words best describe the state of mind of life sciences executives as we enter the second half of 2024. Having experienced one of its hardest-ever years in 2023 – in terms of depressed valuations, public and private fundraising drought, and challenging geopolitical fluctuations – the US life sciences industry is now embracing recovery mode.

The US remains the leading force in the life sciences industry worldwide, providing an unparalleled ecosystem of VC and institutional investors funding the most promising technologies that emerged out of the brightest minds. From the cloisters of the Ivy League in the East, passing by the shining towers of Wall Street, through the start-up labs of California, and with a flurry of growing hubs across the country, the US remains the premier life sciences hub in the world. Its position as the biggest pharmaceutical market globally attracted an unprecedented number of foreign players in 2023, with Indian CROs, European CDMOs, and South Korean mega-conglomerates establishing a presence there.

Yet, big pharma and biotechs face perhaps their biggest challenge to date: That of having to reinvent their business model. Despite a record year for FDA approval (with 55 novel drugs), the release in recent years of the anti-obesity GLP-1s, the first ever FDA-approved early-treatment Alzheimer's drug, and unprecedented strides in oncology, Big Pharma returns lagged the S&P 500 in the period since the pandemic, and biotech did even worse. Reincorporating risk – despite the high chance of failure – and targeting assets in less crowded therapeutic areas will represent key strategic considerations for executives going forward.

Fortunately, US biopharma companies can rely on a diverse ecosystem of CDMOs, CROs, and specialty chemical firms to ensure their molecules make a difference for patients. This segment, however, will have to face challenges of its own in 2025. Be it small or large, manufacturing molecules is a matter of national security, and the recently proposed BIOSECURE Act could become a catalyst for reshaping the contract manufacturing scene in the US. As tensions between the US and China heat up, drugmakers and biotechs will keep accelerating their contingency plans.

Drawing from almost a hundred interviews with biopharma, biotech, investors, CDMOs, CROs, specialty chemical, technology, and AI executives, the following pages present a comprehensive overview of the US life sciences industry today, and offer insights into the country's capability to attract foreign capital, talent, and science. The report concludes by pondering the debate on the relationship between viruses – of which a number have recently spread beyond their "tropical" places of origin – and humanity, and how proactive investment in this area can lead to both returns and the well-being of our species. We would like to thank the executives who took the time to share their invaluable insights with us, along with our association partners at BioNJ, MassBio, and Biocom California. We hope you enjoy the read.

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

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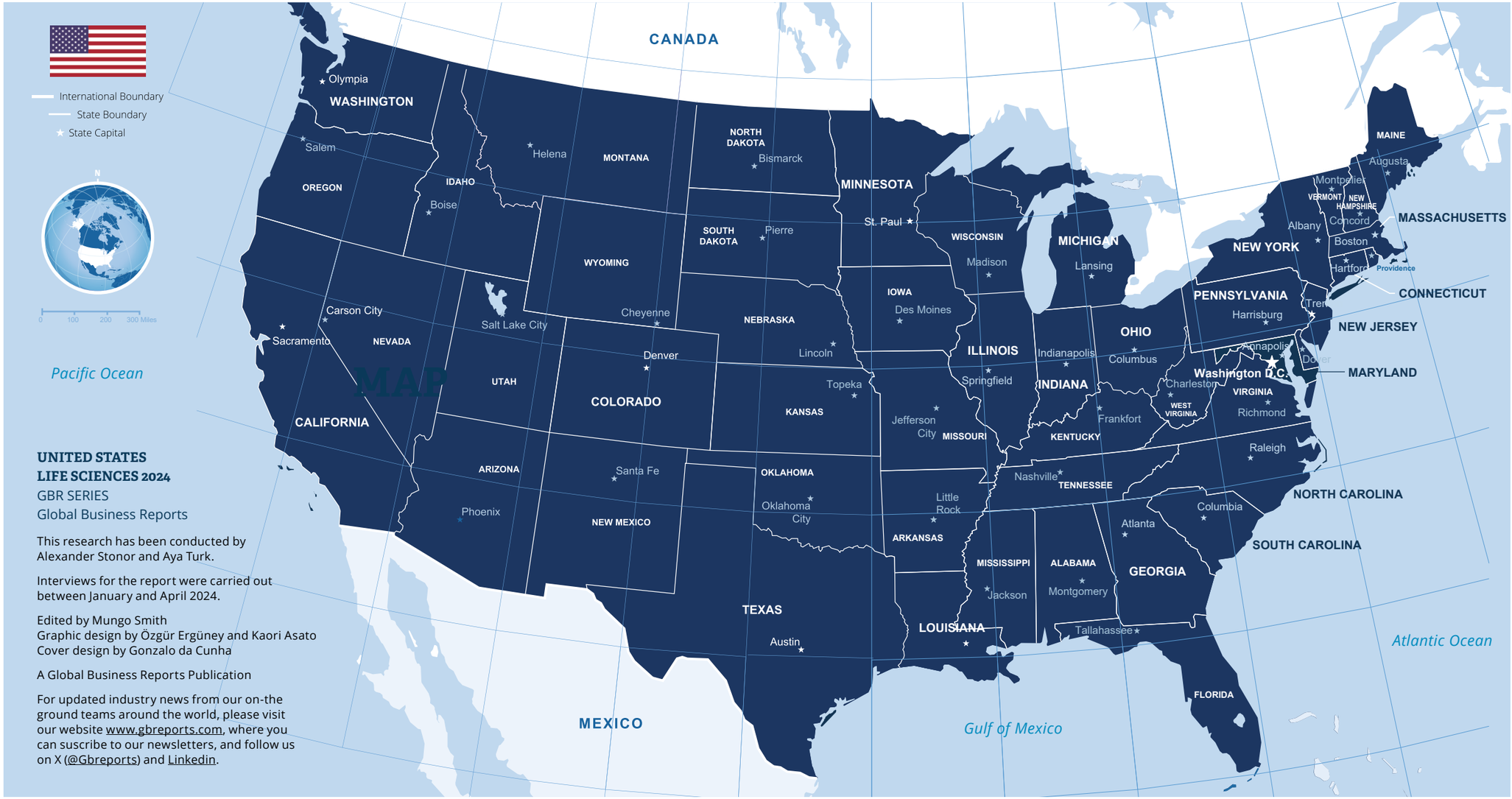



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This research has been conducted by Alexander Stonor and Aya Turk.

Interviews for the report were carried out between January and April 2024.

Edited by Mungo Smith
Graphic design by Özgür Ergüney and Kaori Asato
Cover design by Gonzalo da Cunha

A Global Business Reports Publication

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# Introduction

> Overall, 2023 was one of the most challenging years the biotech industry has faced.

**Joe Panetta**
President and CEO
**BIOCOM CALIFORNIA**

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Image courtesy of IMCD

# Introduction to United States Life Sciences

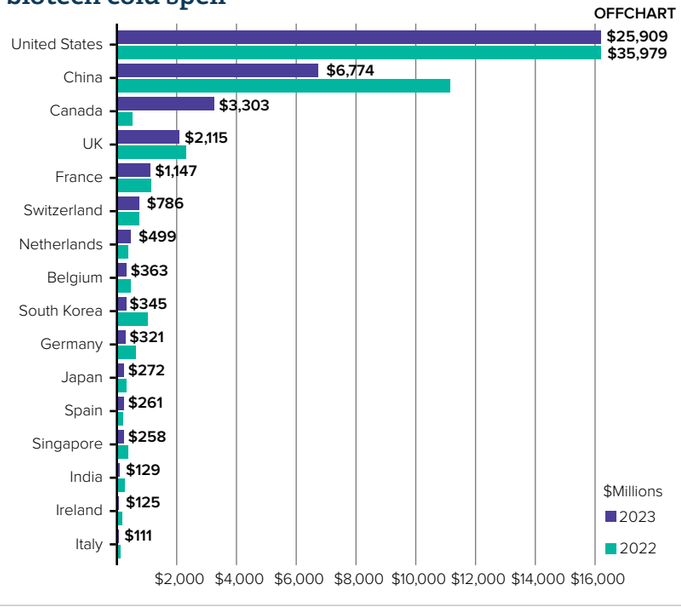
## Cautious optimism following a tumultuous period

In January 2024, thousands of executives, investors, entrepreneurs, scientists, and bankers had the chance to take the temperature of the life sciences industry at the JPM Health Care Conference in San Francisco. A shadow of uncertainty was cast over the event before it began, given the tumultuous previous months for the sector. 2023 saw many biotech stocks hitting rock bottom, high interest rates, and sustained geopolitical uncertainties. Amidst depressed valuations and a recovering sector, R&D also appeared in peril due to a challenging regulatory environment.

Nevertheless, conversations took an optimistic tone in San Francisco that week. Indeed, the earlier months of 2024 have shown that the pendulum is now swinging towards what many industry leaders have referred to as "cautious optimism". The industry certainly is not back to pre-pandemic levels of venture capital flowing into early-stage, highly ambitious technologies (some of which, perhaps, having been dispersed before necessary due diligence was made), however, strong innovation and a bolstered M&A and IPO environment have the potential to lay the ground for a virtuous cycle that will reward companies and patients.

What is certain is that the US will remain the driving force of the industry globally. Statista estimates the projected revenue in the pharmaceutical industry to reach US$1.156 trillion in 2024. The US alone is forecast to account for over half of that revenue, with a figure as high as US$636 billion. Indeed, it is the stronger investment outlook in the country that is positioning the global industry on a positive growth trajectory in 2024. According to EY figures, life sciences M&A spending rose to US$191 billion in 2023, a 34% YoY increase, with patent cliffs and a vast amount of capital to be deployed adding urgency to big pharma's dealmaking capabilities. In December, Pfizer finalized the US$43 billion acquisition of Seagen, bringing its total to nine cancer drugs that are either blockbusters or have that potential, and serving as a keen reminder that antibody-drug conjugates (ADCs) and oncology remain leading value-creating therapeutic areas. In January 2024, following one of the worst IPO periods in the industry's history, four firms held IPOs on the Nasdaq, worth a combined US$800 million. This was closely followed by two other biotechs, suggesting that the IPO window had, finally, cracked open (2023 only recorded 19 public offerings, a considerable drop following the over 100 in 2020).

### US top destination for VC funding despite 2023 biotech cold spell

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**Headwinds and tailwinds: Innovation as a lifeline**

Amongst the factors that set the US life sciences industry apart is its capacity to innovate. Having mobilized at an unprecedented level and pace during the COVID-19 pandemic, which was enabled by decades of research and innovation, the industry showed it was able to achieve results that could only be conceived as science fiction in the recent past. Indeed, the idea of an mRNA vaccine "on demand" was debated in a research piece published in the National Library of Medicine in 2015. Less than a decade later, Katalin Karikó and Drew Weissman received a Nobel Prize for their discoveries concerning nucleoside base modifications that enabled the development of effective mRNA vaccines used by Pfizer-BioNTech and Moderna against COVID-19. Both Nobel laureates received education from the US' top universities, where they today direct innovation institutes and teach neurology and RNA biology.

Post-pandemic, as mRNA pipelines slowly dry up amidst sluggish demand (Moderna reported a quarterly loss in Q3 2023 amid plummeting demand for its Covid shots), 2023 saw notable advancements made in vaccine development, cancer treatments, GLP-1 drugs transforming obesity management, gene therapy, and gene editing technologies targeting rare diseases, alongside novel treatments for complex ailments such as Alzheimer's. Despite these breakthroughs, the challenge of realizing their value remains, leaving investors dissatisfied. The sector continues to lag in capital markets compared to the broader market index. After a challenging year in public and private markets, the sector's ability to capitalize on these innovations will most likely make the difference between success and failure.

Among the challenges that persist in 2024 are the sustained high interest rates, ongoing geopolitical tensions, and the implications of the Inflation Reduction Act (IRA). Concerning the latter, numerous industry leaders express apprehension regarding its adverse effects on innovation. One notable catalyst will be the finalization of drug prices in September 2024, with several pharmaceutical firms having already initiated legal challenges questioning the constitutionality of this policy, with speculation mounting that the matter may eventually reach the US Supreme Court. Beyond the regulatory landscape, the political one might also impact the industry, as the US braces for an undoubtedly tumultuous presidential election in November. Expanding on the importance of innovation, William Lewis, CEO of Insmed, a biopharma developing its pipeline in the rare disease space, shared: "Global financial markets, geopolitical events, regulatory and legislative changes, and evolving technologies will continue to influence our sector in the year ahead. I believe that companies with the ability to innovate have enormous opportunities to succeed."

Building on a strong innovation pipeline, the US has maintained its ability to remain the innovation powerhouse of the world, and this ability will more than ever constitute its lifeline, with several therapeutic areas poised to benefit from the commercialization of novel drugs. The FDA approved 55 novel drugs in 2023, a slight increase from the five-year average of 53. With an exceptional 17 approvals for the treatment of tumors, significant scientific improvements in the field of cancer have materialized into commercially available new drugs on the market. As such, oncology remains the biggest target for dealmaking, with 2023 investment hitting US$65 billion.

The notorious GLP-1s (such as Wegovy, Zepbound, and Ozempic, the blockbuster weight-loss drugs) will most likely see huge runaway demand, and with more innovation from pharma giants like Novo Nordisk and Eli Lilly, as well as 230 biotechs in the space, the life sciences industry seem to have entered a race to develop the next generation of these drugs. As obesity affects over 40% of US adults and 1 billion people worldwide, that market is expected to be worth US$150 billion by 2030, according to the Financial Times. Separately, investment in advanced modalities like cell, gene, and RNA therapies will continue to shape the innovation landscape.

**Beyond the labs, innovating in the business model**

In early 2024, a PwC report highlighted pharma companies' growing challenges in driving value growth, despite the historic achievements of the past years. Indeed, since the pandemic, Big Pharma returns lagged the S&P 500, and biotech did even worse. The evidence is clear: Great science is not enough to generate value growth. As market headwinds affect all industries, perhaps the sting is more acute for pharma, and the coming years might see C-level executives reshaping their strategic model. Indeed, in that same PwC report, 45% of the CEOs interviewed were concerned that their business model would run out of steam within a decade.

Another model does not necessarily mean inventing something new, and a return to fundamentals is the solution for many pharma CEOs. The first-mover advantage theory was coined in the 1980s, and for Greg Rotz, transformation consulting leader for pharmaceuticals & life sciences at PwC, it might be the way forward for executives. Pharma expenditure rose between 2018-2023 to a record US$161 billion, but effects on returns have been limited as many firms have competed for asserts in the same therapeutic areas. "We have more assets chasing the same areas, creating more head-to-head competition" explained Rotz. Simply put, more products in the same space means more competition and, therefore, less returns.

One way to regain investor trust in leadership models could be to reincorporate risk, despite the higher chance of failure. Pharma is innovative by nature, but Rotz and other experts suggest infusing a culture deeply rooted in innovation, reinforcing differentiation, and going outside of traditional comfort zones for the sector to thrive again. This approach, however will have to be managed with caution, as the investment community almost unequivocally expressed to us their preference for de-risked assets.

Following one of its toughest periods in 2023, the industry has many reasons to be cautiously optimistic for the remainder of 2024. The world's top brains and best-educated pool of investors are found in the US, and they have room to keep funding innovation in areas such as oncology, CNS, or auto-immune diseases. The focus on R&D will be supported by ever-so-important development and manufacturing partners, for whom the US offers unparalleled areas for growth. Importantly, long-term exogenous events such as climate change, an aging population, and growing demographics mean the industry will have to adapt to a proactive stance in the creation of vaccines and drugs fit for a changing environment.

The following pages will analyze the different segments – from public to private markets, law firms, and consultancies, pharma and biotechs, CDMOs, CROs, and service providers, wrapping up with technology and AI-focused companies – that, through collaboration and unstopped innovation, ensure that the US remains the leading life sciences hub in the world. ■







> "The biotech sector faces a tale of two cities, with companies in late-stage development or already marketed products thriving, while a significant portion of earlier-stage biotech companies find themselves without sufficient cash reserves to last a year."

# Arda Ural

Partner & Americas Industry Market Leader,
Health Sciences and Wellness
**EY USA**

**After the J.P. Morgan Healthcare Conference in January, how do you assess the health of the life sciences industry headed into 2024?**

I had an initial feeling of "cautious optimism" heading into the J.P. Morgan Conference that was reinforced by the deal flow and conversations that took place there. However, the industry still grapples with significant challenges, particularly the patent expirations of large biologic assets that could result in a potential loss exceeding US$350 billion in total aggregate revenue between 2023 and 2028. The industry showcased resilience and adaptability, addressing these issues through both organic and inorganic growth. Our annual "Firepower" report, which analyzes growth strategies, indicates that the industry crossed the US$200 billion value mark in acquisitions in 2023, despite a slower pace earlier in the year.

The industry is poised for further growth, with approximately $1.4 trillion in available capital tracked by our "Firepower" report, matching last year's record. This substantial amount enables pharmaceutical companies to pursue acquisitions, particularly of late-stage assets. Asset valuations, which experienced an artificial surge due to unconventional capital inflow during the peak of COVID-19-related activities, have now stabilized. However, the biotech sector faces a tale of two cities, with companies in late-stage development or already marketed products thriving, while a significant portion of earlier-stage biotech companies, around 27%, find themselves without sufficient cash reserves to last a year.

**Can you provide insights into the challenges faced by the biotech sector in 2023 and how to solve those?**

Last year presented significant challenges for the biotech sector, with drops in valuations and limited IPOs. The "sugar high" from the COVID-19 era is over, affecting companies that entered clinical trials at phase one. The key issue lies in companies going public too soon, resulting in decreased valuations. Despite this, there is a positive aspect with substantial deal-making in 2024.

The biotech sector has room to grow. The next few months are pivotal for venture capital to regain confidence in deploying funds. While the IPO market is not expected to open soon, biotechs must secure funding for innovation. The FDA's CDER approved 55 products last year, above the ten-year average of 43, emphasizing the importance of consistent funding for sustained innovation. There is concern about disrupting this flow with artificial regulations or market conditions. Oncology, blood disorders, immunology, inflammation, rare diseases, and neurology are key therapeutic areas attracting capital and fostering innovation.

**With Pfizer's acquisition of Seagen, how will the oncology space shape in the coming months? What about other "hot" therapeutic areas?**

We have been closely monitoring developments in therapeutic areas, including the dynamic landscape of cell and gene therapies. Last year, there was considerable discussion about cell therapies, particularly mRNA. While the focus on mRNA has somewhat subsided, the field continues to evolve.

**Have you noticed larger companies willing to invest in Generative AI for their lead candidate programs?**

The challenge for biotechs in deploying generative AI lies in limited resources. However, larger pharmaceutical and established companies, with greater scale, are actively exploring and investing in various use cases of AI. We recently analyzed how these companies aim to lower costs, automate tasks, and accelerate R&D exercises through AI, showcasing the potential impact on different aspects of their operations. While biotechs may not prioritize AI in their current capital deployment, they can tap into third-party vendors for AI-enabled capabilities to navigate their journey toward the next inflection point.

**What key catalysts are you monitoring in 2024, especially in terms of regulatory, investment, and operational aspects?**

In 2024, the focus on the regulatory front includes three key areas. Firstly, the Inflation Reduction Act will have a longer-term impact when negotiated prices for Medicare are disclosed in September. This could potentially shift the treatment modality from small molecules to biologics, impacting industry dynamics. Secondly, the increased scrutiny by the Federal Trade Commission on deals will pose challenges for companies looking to sell assets, adding another layer of complexity to the landscape. Lastly, the Bayh-Dole Act, although not showing an immediate impact, raises concerns about heightened regulatory scrutiny affecting innovation. As for EY's priorities, we are also concentrating on Generative AIs for innovative problem-solving and exploring managed services as strategic avenues to address industry challenges. ■

# The US, an Eldorado for Pharma Logistics

## The air against the ocean, value versus volume, and decarbonizing logistics

What comes next after the deployment of the COVID-19 vaccines to the world? Widely seen as the largest-ever product launch, with 13 billion doses distributed globally, the pandemic created a boom in demand for cargo logistics services that has not waned. On the contrary, the new generation of mRNA vaccines or C&G technologies have temperature requirements (sub-zero refrigeration for production and distribution) that point to, beyond the growing role of technology to match the science, the prevalence of air cargo for high-value pharmaceutical products. Today, pharmaceutical goods represent over 28% of all cargo. For providers able to navigate the complex requirements needed to establish GDP-compliant cold chains, business will boom: The pharmaceutical logistics market, currently valued at US$85 billion, is expected to grow at a CAGR of 8.6% by 2030, according to Precedence Research.



### Flying pharma

Post-pandemic, the demand for high-value pharmaceutical products to uphold a seamless cold chain has never been higher, particularly in the US. In that regard, freight has mostly relied on air transportation. Air freight for pharma goods therefore embodies the dilemma of value versus volume. IATA data shows that air freight numbers (with demand measured in cargo tonne-kilometers and capacity in available CTKs) were the strongest in 2023 compared with previous years, despite 80-90% of pharma products being shipped by sea.

The US market will continue to remain an attractive playingfield for air carriers. In the Gulf, major airlines' cargo branches announced in 2023 new connections with the US, as the size and value of the pharmaceutical industry remain unmatched worldwide. Indeed, IATA numbers indicate that North America makes for over 28% of the total air cargo market share, in second position behind Asia Pacific. Fabrice Panza, manager of global cool chain solutions at Etihad Cargo, who launched a new Abu Dhabi to Boston regular service in March 2024, laid down the fundamentals: "10% to 20% of pharma products is a significant volume and, foremost, is the highest commercial value share. There will always be time-sensitive products in the pharma space, and for these products air shipment will always remain crucial."

The highly sensitive nature of life sciences cargo means that an uninterrupted supply chain is of paramount importance. To achieve that, beyond maintaining temperature control, air freight carriers must relentlessly invest in new technologies to transport cargo safely across the world. For instance, Emirates SkyCargo invested in cool dollies to mitigate the risk of sensitive cargo being affected while on the ramp on or off the aircraft, where it is most vulnerable. Similarly, Etihad Cargo began the rollout a new temperature-controlled and energy-efficient cool dolly ground equipment, which will be fully operational in 2024.

Indeed, minor temperature fluctuations of just one degree can lead to entire shipments being deemed unusable. A 2023 report from the IQVIA Institute for Human Data Science projected that mishaps in temperature-controlled cold chain logistics have cost the pharmaceutical industry around US$35 billion earlier this year. Packaging solutions providers like Cold Chain Technologies (CCT) have understood that keeping cool is a requirement more than an attitude in this industry and have tailored their thermal services accordingly. As put by Amardeep Chahal, SVP marketing corporate development at CCT: "The zero-failure expectation emphasizes the importance of precise temperature control and timely logistics coordination."

### Cell and gene therapies: No room for error

While the cell and gene market is not as large as other well-established therapeutic areas, it is expected to see double-digit growth annually until 2033, due to the exponential progress of the clinical pipeline, coupled with a rising number of regulatory approvals for advanced therapies. The shift towards personalized healthcare places greater demands on the logistics ecosystem to guarantee the accurate transportation of invaluable cargo consistently. For logistics players, cell and gene therapy, clinical trials, and human samples have skyrocketed from approximately 200,000 kg/y five years ago to already exceeding 1.3 million kg/y in 2023.

This segment is in parallel driving opportunity for logistics providers, who see C&G therapies' extreme temperature sensitivity requirements and high value as growth drivers. Emirates SkyCargo moves on average 2 million kgs of pharmaceutical products weekly. And while C&G therapies do not account for the lion's share of the distribution now, Julian Sutch, head of global pharma sales, highlighted the dynamics: "Personalized healthcare is the future of the industry, with the market expected to reach US$3.18 trillion by 2025. However, personalized treatments are priceless and often irreplaceable, meaning there is no room for error during transit."

### Decarbonizing pharma logistics

Cutting the carbon footprint of pharma's supply chain will require a collective effort. Pharmaceutical companies have, for the major part, drafted ambitious "net zero by 2040" targets, with plans to reduce their Scope 1 and 2 (direct) emissions. These GHG emissions can be tackled by leveraging green chemistry, building energy-efficient boilers, or responsibly sourcing raw materials. The real challenge lies in targeting Scope 3 emissions (indirect, outside of pharma firms' control), which make up around 80% of their carbon footprint. Merck, for instance, reported Scope 3 emissions of 6.6 million metric tons of CO2eq, 79.9% of its total emissions, in 2022, while 93% of GSK's GHG emissions were indirect in 2023. In that endeavor, cold chain shipping has, for long, been seen as a carbon culprit. But a wind of change is underway.

What will pharma firms' decarbonization initiatives mean for air freight? Distributing medicine outside the factory into patients' homes has a significant environmental impact, particularly for certain technologies that are temperature-sensitive (like vaccines, insulin, or cell and gene therapies). And while air cargo accounts for most high-value sensitive medicine shipping globally, cargo players have acknowledged the potential for firms to resort to ocean freight to reduce their Scope 3 emissions. Trevor Caswell,



Image courtesy of SkyCell

**Rohit Bhuwania**
Managing Director
**CORAL DRUGS**

> Rapidly changing government policies worsen instability, and the current landscape demands proactive management. In 2024, over 50 countries will head to the polls impacting over 45% of the population. This includes large economies like the US, EU, and India. This is further expected to drive major policy changes.



chairman of Pharma.Aero, a collaboration platform bringing together cargo firms and life sciences companies, is aware of the potential shift: "Air shipping contributes to the resiliency of the supply chain, but we also understand that ocean freight will probably become the more dominant mode of transport over the next years due to lower costs, higher volumes that can be shipped, and environmental considerations."

To set standards to qualify and quantify a green air lane in the life sciences supply chain, Pharma.Aero launched in 2023 the first "Green Air Pharma Logistics" project. "The project focused on defining a green lane to support pharma manufacturers, shippers, and freight forwarders in their sustainability consideration during the lane assessment process and towards their Scope 3 decarbonization targets" detailed Caswell.

Looking ahead, one of the key aspects of pharmaceutical logistics will be defining the value of a ton of $CO_2$. The challenge will lie in balancing emission reduction, efficiency, safety, and regulatory compliance. Because of the complexity of the pharma value chain, where time, temperature, and safety are of the essence, the shift to ocean transport is not without complexity. Swiss company SkyCell assists pharma firms in distributing their medicine globally, with a mission to change the supply chains through a combination of hybrid containers, tracking software, and risk management services. Its CEO and co-founder Richard Ettl commented: "Air freight is often considered as the most polluting mode of transport, and can be offset at a reasonable cost of approximately 3-8 cents per vial. Over the next years, the cost of offsetting emissions will become evident in supply chain budgets. Leading companies are already implementing initiatives to mitigate this expense. In the pharmaceutical supply chain, the new formula is Risk + Cost + $CO_2$ reductions."

Beyond the transportation of cargo, decarbonizing the packaging of pharmaceutical products is also a key effort in making the pharma supply chain more sustainable. With packaging accounting for a sizable share of Scope 3 emissions, suppliers have noted a shift towards sustainable packaging requirements from their pharma customers post-pandemic. Innovation, R&D, and investments to move from single-use packaging to efficient multiuse containers can reduce $CO_2$ emissions by around 50% due to the higher volume efficiency for instance. CCT executive Kristof de Smet emphasized the recent regulatory changes toward sustainability: "In response to increased demand post-COVID-19, spurred by regulatory calls for sustainable packaging, we have introduced innovative products like 'Natural', a fully recyclable packaging solution."

The pandemic tested logistics partners' cold chain capabilities. As global trade continues to grow, the demand for temperature-sensitive products is anticipated to rise, necessitating more reliable cold chain solutions. Furthermore, the adoption of autonomous vehicles and drones for transportation and delivery is expected to expand, offering increased flexibility and speed in pharma operations. Going forward, air cargo and packaging partners alike are presented with a unique opportunity to use sustainable practices to cement their partnerships with pharma leaders. ■





> We now offer an open platform for life science companies to have conversations around priorities in their field and discuss challenges in the supply chain.

# Trevor Caswell

Chairman
**PHARMA.AERO**

**What have been the main highlights for Pharma.Aero in 2023?**
Pharma.Aero has seen significant organic growth and our membership has increased by 100% in the past three years, with DB Schenker being one of the latest members to join. Increased membership growth also means increasing the number and quality of projects and the expected delivery of those.

The start of our Life Sciences Manufacturers Advisory Platform (LMAP) has also been a great highlight, and we now offer an open platform for life sciences companies to have conversations around priorities in their field and discuss challenges in the supply chain. It is a neutral and safe area for life sciences companies to drive value for the organization by identifying opportunities and challenges for us to focus on. LMAP has brought significant quality and attention to our organization.

After the success of the last one in Singapore, we are excited about our fourth Pharma Logistics Masterclass held in Dallas in 2024. This Masterclass covers current critical aspects of pharma logistics and is a wonderful opportunity for seasoned professionals, policymakers, and academics in the business to gain more in-depth knowledge of how pharmaceutical supply chains are organized and what scientific methods can be applied to optimize logistics processes for the pharma and life sciences sector.

**How is Pharma.Aero helping to balance innovation with aerial regulation?**
Pharma.Aero conducted a regulatory project, where we worked with IATA to streamline the Pharma CEIV certification based on the feedback and insights provided by our CEIV Pharma-certified members. In its first phase, the project aimed to evaluate how CEIV Pharma-certified companies perceive the impact of the CEIV certification on their daily business and the value that the certification has brought. We then rolled out a second phase of this project, further exploring concrete actions to implement some of the suggested potential solutions to optimize the program.
Another notable initiative is our first Green Air Pharma Logistics project to develop a set of standards and measurements to qualify and quantify a green air lane in the life sciences and medtech supply chain industry. The project focused on defining a green lane to support pharma manufacturers, shippers, and freight forwarders in their sustainability consideration during the lane assessment process and towards their Scope 3 decarbonization targets. It also provided important support for air cargo stakeholders in pursuing green air logistics initiatives as part of their Scope 1 decarbonization efforts. All our projects result in comprehensive technical reports that are shared exclusively with our Pharma.Aero members, followed by white papers that are available for the wider industry, as our mission, as Pharma.Aero, is to provide valuable industry insights and contribute to progress in our field.

**Looking ahead, how important will pharmaceutical air cargo shipping be for the industry?**
Resiliency in the supply chain is a big focus as instability can create huge issues, as we saw with the pandemic. Air shipping contributes to the resiliency of the supply chain and we will continue to focus on air, but we also understand that ocean freight will probably become the more dominant mode of transport over the next years due to lower costs, higher volumes that can be shipped, and environmental considerations. As an organization, we are fully aware of this shift, and we will put in the effort to understand these other modes of transport and support the logistics supply chain by connecting partners in the chain, whether it is by ocean, air, or road.

**How do you assess the health of the life sciences industry as we head into 2024?**
There has been a reset on supply with currently significant capacity available. Pharma.Aero will invest further in presenting cross-industry collaboration to find additional initiatives and services for our partners, driving more top-quality projects. We are becoming more focused on the importance of data security and data quality as security requirements in the supply chain are becoming an increasingly common area for concern with the trend of digitalization.

**What is Pharma.Aero's growth strategy moving forward?**
Pharma.Aero's membership growth is a direct result of delivering high-value projects. We will continue to deliver this quality to our members, meeting and exceeding their expectations, and we will continue to drive efficiency and value with our association partners. ■

KS

AC

# Kristof De Smedt and Amardeep Chahal

KS: Global Business Unit Director
AC: Senior VP Marketing
**COLD CHAIN TECHNOLOGIES (CCT)**

**How does Cold Chain Technologies (CCT) serve the life sciences space?**
AC: Since its establishment in 1967, Cold Chain Technologies has been a leading force in the thermal packaging industry. With a portfolio comprising of a wide range of passive thermal packaging solutions that emphasize sustainability and efficiency, we continue to meet the evolving demands of our global clientele with innovative and dependable solutions. In the pharmaceutical industry, sustainability and traceability are fast becoming crucial factors in thermal packaging solutions. We also prioritize traceability to ensure greater visibility in global medication shipments. By focusing on performance, cost-effectiveness, compliance, sustainability, and visibility, we help our pharmaceutical customers achieve the optimal balance in their thermal packaging solutions.

KS: Our company specializes in parcel and palletized cargo solutions, in all aspects of life sciences including the emerging cell and gene therapy sectors due to their stringent temperature control and handling requirements. Furthermore, in response to increased demand post-COVID-19, spurred by regulatory calls for sustainable packaging, we have introduced innovative products like "CCT Naturals," a fully recyclable packaging solution.

**What are life sciences companies looking for in a logistic partner these days?**
AC: Life sciences partners are seeking a blend of efficiency, cost-effectiveness, sustainability, compliance, and digital track and trace capabilities. They prioritize performance to ensure medications arrive safely and efficaciously to patients. Cost optimization is crucial due to high freight expenses, while compliance is essential to avoid jeopardizing patient safety. Since COVID-19, there has been a notable shift towards sustainability, with customers actively seeking reusable and environmentally friendly packaging solutions. Additionally, digital track and trace capabilities are increasingly vital for visibility and risk mitigation.

KS: The logistics landscape has seen a shift towards a balanced approach to mode selection, considering factors like urgency, cost, and risk mitigation. While air freight was traditionally favored for urgent shipments, there has now been recognition of the criticality of various transport modes. Collaborations between logistics partners and suppliers help ensure product integrity across different modes, mitigating risks associated with unforeseen events like geopolitical conflicts or disruptions in sea freight routes.

**What will come of air cargo in the pharma logistics landscape?**
KS: The expectations for 2024 and beyond are that this market remains somewhat flat or may even experience a slight drop, but the need for air freight will always remain, especially for time-sensitive shipments like cell and gene therapies. Trends show increasing use of intermodal transport modes versus traditional road freight in Europe, and the industry must adapt to innovations like drones.

**How does CCT view the potential for growth in the cell and gene therapy space?**
AC: Even though the volume of products may not be substantial, they are critical therapies and have high costs. The zero-failure expectation emphasizes the importance of precise temperature control and timely logistics coordination, necessitating a comprehensive service model beyond packaging.

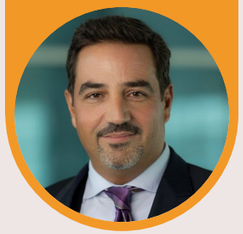
**How important will AI and ML become in the pharma logistics space?**
AC: Currently, our focus lies on tracking and tracing our shipments, both domestically and globally. By capturing extensive data on shipment routes, weather conditions, and transit times, we can identify potential disruptions and notify our customers promptly. This proactive approach, while more aligned with machine learning, enables us to provide valuable insights to our customers and enhance inventory management. As we continue to gather and analyze data, we anticipate advancing toward more sophisticated AI-driven solutions.

**What will be the key priorities for Cold Chain Technologies in 2024 and beyond?**
KS: Sustainability will be paramount. We must work closely with our customers in the life science industry, understanding their needs and facilitating their goals, particularly regarding reusability and other sustainable practices. CCT is committed to helping achieve this goal by offering a robust portfolio of innovative and comprehensive temperature assurance solutions and offering technical expertise to choose the right solution based on the temperature needs of their products.

AC: The trend is shifting towards providing comprehensive solutions and services beyond just packaging. ■







# Fabrice Panza

Manager Global Cool Chain Solutions
**ETIHAD CARGO**

# Julian Sutch

Head of Global Pharma Sales
**EMIRATES SKYCARGO**

# Richard Ettl

CEO and Co-Founder
**SKYCELL**

**What have been the main highlights for Etihad Cargo over the past 12 months?**
It has been a great year for Etihad Cargo, and we have been developing significantly on the pharmaceutical side. We launched a new fully IATA CEIV-compliant pharma center in June 2023. Etihad Cargo immediately saw an increase in volumes and ended 2023 with a 37% increase in PharmaLife shipments. We also began the rollout of our new temperature-controlled and energy-efficient cool dolly ground equipment, which will be fully operational by Q2 2024. This was the last piece in our master plan that we started three years ago. Etihad Cargo has continued to expand our global presence and capabilities with the launch of our Pharma Champions Program to enhance customer service and team expertise through the delivery of dedicated PharmaLife training sessions in key pharma markets. We are proud to say that our PharmaLife business has achieved double-digit growth for the past three years.

**How do you see air cargo logistics serving the pharma industry in the future?**
Over the past 10 years, the pharma industry has been shifting more towards ocean freight. This is not a problem for the air logistics space, as 10% to 20% of pharma products is still a significant volume and, foremost, is the highest commercial value share. ■

**Can you present Emirates Pharma, the Emirates SkyPharma facility, and the demand from US life sciences customers for pharma transportation?**
Leveraging our industry-leading Life Sciences and Healthcare product portfolio, we move an average of 2 million kg of pharmaceutical cargo every week, with high volumes from key pharmaceutical markets such as India, the US, and European markets. In addition to Emirates Vital and Emirates Medical Device, we offer Emirates Pharma, Emirates Pharma Plus, and Emirates Pharma Active; the three-tier product range provides shipping capabilities for everything from high-temperature tolerance pharmaceuticals, right the way through to high-value cargo requiring active container temperature control.

The backbone of our pharmaceutical cargo business is our world-class GDP-certified facilities, with 15,000 m2 of dedicated storage for temperature-sensitive goods such as perishables and pharmaceuticals. We operate the world's largest fleet of cool dollies, which regulate the temperature while in transit, and continually invest in innovative technology to offer increased protection to our customers.

We plan to double our existing capacity with 15 confirmed freighters joining our fleet over the next decade, accounting for brand-new aircraft and converted freighters. ■

**Can you give an overview of SkyCell and the milestones the company achieved over the past year?**
SkyCell was founded in 2013 to provide temperature-controlled hybrid containers and software solutions, preserving drug efficacy and shelf life. The value and temperature sensitivity of biologics, along with the introduction of new regulations, contributed to the success of SkyCell's launch.

Since the company's inception we have upheld an impeccable record: Not a single pallet has been lost in distribution. We are present in more than 30 locations across the world - 7 in the US – on the East Coast, Midwest, border to Canada, and the West Coast – and plan to expand to approximately 12 locations in 2024.

**What are the catalysts for the air cargo space?**
Air transport remains the preferred choice for the pharma industry for high-value products, but for low-value products that are low sensitivity and transported in large volumes, ocean shipping is growing.

**What are SkyCell's key priorities for 2024?**
We will continue to deliver quality, sustainable solutions to pharmaceutical supply chains, offering temperature-controlled hybrid containers and technological solutions that prevent damage to vital medicine, all while helping pharma companies reduce their scope 3 emissions by 50%. ■

# Financial and Regulatory Environment

“2023 was turbulent in the market due to inflation and tightening fiscal policies, making capital formation challenging. This resulted in a dampening effect on IPO markets globally.”

**Chris King**
SVP
**OTC MARKETS GROUP**

GBR Series • UNITED STATES
LIFE SCIENCES 2024

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# Public Markets in Recovery Mode

## Navigating public markets when great science is not enough anymore

The downturn was sobering, but the hangover is waning. In the past years, in an era of unprecedented innovation, the harsh realities of public markets have hit biotechs and pharmaceutical companies hard. The period since 2019 has seen the industry saving the world from one of the deadliest pandemics, achieved more FDA approvals for novel drugs than ever before, and reducing the mortality of cancer, just to cite a few achievements. Yet, great science is not enough anymore to guarantee returns, and pharma companies feel that the unprecedented wave of innovation that they produced has been unrewarded. Aggregated together, the top 50 pharma firms have underperformed the S&P 500 by a third, with biotechs faring worse. Michael Ehlers, president and CEO of Ascidian, a biotech eager to harness the potential of RNA exon editing, said: "Biotech in 2023 was a tale of two worlds: Unprecedented scientific advancements, such as the first gene editing approved therapy, tempered by once-in-a-generation financial constraints, even austerity, and many great companies unable to raise capital."

**Difficulties in raising funds**

The first months of 2024 have witnessed biotech stocks undergoing intense surgery, after two cataclysmic years on the public markets. In March 2024, Pfizer's stock was trading at a 52-week low of US$25, down 32% YoY. In October 2023, before the recent market rally, a record 232 life sciences companies globally were trading with a market capitalization below their cash reserves.

Ask any biotech CEO how his or her stock performed in the past 24 months, and the conversation might turn rather unpleasant. The downturn in private biotech financing in 2022 and 2023 (in 2023, funding decreased by 43.2% compared to 2022 and by 52.3% compared to 2021) can be notably attributed to macroeconomic pressures causing investors to be more cautious and prioritize existing portfolios, along with investors recovering after having been "burnt" during the post-COVID-19 exuberance in public markets. Today, biotechs are feeling the repercussions of the latter point, when arguably many technologies were funded without the right due diligence from investors. Brian Frenzel, president and CEO of Tosk, a small-molecule drug discovery and development company in the oncology space, summed up the period: "Simply put, 2022 and 2023 were abysmal for biotech."

Compared with the pre-COVID bull market and the post-pandemic exuberance, raising funds is simply harder for biotechs in today's environment. Given the abundance of companies looking for cash, investors can take their time making funding decisions, sometimes to the dismay of the companies. "In the past, it was quite easy to raise US$100 million on the promise that there would be a potential therapy. The investment community has evolved significantly since then, and every element of risk is today much better understood and evaluated. Advances in medical technologies have grown significantly due to the medical community's ability to interact with the financial community, but for a small biotech and being a future-orientated business, attracting funding can still be a challenge," confessed Mark Godsy, CEO of CNS-focused Shackelford Pharma.

**Silver lining: The IPO window cracks open**

Compared with the nearly 100 biotech firms that went public in 2020, 22 went public in 2022 and 19 in 2023, according to a BioPharma Drive tracker. Simply put, 2023 was (also) cataclysmic for IPOs. As the lifeblood of the industry, IPOs provide firms with critical capital to develop their technologies. However, the IPO market is well and alive in early 2024. In the first two months of the year, six firms jumped into the fray. Diabetes and weight-loss drug developer Fractyl Health, psychiatric drug maker Alto Neuroscience, and cancer drug developers Arrivent and CG Oncology held IPOs, with Metagenomi and Kyverna Therapeutics closing their IPO shortly after. That run of offerings at US$100 million and more put the sector at its strongest pace since 2021. Jordan Saxe, head of listings at Nasdaq, the leading healthcare exchange with a 98% market share of IPOs in the biopharma space, said: "We are in a new chapter for biotech, and the window for IPO is open."

In 2024, investors are eyeing specific "hot" therapeutic areas including oncology, autoimmune, and cardiometabolic disease for successful IPOs. One fundamental appears stronger than ever: Favoring de-risked assets. Since early 2023, there has been a notable shift in the types of companies successfully going public. According to data from BioPharma Dive, more than half of the 28 IPOs since then, including nine of the 10 largest offerings, were from companies with drugs in mid-stage testing or beyond. In contrast, only six companies without a drug in human trials have managed to price their IPOs, raising an average of approximately US$88 million, with half of them securing less than US$10 million. This change reflects investors' preference for more secure investments. In 2020 and 2021, a majority of the companies going public were in the preclinical or Phase 1 testing stages. Now, companies with early-stage or broad drug-making technologies are facing greater challenges. Gene editing biotech Metagenomi is a good example. The firm has not yet identified a lead drug candidate but has partnerships with Ionis Pharmaceuticals and Moderna.

The question now is: Will the surge last? After the torrid early weeks of 2024, biotech IPOs have tempered in March/April 2024. But the summer months are – historically – when opportunities line up. This coincides with the Federal Reserve's indication of lowering interest rates, and it is also the time when numerous biotech companies in Nasdaq's pipeline are projected to have data readouts, facilitating the commencement of IPO roadshows. In that regard, H2 2024 will be a crucial indicator in determining the industry's health for the coming years. "Companies are going public with later-stage data and a shorter time to when the market will see the data flip for the next readout, and this makes for an interesting and attractive opportunity for investors, which is driving this new class of IPOs. The backdrop of greater macroeconomic clarity and potentially positive news coming out of the Fed later in the year will lead to increased levels of IPO activity in 2024 compared to 2023" added Nasdaq's Saxe.

**Deals are back**

New revenue growth and patent cliffs are (finally) fueling M&A activity again in the life sciences industry. In 2023, M&A investment rose over 30% YoY to US$191 billion. Following that trend, the first quarter of 2024 saw big pharma snapping up some smaller but impactful late-stage companies through M&A. Involved with more than two-thirds of deal-making, Big Pharma seems poised to further deploy its firepower in 2024. For pharmaceutical companies, acquiring pre-commercial biotech assets has reignited deal success and fueled growth, while medical technology companies have found that proactively shaping their business portfolios to enhance profitability is the key to success. Kathryn McDonough, head of middle market life sciences, J.P. Morgan commercial banking, said: "In terms of M&A, there is no shortage of news on the patent cliff and the loss of exclusivity that many big pharma companies are facing, but everyone is aware that this is coming in 2025. Innovation and new company creation have continued and big pharma is constantly evaluating acquisition opportunities to add to their pipelines. We will see more M&A activity in 2024."

One of the main reasons suggesting a sustained trend in M&A in the coming years is large pharmaceutical companies' search for growth in the form of pre-commercial biotech assets. Depressed valuations, many have lost over 70% since their peak, make them even more attractive targets. Accelerating R&D through acquiring biotech assets can reduce the projected timeline for assets in the pipeline by at least 30% according to McKinsey. Following that logic, the earlier months of 2024 saw a plethora of M&A activity, with notably Gilead acquiring CymaBay Therapeutics, Novartis' US$2.77 billion buyout of cancer specialist Morphosys, and AstraZeneca's outlay for Fusion Pharmaceuticals. These deals all spoke to the Big Pharma trend of snapping up small biotechs with a late-stage development focus.

In 2024, and most likely headed into 2025, biotechs will continue to grapple with challenges stemming from inflation and high interest rates. Declines in valuation over the past couple of years have discouraged new investment which has hindered fundraising. But with approximately US$1.4 trillion in available capital, the industry remains poised for growth. This substantial amount enables pharmaceutical companies to pursue acquisitions, particularly of late-stage assets. "However, the biotech sector faces a tale of two cities, with companies in late-stage development or already marketed products thriving, while a significant portion of earlier-stage biotech companies, around 27%, find themselves without sufficient cash reserves to last a year", commented Arda Ural, partner and Americas industry market leader, health sciences and wellness, at EY.

For the innovation powerhouse of the world, there are unique opportunities to be seized. Supported by pharma giants, the best-educated pool of institutional and private investors, along with the gold standard of pharma exchanges (the Nasdaq Biotechnology Index), the US remains the Eldorado for companies looking to fund and commercialize their promising science. Andreas Grassauer, CEO of the Vienna-based biotech Marinomed, said: "In terms of biotech funding, the US remains ahead of the world. The US is more innovative and moves faster. European investors are still slow to react on US stock exchanges." ■

Image by Rawpixel.com at Adobe Stock

# Jordan Saxe

Head of Healthcare Listings
**NASDAQ**

> "Companies are going public with later-stage data and a shorter time to when the market will see the data flip for the next readout, and this makes for an attractive opportunity for investors, which is driving this new class of IPOs."

**Can you discuss the Nasdaq Biotechnology Index and how the last months looked like for this stock market?**

Nasdaq is the leading exchange for all healthcare listings, and we have a 98% market share of IPOs in the biopharma space. Our support for biotech and healthcare is unique as we provide best-in-class services and tools, data, and the most efficient trading platform for companies in these sectors to reach investors.

The Nasdaq Biotechnology Index (NBI) is the gold standard and it elevates a company's profile from a global visibility standpoint. By listing on the Nasdaq, companies are reaching the largest set of sophisticated healthcare investors in the world. The leading research and expertise of the US healthcare scientific community, deep pools of liquidity from educated investors, and the branding opportunity of being listed on the world's most innovative healthcare exchange for disruptive growth companies are extremely attractive and valuable for companies looking to go public.

**How have life sciences companies performed on the Nasdaq in 2023?**

Judging a life sciences company on a one-year performance is a tough lens as it can skew either up or down depending on macroeconomic factors. A short-term investment in healthcare has a five-year horizon, whereas a long-term investment is 10 years. For many companies, it is a binary outcome with drug approval, and you cannot judge performance until they reach their clinical milestones. The most interesting key performance indicators (KPIs) when measuring a newly listed company are - how is the milestone data being interpreted, and how is the efficacy and safety of the clinical trial performing?

Over the past 10 years, the biopharma sector has performed well, and we have seen many companies tap into the markets.

**There were six notable IPOs on the Nasdaq in January. Has the IPO window fully opened?**

We are in a new chapter for biotech, and the window for IPO is open. We are seeing a new class of biotech IPOs, which are companies that have achieved later-stage data milestones. This means there is some degree of visibility into what the future holds for the data readouts and there is a lower chance of failure. Investors are heavily interested in these kinds of companies versus the pre-clinical brands we have seen in the market in prior years. The companies that are now listing also have shorter-term inflection points from IPO. Companies are going public with later-stage data and a shorter time to when the market will see the data flip for the next readout, and this makes for an interesting and attractive opportunity for investors, which is driving this new class of IPOs. The backdrop of greater macroeconomic clarity and potentially positive news coming out of the Fed later in the year will lead to increased levels of IPO activity in 2024 compared to 2023, and over the past six months, we have seen a significant increase in applications versus the last two years.

**What should investors consider before entering the life sciences space?**

Company data and the therapeutic stage are the most important factors for investors. Big companies with good data and experienced management teams will always be able to IPO. Looking back on historic periods of market volatility, you still saw biotech IPOs get out. That is because they are taking a longer-term view of the markets and are not beholden to a one-year Fed fund target rate but rather looking at whether the drug will advance in the clinic, whether there is a path to approval, and where healthcare investors are willing to tie up money for a longer term because they believe in the science and the ability to get this drug to market.

**What are Nasdaq's key priorities in 2024?**

Nasdaq is laser-focused on innovating and providing the most robust set of tools, data, and services for life sciences companies to target investors and ensure that as a public company, they are maximizing the value for their shareholders. We have seen an immense amount of interest in going public over the last few months, and we are extremely excited about the road forward in 2024. ■

## Kathryn McDonough

Head of Middle Market Life Sciences
**J.P. MORGAN COMMERCIAL BANKING**

**Are you seeing companies having more success in raising funds now compared with early 2023?**
There remains a bifurcation between companies that are well-capitalized and de-risked, and those that are not. Investors may take a pause when they are evaluating companies with less than 12 months of cash. The private capital markets are flush with cash, but private investors are becoming much more thoughtful about how they deploy capital, ensuring that every dollar they apply to an investment is carefully vetted. Given the abundance of companies looking for cash, investors can take their time making funding decisions, sometimes to the dismay of the companies.

In terms of the public markets, we have seen several IPOs in the life sciences sector year-to-date, which is a positive signal for the market and broader healthcare ecosystem. Many of the companies that are now coming to market are at the right stage of development, have the right cap table, and have the right milestones on the horizon that public investors are looking for. Signs are pointing toward a cautiously optimistic 2024 for life sciences.

**How do you anticipate the public markets to shape up in 2024?**
There was more than US$100 billion in healthcare issuance in 2020, of which a significant amount of funds went to early-stage companies. It seems that the investor base has healed enough that they are willing and interested in putting money to work in the life sciences sector again, and the names that have gone public this year are largely trading well in the aftermarket.

In terms of M&A, there is no shortage of news on the patent cliff and the loss of exclusivity that many big pharma companies are facing, but everyone is aware that this is coming in 2025. Innovation and new company creation have continued and big pharma is constantly evaluating acquisition opportunities to add to their pipelines. ■

## Greg Rotz

Transformation Consulting Leader for Pharmaceuticals & Life Sciences
**PWC**

**What are the key takeaways of PwC's 'Next in pharma 2024: Reinventing for returns' report?**
At a macro level across sectors, CEOs are increasingly concerned about the viability of their business. In the report PwC issued in January 2024, 45% of CEOs voiced that they were concerned that their business model would run out of steam within a decade. Changing customer dynamics, new regulatory policies, and advances in technology are all contributing to a general concern about the threat of disruption and whether today's business models can deliver over a longer period.

In pharmaceuticals, great science alone is not enough to power the business model of the future. Over the past five years, despite all the advances in science, the top 50 pharmaceutical companies when aggregated together have underperformed in the capital markets. This is in a period where the FDA has approved more drugs than in the prior period, where the industry has saved the world from a pandemic, where we have commercialized fundamentally new pharmaceutical technologies, and where we have reduced the mortality of cancer.

The double edge of science means we have more assets chasing the same areas, creating more head-to-head competition. Meanwhile, pressure on drug pricing has never been higher, especially with Medicare now directly involved in lowering prices. These new market realities are coming at a time when the costs of every line item in the profit and loss statement have been increasing, such as labor costs, input costs, capital costs, and tax costs. So, you can see why innovation is not just important in the labs, but also in the business model.

**What is your take on how the public markets will look for the remainder of the year?**
In 2023, deal activity finally returned to pre-pandemic levels, and across all sectors of life sciences, we expect healthy deal activity to continue in 2024. ■





# Venture Capital

## Lessons learned

Investing in the life sciences industry is a high-risk activity. Less than 5% of drug discovery projects ever make it to the market, not just because of setbacks in science, but often due to macroeconomic headwinds. The latter, coupled with a shift in how venture capitalists approach deals after the sugar high post-COVID, led to a significant correction in VC investment in the biopharma industry in 2023. The outlook for the remainder of 2024 remains cautious, although early signs have shown that biotechs and their backers are optimistic that the sector's downturn might be nearing its end.

### Strategic pivots in response to downturns

The explosive growth in VC investing seen during the pandemic is but a distant memory for biotech executives. Back then, a whole new ecosystem of investors piled into the industry: Traditional investors, generalist investors, as well as worldwide investors such as the sovereign wealth funds and other players that do not traditionally invest in the biotech sector, all looking for a piece of the action. VC backers that we interviewed recalled that biotech investment firms could not afford not to participate in IPOs, as each offering was generating excessive value.

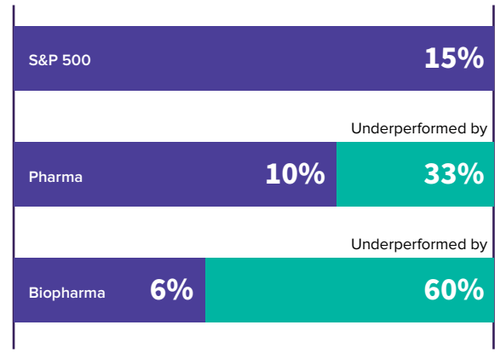
That capital has since rotated out of biotech into other sectors, and as the industry must rely on traditional means of raising funds, many firms are feeling the pinch: A GlobalData report shows that 607 venture-backed companies headquartered in the US are currently affected by the downturn in biotech funding, with over 1,500 drugs at stake (including pre-clinical). Most dramatically, approximately a third of these firms have not raised any capital in the past three years, the period coinciding with the start of the post-COVID correction. Venture financing for US-headquartered companies with innovator drugs peaked in 2021, reaching US$20.7 billion, and many early-stage biotechs went public that year, often with inflated valuations. This resulted in many overvalued biotechs that were unable to deliver milestone outcomes, causing a decline in investor confidence and increasing selectivity in new investments.

In response to public and private market downturns, VCs have made a strategic pivot towards quality and clinical data validation in the latter part of 2023 and so far in 2024. With limited funds entering the sector in 2023, only the companies that had meaningful data, regulatory approval, and truly value-creating events were able to raise financing. Data from McKinsey shows that innovative platform technologies such as drug discovery enabled by machine learning (ML), cell therapies, and gene therapies have dominated biotech funding over the past few years because they typically promise to address a broad array of indications over time. In the current risk-averse climate, exacerbated by the uncertainty that the current geopolitical environment brings, investors remain focused on clinical validation, with standard clinical milestones being pushed to earlier funding rounds.

Biotechs must now be in the clinic or possess a unique Phase 2 asset in a "hot" indication to receive VC attention, whereas many firms listed at Phase 1 in 2019-2020. Gone are the days when biotechs could quickly pivot from Series A to a "crossover" round, and then an IPO. In 2023, Xontogeny

### Pharma underperforms cross-industry shareholder returns in the past 7 years

Total Shareholder Return over the last 7 years



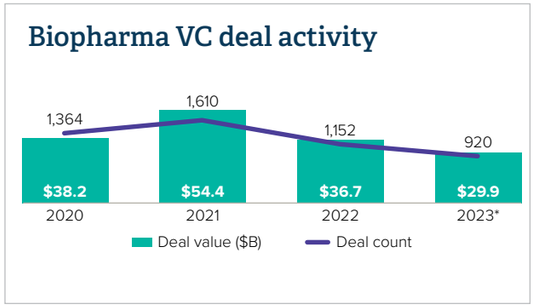

Source: S&P Pharmaceuticals, S&P Biopharma

Image courtesy of LaVoie Health Science

co-led a US$200 million Series A financing for CARGO Therapeutics with a CD-22 CAR-T treatment for lymphoma. Chris Garabedian, CEO of the biotech aggregator, explained the trend: "In recent years, there has been a noticeable shift towards data-driven valuation in the biotech sector. We have seen a return to fundamental principles, where specialized investors engage in thorough due diligence, and with discipline and selectively invest in the best opportunities with the highest probability of success."

John Pennett, partner at EisnerAmper, commented: "There is a trend of increased due diligence by financiers seeking to invest in companies at all stages of development. The overarching theme appears to be a "return to quality". Investors are eager to reduce risk by backing companies with higher chances of success. They emphasize stronger science, robust teams, and reputable investors."

Going forward, seed-stage investments may require in vitro data and mouse models, while Series A funding may demand a complete demonstration of AI & machine learning algorithms sourced from academia or validated with high-throughput biology platforms. In 2021, many biopharma companies went public without advanced clinical candidates. However, a larger proportion of biotech IPOs in 2022 and 2023 had phase 3 trials underway at the time of their public listing, and we anticipate this trend will persist. James Gale, founding partner at Signet Healthcare Partners, touched upon what VC are looking for in a biotech: "Effective validation in the biotech industry hinges on real-world clinical evidence in humans. To succeed, biotech companies must articulate a clear market (therapeutic) potential. Drug development today must consider factors like reimbursement, clinician utilization, and market differentiation. A well-supported market study, robust clinical data, a defined regulatory path, and realistic timelines are essential components of a compelling pitch."




Source: PitchBook

**VC funding outlook**

Despite drug developers having been slow to experiment with AI for their lead candidate, VC investor sentiment is insistent that early-stage biotechs incorporate this technology. During the J.P. Morgan Conference in January 2024, Pitchbook reported that the AI firm Alphabet's Isomorphic Labs dominated VC conversations after the firm signed two partnerships with Eli Lilly and Novartis worth US$3 billion.

Industry leaders have learned their lessons. There is a consensus that too many biotechs were created in recent years, many formed around the same technologies and targeting similar diseases, leading to companies fighting for the same pool of capital. Hopefully, unlike in previous downturns, VC companies are flush with cash. Several early-stage life sciences investors, including Arch Venture Partners, Versant, Flagship Pioneering, and Third Rock Ventures, have recently closed significant new funding rounds in 2022-2023. This provides them with substantial resources to either bolster existing companies or launch new ventures.

Overall, 2023 figures indicate that VC funding has stabilized from the peaks seen in 2021. But in this environment, biotechs still do not have an easy path to Wall Street. Those that will focus on strong building blocks like clinical data, an experienced management team, and innovative platforms will likely emerge as leaders in securing the substantial VC funding necessary to advance transformative drugs toward approval. Despite their caution, the tone among investors is more upbeat than in 2023, and technologies that have the potential to have life-changing impacts on patients will most likely receive attention. As concluded by Chris King, SVP at OTC Markets Group: "We anticipate an acceleration of IPO activity in the second half of the year, not just due to financing needs but also in the hope of interest rate cuts and robust financial markets." ■







## Donna LaVoie

President and CEO
**LAVOIE HEALTH SCIENCE**

**To what extent do biotechs' communication strategies adapt at different stages of funding?**
Our communication strategies are directed either to advance discussions on funding or partnerships or for broader audiences such as healthcare providers, patients and other stakeholders. During a company's evolution, audiences shift in years one, two, and three in a communications program. For example, during a financial raise period, you are appealing to strategic partners, potential backers, or a combination of these, but later on, after you have attained capital, you might be shifting to the customer base in which you eventually would be selling into, such as a targeted health care provider audience.

**How do you assess the current IPO market and M&A environment?**
There is currently an insatiable appetite for M&A. Large pharma have substantial cash to put to work, and that is certainly giving buoyancy to the sector. Over the past months, it has really been an M&A market rather than an IPO market. Although we are always moving towards a potential IPO, we must adjust to the market conditions and are developing plans to support deal-making strategies, assuming that an IPO might not happen.

**How do you see the relationship between regulation and innovation in the US in the coming year?**
The IRA has been ready to rear its ugly head for a long time – it is not new. The challenge with it is you already have a skittish public market where there is an insatiable demand for capital and there is too much innovation to fund. To ensure we are funding the right things, the right questions about value and opportunity will have to be asked in terms of what the innovation creates, at what cost, and whether is it something that is enough to demand a certain price. The IRA is a wake-up call that we have to be smarter about the way we approach innovation, pricing and value. ■

## Christiana Bardon

Co-Managing Partner
**MPM CAPITAL**

**How has the market evolved in the past couple of years?**
During 2023, investment capital was still in short supply and the industry saw very few financings and IPOs. With limited funds entering the sector in 2023, only the companies that had meaningful data, regulatory approval, and truly value-creating events were able to raise financing. The market was functioning but was extremely selective in its investments. Weaker companies saw down rounds, or an inability to finance at all.

**Are there any therapeutic areas that MPM Capital will continue honing its investment towards?**
New technologies are extremely important across the board as they are protected by the IRA and with much longer protection than small molecules. RNA technology is an area that we will continue to focus on. In terms of therapeutic areas, oncology continues to be a huge unmet medical need and a big area of drug development. Precision approaches to cancer are the dominant theme here, as we can now hit cancer targets with multiple modalities such as bi-specifics, antibody-drug conjugates, and cell therapy.

**How will the political environment in the US affect the investor mindset?**
In regard to the presidential election in 2024, Republicans are considered to be more supportive of our industry than Democrats so I think that the presidential election will be neutral to positive for our industry.

**What are MPM Capital's key priorities and growth goals in 2024?**
Now is a great time to deploy new capital into biotech, as valuations are still low, assets are extremely cheap, and the long-term prospects for the industry look fantastic. The biotech sector will continue to grow for the next 30 years due to the aging demographic and tremendous innovation in the industry, and the timing is now perfect for investing in the sector as the market is at a low, but by the stage where it is time to exit, market conditions will have improved. ■

## James Gale

Partner
**SIGNET HEALTHCARE PARTNERS**

## Chris Garabedian

CEO
**XONTOGENY**

Venture Portfolio Manager
**PERCEPTIVE ADVISORS**

## Louis P. Kassa III

President and CEO
**PENNSYLVANIA BIOTECHNOLOGY CENTER (PABC)**

**Can you outline some of Signet's strategic investments in the past months?**
2023 has been a positive year for our sector, with many younger growth companies successfully attracting financing and thriving. We made a couple of investments and exited two companies. Although declining share prices have negatively impacted certain sectors of the contract pharma services market, we see continued strong interest in research and development in our areas of emphasis. In the generic drug sector, market pricing has shown signs of stabilizing.

**What do you forecast is crucial for early-stage biotech companies to attract capital in this market?**
Effective validation in the biotech industry hinges on real-world clinical evidence in humans. To succeed, biotech companies must articulate a clear market (therapeutic) potential. Drug development today must consider factors like reimbursement, clinician utilization, and market differentiation. A well-supported market study, robust clinical data, a defined regulatory path, and realistic timelines are essential components of a compelling pitch. Our focus remains on investing in emerging commercial-stage companies equipped with unique technologies and skill sets that facilitate the efficient launch of pharmaceutical products for companies of varying sizes. ■

**Can you touch upon some of the latest investments made by Xontogeny?**
Despite market challenges, we expanded our investment portfolio, including investments in the clinical-stage companies. We invested in two companies that went public this year via an IPO: Apogee Therapeutics, with a potential best-in-class atopic dermatitis drug as their lead program, and CARGO Therapeutics with a CD-22 CAR-T treatment for lymphoma, in which we co-led a large Series A financing based on early clinical data. We also invested in two other clinical-stage private companies, including TORL BioTherapeutics, focusing on ADCs targeting claudin 6 and 18.2, and Avalyn BioPharm, which is developing inhaled versions of two approved drugs for pulmonary fibrosis. Outside of therapeutics, we invested in a Delve Bio, a metagenomic diagnostic company that was a collaboration between UCSF and MIT-Broad. Despite the industry's funding challenges, we have been strategic in managing our existing portfolio with capital efficiency to provide ample runway to achieve value-driving key milestones.

**What does a biotech company need to secure funding in the current competitive landscape?**
There has been a noticeable shift towards data-driven valuation in the biotech sector. ■

**What were the main highlights for the PABC in 2023?**
We rolled out PABC's Academic Innovation Zone (AIZ) grant with US$5 million in state funding, enabling us to award companies either free lab space, the hiring of staff from C suite down to scientist assistants, IP expenses, or business expenses.

We are also proud to have spun out five companies into our incubator from the Blumberg Institute. We do not kick companies out as we are building a know-how network where starter companies can connect and collaborate with experienced companies. On any given day, there are approximately 60 students at the PABC.

**How does PABC help companies succeed beyond the incubator stage?**
Beyond the incubator stage, we can help companies grow their presence and relationships in the industry, and using our network we can connect them with hospital systems, for example. The benefit of being in our incubator is that we nurture companies. We want scientists to focus on science, and we thus offer them the equipment and services to do so. Companies are vetted on 22 data points before selection - of which the most important is the science, the team, and their funding mechanisms. PABC hopes to have another three to five incubators in our model which can benefit the clusters we go to. We are also excited about rolling out AI in our incubators. ■






# The Life Sciences Regulatory Environment

## The IRA: Long-term repercussions, immediate impact

"We finally, after all these years, beat Big Pharma when I signed the Inflation Reduction Act to get seniors and taxpayers a better deal."

In a speech given in December 2023 at the National Institutes of Health (NIH) in Maryland, President Biden made it clear that the IRA and upcoming drug price negotiations were a win over Big Pharma, which he accused of "ripping off" Medicare and the American people with high drug prices.

Although price negotiations included in the IRA will only into effect in 2026, the Act remains the top regulatory priority for Big Pharma and association groups halfway into 2024. In 2023, the IRA was signed into law, thus allowing Medicare (which covers 66 million Americans mostly aged 65 and older) to negotiate prices of the most costly drugs. The aim (according to the Biden Administration): Saving the government and taxpayers US$160 billion over the next 10 years.

In response, pharma firms and industry groups filed last year over half a dozen lawsuits against drug negotiations taking place, calling them "unlawful". Why then has this seemingly noble Act received so much pushback from the industry? Mostly because Big Pharma draws on the revenue and fatter margins generated from their lead drugs (like Pfizer's Eliquis, J&J's Xarelto, or Lilly's Jardiance) to fund innovation and R&D into riskier assets. Indeed, the IRA continues to resonate as a legislative defeat for Big Pharma, and the price negotiations that will ultimately issue from it are seen as a strong headwind for the industry's capacity to innovate.

**Modality shifts ahead?**
The IRA has already earned itself a couple of unsavoury nicknames amongst industry leaders, such as the "Innovation Reduction Act" or "Small Molecule Penalty". The latter is of particular interest because it implies that drugmakers and investors alike might be moving from a particularly penalized modality to ensure margins and returns. Gil Roth, president of PBOA, an industry group representing CDMOs, expanded: "The IRA's section on Medicare drug pricing negotiation marks a momentous shift in US policy. The impact of the IRA will be wide-ranging and has led to legal challenges. The R&D landscape might strongly shift toward biologics at the expense of small molecules."

In March 2024, Pfizer revealed intentions to transition its focus from small molecule therapies within its oncology pipeline to biologics. This strategic shift aligns Pfizer with a trend observed among several pharmaceutical companies, which are increasingly closing their small molecule programs: Vir Biotechnology has halted the development of its small molecule pipeline focused on innate immunity, including a potential hepatitis B cure. Genentech is considering postponing the release of its small-molecule oncology drugs until it obtains approval for a broader patient demographic. Protagonist Therapeutics revealed intentions to discontinue a small molecule treatment for ulcerative colitis in its Q4 earnings report for 2023.

Ironically, incentives towards biologics provided in the IRA come at a time when the scientific potential for small molecules has never been higher: 34 of the 55 novel drugs approved by the FDA in 2023 were small molecules. The IRA however states that small molecule drugs become eligible for price negotiations four years earlier than biologics, potentially resulting in missed opportunities for significant sales revenue. Debbie Hart, president and CEO of BioNJ, explained the challenge: "One troubling aspect is the differential treatment between small and large molecules, with small molecule patent life reduced to 9 years compared to the 13-year timeframe for large molecules. The reduction from 13 to 9 years is discouraging investment in small molecule therapeutic development. Estimates from Vital Transformation suggest that numerous drugs currently available would not have reached the market under IRA policies, and as many as 139 therapies may not be developed over the next decade due to these regulations."

If the current law remains unchanged, it will take years to comprehend fully the ramifications of the small molecule penalty. This is because small molecule drugs currently undergoing trials and nearing approval will continue to be introduced in the coming years, largely due to investment decisions made well before the legislation was enacted. It is likely to be a decade before we experience the full consequences of the absence of innovative, potentially life-saving treatments that never came to fruition. But a bipartisan group of lawmakers is also striving to reverse the small molecule penalty. The Ensuring Pathways to Innovative Cures

Image by W.Scott McGill at Adobe Stock

(EPIC) Act proposes granting small molecule drugs the same 13-year exemption from Medicare price negotiations that biologics receive, thus aligning investment incentives for both classes at a manageable level. The EPIC Act would ensure that whether a drug is a small molecule or a biologic, the most promising candidates receive equal enthusiasm from investors.

Overall, the amount of scaled-back programs poses the harsh question of the long-term threat to innovation in the US – and ultimately to investment. While it is too early to assess if the IRA will affect the investment attractiveness of the US life sciences industry, prominent voices are raising the alarm.

**The 2024 Presidential election: Smokescreen or real impact on pharma policy?**

While November is still a long way off, the industry finds itself between Scylla and Charybdis: Both the Democrat and Republican parties have expressed a will to reform the industry. With drug pricing being a core tenet of Biden's policy, a win in November would make any amendments to the IRA challenging. And while Trump spoke against the IRA earlier in 2023, his campaign is also rallying votes around drug pricing. Unfortunately for the industry, the reduction of drug prices seems to be the only policy that both candidates agree on, a unique feat in today's divided political climate. For Christiana Bardon, MPM Capital's co-managing partner, the election will only result in a status-quo for the industry: "Regarding the presidential election in 2024, Republicans are considered to be more supportive of our industry than Democrats so I think that the presidential election will be neutral to positive."

The IRA changed the policy and regulatory landscapes forever. Regulatory compliance consultancies, industry groups, and pharma firms alike are assessing both the short-term and long-term effects of the IRA. This involves reassessing their product portfolios to identify disease areas or products less susceptible to government price controls and stress-testing their current pricing approaches to shield products from IRA-related rebates while maintaining optimal return on investment. Moreover, manufacturers are exploring opportunities in other markets where market entry barriers are less stringent to ensure sustainable growth while minimizing risks.

For now, the industry is coming out of a record year for drug approvals, with the FDA approving a five-year high of 55 innovative drugs in 2023. The coming years will determine to what extent will this innovative momentum be restrained. Going forward, manufacturers must urgently reassess their fundamental assumptions regarding budgets, underlying costs, profitability, and commercialization strategies, among other factors. For Big Pharma, what is certain is that the forecast portends to more stringent regulations, scrutiny from lawmakers, and pushback from Congress. However, for an industry used to reinventing itself, this changing regulatory environment could provide the opportunity to shift bets across different modalities. ■







"RLDatix is a one-stop-shop offering comprehensive solutions to navigate critical operational and compliance challenges in the life sciences industry."

# John Patrick Oroho

President and General Manager
**RLDATIX LIFE SCIENCES**

**What have been the main highlights for RLDatix Life Sciences over the past year?**

RLDatix Life Sciences is an integration of Porzio Life Sciences, iContracts, and iCoachFirst, with me heading the combined company as of January. The strategic union of the three companies allows us to be an all-inclusive solutions provider to the life sciences industry. RLDatix is a one-stop-shop offering comprehensive solutions to navigate critical operational and compliance challenges in the life sciences industry.

Our Porzio product suite offers a comprehensive compliance solution to life sciences companies, helping them with compliance research, data analytics, automated spend and price transparency reporting, and high-risk engagements in jurisdictions around the world. We have a price transparency reporting system. IContracts has developed a comprehensive suite of solutions to manage all aspects of a company's critical contract processes, which include processing chargebacks, rebates, Medicaid rebates, Medicare GAP payments, other transactions, government pricing calculations, accruals, and managing federal and state compliance requirements at all levels. The only area IContracts and Porzio competed in was around price transparency reporting in the US, but we have now merged the two systems and the combined company does the state price transparency reporting utilizing the Porzio platform. iCoachFirst is a salesforce coaching and talent development platform that focuses on helping life science companies maximize the efficacy of their sales forces out in the field.

**Are the healthcare and life sciences ecosystems poised to become more interconnected than they are today?**

I believe that the healthcare and life sciences ecosystems will become even more interconnected. Major academic medical centers have been doing research for many years, but for the longest time, they would get the research to a certain point, and then license that intellectual property (IP) to traditional pharmaceutical and medical device companies. Today we are seeing a different approach: Instead of licensing the IP out, academia is partnering with the industry or even taking it to market themselves.

I believe New Jersey is at the epicenter of the convergence of the healthcare and life science ecosystem and innovation and technology, and we are seeing the emergence of the Health & Life Science Exchange (HELIX NJ), an innovation district providing industry, universities, and the state with the critical ecosystem to research, learn, work, and collaborate. Companies that were leaving New Jersey to set up in new emerging life sciences hubs are now returning as the state is investing in the future, a connected healthcare ecosystem that encompasses everything from proof of concept on drugs and devices through to development, marketing, sales, and distribution of the drugs and devices so that they can be utilized to provide better care.

**What is your take on the state of the regulatory environment in the US?**

There are regulatory burdens in the US, and part of it is the complexity that the life sciences, pharmaceutical drugs and devices, and biotech areas are regulated both on a state and federal level. The biggest area states are currently regulating life sciences companies is price transparency, as they are spending substantial amounts of money on pharmaceutical drugs, devices, etc., and want to understand why there are price increases. The many regulations and requirements for life sciences companies can be daunting for foreign companies coming into the US, but they can partner with RLDatix Life Sciences as we know the laws and regulations and can help companies on their compliance journey. Our solutions are built from the law and are focused on compliant commercialization, giving companies the ability to understand what they will have to do from a regulatory standpoint across the US.

**What are RLDatix Life Sciences' key priorities for 2024?**

The Inflation Reduction Act is looking to add 20 to 25 new drugs a year, but President Biden wants to up that to 50. If you go from 20 to 50 new drugs a year, before long many of the everyday drugs you see on the market will be subject to price negotiations, and that will be a major issue moving forward. I believe the regulatory framework will continue to get more complicated as we move forward, and RLDatix Life Sciences' focus will be to stay ahead of the curve, understand where the new laws and regulations are coming from. ■

> There are signs of funding returning in the first half of this year, potentially revitalizing early-stage projects, and benefiting the CDMO sector.

# Gil Roth

President
**PBOA**

**Could you provide an overview of how 2023 has unfolded for PBOA and its members?**
In 2023, our focus shifted to the pharmaceutical supply chain and how the CDMO sector can (and can't) help address drug shortages. We are engaged in working with the US Congress and the FDA to enhance their understanding of supply chain intricacies. The primary focus is on achieving supply chain transparency, especially regarding drug origins. We are working with Congress to define reporting responsibilities for CMOs versus those of license holders, recognizing the latter's clearer view of its supply chains. We've worked with those regulators and legislators, and other stakeholders to explore ways to better understand not just upstream drug supply chains, but also the forces that can lead to drug shortages, and how some of them are outside the realm of actual drug manufacturing.

**Can you share your insights on the current state of the industry, particularly upcoming challenges and opportunities for CDMOs?**
The R&D funding drought during 2022 and 2023 has impacted many CDMOs, especially those relying on early-stage clients. This led to challenges when funding dried up. At the same time, the COVID Cliff has impacted CDMOs who played a key role in the global COVID response.

Despite challenges, there are opportunities. There are signs of funding returning in the first half of this year, potentially revitalizing early-stage projects, and benefiting the CDMO sector, and there's also massive demand for prefilled syringe manufacturing capacity and secondary packaging driven by compounds like Novo Nordisk's Ozempic and Lilly's Monjauro. CDMOs have had to evaluate their offerings and, in some cases, rationalize their operations, but navigating this industry requires a strategic approach, especially with the introduction of new projects and new modalities.

Of course, the biggest news in the sector is Novo Holdings' planned acquisition of Catalent Pharma Solutions, and NH's follow-on sale of Catalent's three fill-finish sites to Novo Nordisk, to increase their capacity to deliver Ozempic/Wegovy and next-gen treatments. I'm interested — to put it mildly — to see how that transaction affects the CDMO landscape, particularly in the sterile injectable space.

**How has the reshoring conversation evolved?**
In November and December 2023, White House statements emphasized a national security approach to supply chain resilience. Thankfully, the focus is not on complete domestic production but rather on establishing resilient supply chains through 'friendshoring'. Recent legislative developments include a bill for mapping the supply chain that includes key starting materials and excipients. This reveals the complexity of reducing dependence on specific countries.

**How will the current regulatory changes and potential shifts in drug pricing negotiations impact the life science industry in 2024?**
Drug pricing legislation — through the Inflation Reduction Act's section on Medicare drug pricing negotiation — marks a momentous shift in US policy. The impact of the IRA will be wide-ranging and has led to legal challenges. The implications for the CDMO sector could be significant, as potential changes in clients' reimbursement may influence development decisions. The R&D landscape might strongly shift toward biologics at the expense of small molecules, to extend product lifespan before price negotiations.

Despite the IRA, the pharma industry's commitment to patient well-being remains, and CDMOs will be there to help companies innovate and bring new solutions. Still, the IRA may introduce uncertainty in the R&D space, and there have even been calls to extend it from Medicare to private insurance in the US, which could significantly alter drug pipelines.

On the regulatory front, one area of interest to our members is FDA's pursuit of a Quality Management Maturity "scorecard" for drug facilities. FDA hopes QMM can be used to track facilities' quality over time, to see which are trending better or worse. It's an approach that has undergone a few evolutions since FDA first proposed it, and we are doing our best to make sure that they work on this responsibly, and that the end-product remains confidential.

**In 2024, what will be the main objectives for PBOA?**
I'm optimistic about the sector's future, especially as R&D funding refuels drug pipelines. Our main objectives for 2024 are addressing supply chain and drug shortage issues, helping members navigate regulatory complexities, and providing a space for CDMOs to discuss best practices with their peers. ■





# Insights on Biotech Stocks

**Kathryn McDonough**, Head of Middle Market Life Sciences, **J.P. MORGAN COMMERCIAL BANKING**
"The private capital markets are flush with cash, but private investors are becoming much more thoughtful about how they deploy capital, ensuring that every dollar they apply to an investment is carefully vetted."

**Joe Oltmanns**, SVP, **OTC MARKETS GROUP**
"In 2023, most major industries performed well, but biotech companies did not see much growth in value. Financing in the sector, particularly for micro-cap companies, decreased by about 30% compared to 2022, with 48 financings. The IPO market, which was robust a couple of years ago, especially in life sciences, saw a downturn last year."

**David Schaffer**, Executive Director, **QB3**
"With challenges in the biotech capital markets since 2021, the shift in funding dynamics has made venture capitalists more selective. There are, however, positive market signs. Last year saw a record number of mergers and acquisitions, with 32 deals exceeding a billion upfront."

**Jordan Saxe**, Head of Healthcare Listings, **NASDAQ**
"Company data and the therapeutic stage are the most important factors for investors. Big companies with good data and experienced management teams will always be able to IPO."

**Peter Schiemann**, CEO, **YMMUNOBIO**
"Investors place significant emphasis on the caliber of the team driving biotech ventures forward. While there is variation in team composition across startups, ranging from research-focused to more diverse and experienced groups, investors ultimately seek teams equipped with the expertise to shepherd drug candidates through development stages effectively."

**John Pennett**, Partner-in-Charge of the National Technology and Life Sciences Group, **EISNERAMPER**
"Companies with transformative opportunities stand out because investors seek superior returns to offset risks. The ability of companies to develop themselves, capture early data, and establish a clear regulatory pathway becomes crucial in securing funding."

# The Hubs

“The US and other advanced economies have tremendous expertise in developing new drugs, but we do not have fundamental expertise in developing reserve capacity for addressing unmet population health needs.”

**Roger Erickson**
CEO and Founder
**INTERBIOME**

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# The East Corridor

## The veterans holding the line

The competition to be recognized among the leading US life sciences hubs is formidable. From the veterans of the East Coast, whose manufacturing and research capabilities date back centuries, to the avant-garde entrepreneurs in the West, a handful of states remain the powerhouses of the life sciences industry in the US and keep reinventing themselves to attract the world's best talent and capital.

**Massachusetts: An unparalleled ecosystem**

As states use and abuse statistics to attract investors to their life sciences ecosystems, some data points speak louder than others. For example, one in three venture capitalist dollars invested in the life sciences industry in 2023 landed in a Massachusetts-headquartered company. As public funding remained tenuous for biotechs in 2023 when VC funding provided firms with a much-needed lifeline, such statistics comfort the Bay State's position as the global epicenter for biotechs.

Despite a rough 2023 for the industry, players in Massachusetts leveraged the state's maturity to, like in the past, be the last ones to enter a market reset environment and the first one to exit. And, indeed, 2023 figures signal that the nationwide downturn was less felt in the Boston area than elsewhere. As summed by Kendalle Burlin O'Connell, MassBio's CEO, and president: "Massachusetts saw strong investment in 2023 with approximately US$7.7 billion of VC funding flowing into over 221 Massachusetts headquartered companies. This is our fourth-largest investment year on record. In terms of NIH funding, Massachusetts has long been top of the list per capita as the state is only 2% of the population but receives approximately 9.3% of all NIH funding."

With R&D part of the DNA of most biotechs and biopharma in the state, access to innovation capital will remain key for the state to keep its leading position. And with that, industry leaders have highlighted that more investment is needed towards biomanufacturing. Indeed, MA-located firms are responsible for close to 15% of the entire US drug development pipeline. Such calls have been answered by regional leaders. In June 2023, Governor Healey announced the intent to reauthorize the third iteration of the Life Science Initiative (LSI) that has been in place since 2008, and in early March 2024, she filed an economic development bill that includes a 10-year, US$1 billion extension. Some key components are capital funds, infrastructure dollars, and tax incentives around biomanufacturing.

**New Jersey: Strategically located**

In East Rutherford, Bergen County, during a Jets or Giants football game, chances are your neighbor in the stands works – or has a family member working – in the pharmaceutical industry. Robert Bloder, director Board of Developers and CBO at Ascendia Pharmaceuticals, a NJ-based CDMO, explained: "New Jersey still is the golden triangle and Mecca for pharmaceuticals, and everyone you meet in the state is involved in pharma or knows someone who is."

In the East Coast biopharmaceutical corridor, New Jersey offers the ideal strategic location for firms from around the world. Home to the busiest seaport in the East, and one of the busiest airport in the country – with five-hour flights to Europe – New Jersey can move pharma executives and products like no other state. Korean giant Samsung Biologics elected NJ for its new manufacturing plant. Even Cellares, a San-Fransciso-born cell therapy manufacturer, elected in January 2024 Somerset County for its new 118,000-sq. ft. manufacturing site in Bridgewater.

To maintain its leading position in the country, policymakers and industry associations have recognized the importance of bringing early-stage firms into the state. Since the 19th century, the biopharma landscape in the state has historically been dominated by big pharma in NJ – Merck, BMS, J&J are all there – but several biotechs elected the Garden State as home in recent months, including Elucida Oncology, NovaRock Biotherapeutics, and Tris Pharma to name a few. Statistics highlighting the vitality of New Jersey's ecosystem reveal significant growth in bioscience-related venture capital investments, which surged by US$2.3 million in 2021 compared to 2020, reaching US$706.4 million and marking an increase of over US$100 million since 2018. Building on that VC investment growth, Debbie Hart, president of BioNJ, highlighted two other innitiatives: "The New Jersey Commission on Science, Innovation and Technology's US$16 million investment in 274 startups over four years and the Innovation Evergreen Fund attracting fresh venture capital signal ample growth prospects."

The biggest news coming out of New Jersey in 2024 will most certainly be regarding the upcoming HELIX Health + Life Science Exchange business incubator. Ambitiously presented as a hub "enabling innovators to take action", the three building incubator will provide 1.5 million square feet of multifaceted, state-of-the-art environments supporting the development of health and life science organizations and professions. Innovation hubs like the HELIX in New Brunswick, NEST Center in Kenilworth, and SciTech Scity in Jersey City underscore NJ's commitment to advancement. As put by John Patrick Oroho, president and GM of RLDatix Life Sciences: "New Jersey is at the epicenter of the convergence of the healthcare and life science ecosystem, and we are seeing the emergence of the Health & Life Science Exchange (HELIX NJ), an innovation district providing industry, universities, and the state the critical ecosystem to research, learn, work, and collaborate."

**Philly: From lab to market**

In January 2024, Governor Shapiro elected life sciences as a key priority for his mandate in the first statewide economic development strategy in nearly two decades. Symbolically, that strategy was announced during a visit to life sciences manufacturing company OraSure Technologies.

Indeed, Greater Philadelphia's life sciences industry is booming. The area raised $US2.4 billion across 403 VC deals in 2023. While this marks a drop from 2022, which saw 540 deals for US$5 billion, Philadelphia still solidified its leadership in life sciences, securing six of the top 10 deals of the year in that space, emphasizing the region's strength in key sectors, such as cell & gene therapy. Importantly, the biotech and pharma sector captured US$845.2 million across 38 deals, accounting for six of the 10 largest deals for the region overall.

There is however an obstacle that ought to be overcome for Pennsylvania to unlock its potential fully: The crucial step from scientific research to commercial production. Louis P. Kassa III, president and CEO of the incubator Pennsylvania Biotechnology Center (PABC), highlighted that disconnect: "Pennsylvania is in the top six in NIH funding and patents, but we are near the bottom on the commercialization side."

On the road to more commercial success, the Greater Philadelphia area will be able to count on its unparalleled capabilities in the cell and gene space. Currently, 75% of the companies incubated in B+Labs are in C&G. Roaming the streets of West Philadelphia, one may have noticed a large steel structure copping out of the ground. That site will eventually be Spark Therapeutics' new Gene Therapy Innovation Center, which will bring "hundreds of the greatest minds in gene therapy together under one roof and also serve as Roche's flagship center of excellence for gene therapy manufacturing globally" according to the firm. ■





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> In 2023, Massachusetts made up just shy of 15% of the national drug development pipeline and approximately 7% of the global drug development pipeline.

# Kendalle Burlin O'Connell

CEO and President
**MASSBIO**

**What have been the main highlights and achievements for MassBio in 2023?**
2023 was an interesting year with some market conditions causing concern. We are fortunate in Massachusetts as we have a mature ecosystem, and typically we are the last one to enter a market reset environment and the first one to exit. In 2023, MassBio launched our first-ever Align Summit, a partnering meeting in Massachusetts where we had over 330 attendees, 100 funders, and 150 startups. The Align Summit serves as a strong foundation to continue to build a premier partnering event in the Northeast, and on 25 April 2024, we will have the second event. We look forward to having 50 startups from around the country (and the world) in the pureplay biotech segment, but also the AI and ML space, presenting at this year's event.

Looking at the areas that Massachusetts is most prominently doing R&D in, oncology is always at the top of the list. We are also seeing significant activity in the CNS and cell and gene therapy areas, and anti-infectives remain an area we focus on. We have had exciting announcements recently for the sickle cell community with the work that Vertex Pharmaceuticals (with CRISPR Therapeutics) and Bluebird Bio have done, and these are both homegrown Massachusetts companies.

**How does Massachusetts compare to other life sciences hubs in terms of VC investment, NIH funding, and infrastructure?**
Massachusetts saw strong investment in 2023 with approximately US$7.7 billion of VC funding flowing into over 221 Massachusetts headquartered companies. This is our fourth-largest investment year on record. The IPO window was quite tight with only two IPOs out of Massachusetts, however, they were two out of the top five IPOs for the year, and both are continuing to trade above their initial price. In terms of NIH funding, Massachusetts has long been top of the list per capita as the state is only 2% of the population but receives approximately 9.3% of all NIH funding. In 2023, Massachusetts made up just shy of 15% of the national drug development pipeline and approximately 7% of the global drug development pipeline. Oncology was approximately 35% of that pipeline, CNS 14%, and anti-infectives also 14%.

**Is there enough investment appetite in Massachusetts to move forward in biomanufacturing?**
In June 2023, Governor Healey announced the intent to reauthorize the third iteration of the Life Science Initiative (LSI) that has been in place since 2008 and, in early March 2024, she filed an economic development bill that includes a 10-year, US$1 billion extension. Some key components are capital funds, infrastructure dollars, and tax incentives around biomanufacturing. There are continued efforts to regionalize the life sciences industry around the Commonwealth, and places outside of Boston and Cambridge such as the North Shore and Western Massachusetts will likely be a key focus area for the administration.

**How will the IRA impact innovation in the life sciences industry?**
There have been unintended negative consequences that stifle innovation, particularly in an ecosystem like ours in Massachusetts which is predominantly emerging biotech. At this stage, the IRA and current regulatory environment at the federal level is deterring innovation, especially away from small molecules. Companies are today contemplating their pipeline and making changes away from small molecules or patient populations, and this will have a great impact on particularly rare diseases, orphan diseases, and CNS communities. Investors today are more cautious and looking for more clinical data to make investments. If you compound this with the challenging policies and regulatory landscape, it creates a significant deterrent for companies and investors to innovate and fund innovation.

The Life Sciences Initiative was a bipartisan effort started by a Democratic administration, reauthorized by a Republican administration, and now we have a Democratic at the helm again. This is a testament to the fact that government leaders can and should work collaboratively to see positive outcomes not just for our industry, but as an economic engine for the Commonwealth and ultimately for patients.

**What do you think the financing and dealmaking landscape will look like in 2024?**
We remain cautiously optimistic but have seen M&A activity gain momentum recently. In 2023, there was a 50% increase in M&A activity in the state, with 38 Massachusetts companies being acquired worth US$13 billion, and 30 Massachusetts companies acquiring other companies worth US$9 billion. The momentum for M&A is there, but we are hoping to start seeing mature companies exiting, whether it is an IPO or deal, so we can get that cash flow back in the cycle and investors can start reinvesting into the seed and Series A companies. ■

> We used our voice to educate on the value of medical innovation and boasted the strength of New Jersey's vibrant ecosystem, which was responsible for more than 50% of all novel FDA approvals in 2023.

# Debbie Hart

President
**BIONJ**

**What were BioNJ's main achievements in 2023?**
In 2023, BioNJ rose to the many challenges and opportunities facing the industry. We increased our public policy activities in response to policy challenges at the federal level, including the Inflation Reduction Act, March-In Rights, and the potential for policy changes regarding Pharmacy Benefit Managers (PBMs) being entertained by policymakers. At the same time, we used our voice to educate on the value of medical innovation to the patients who are served by the innovations of our industry and boasted the strength of New Jersey's vibrant ecosystem, which was responsible for more than 50% of all novel FDA approvals in 2023.

**Can you speak to the current regulatory environment in the US, and the impact the IRA will have?**
The Inflation Reduction Act raises significant concerns due to its potential adverse effects on innovation and patient access — seemingly contrary to its intended purpose. One troubling aspect is the reduction from 13 to 9 years, discouraging investment in small molecule therapeutic development and leading to delays or outright failure in bringing vital therapies to patients. Estimates from Vital Transformation suggest that numerous drugs currently available would not have reached the market under IRA policies, and as many as 139 therapies may not be developed over the next decade due to these regulations. Already, companies are scaling back programs due to IRA concerns.

We are hopeful that policymakers will consider supporting a new piece of legislation, the "EPIC Act" (Ensuring Pathways to Innovative Cures Act), which would set both categories of medications at 13 years.

**What makes New Jersey special for life science investment?**
Leveraging its rich pharmaceutical heritage and bolstered by ongoing investments from both industry and government, New Jersey stands poised to expand and deliver crucial innovations for patients. With a unique and diverse workforce, encompassing talent across the spectrum from early-stage discovery to commercialization, the state boasts a comprehensive talent pool. Its ecosystem spans the entire drug development value chain. Moreover, New Jersey hosts more FDA-registered manufacturing facilities than any other state. Notably, over 50% of all novel FDA drug approvals in 2023 originated from companies with a strong presence in New Jersey.

Statistics highlighting the vitality of New Jersey's ecosystem reveal significant growth in bioscience-related venture capital investments, which surged by US$2.3 million in 2021 compared to 2020, reaching US$706.4 million and marking an increase of over US$100 million since 2018. NIH funding has experienced consistent growth since 2018, with the majority directed toward biological, biomedical, and health sciences. Additionally, establishments in the medical devices and equipment sector have grown by 21.4% since 2018.

**What are the catalysts ahead for 2024 to ensure New Jersey remains a leading life sciences hub?**
The growth of New Jersey's ecosystem continues, marked by global companies expanding in the Garden State and concerted efforts to bolster the very earliest-stage companies. Notably, the New Jersey Commission on Science, Innovation and Technology's US$16 million investment in 274 start-ups over four years and the Innovation Evergreen Fund attracting fresh venture capital signal ample growth prospects.

Moving ahead, we will see more partnerships between academia, industry and the public sector to ensure New Jersey remains a leader in life sciences and ultimately bring more drugs to market. Key innovation hubs like the HELIX in New Brunswick, NEST Center in Kenilworth, and SciTech Scity in Jersey City underscore the state's commitment to advancement.

Moreover, Governor Phil Murphy's array of economic innovations and initiatives, including the AI Moonshot and collaboration with Princeton University to establish an AI institute, reaffirm New Jersey's dedication to maintaining a leading position in innovation, cementing its reputation as a premier hub for groundbreaking advancements.

**What are the key priorities for BioNJ in 2024?**
In 2024, BioNJ will maintain its steadfast commitment to policy advocacy, ensuring future innovation and that patients have access to the medicines they need when they need them. Committed to leaving "no patient behind," we will continue to build upon our Health Equity in Clinical Trials Initiative, while telling the value of medical innovation story, including developing and placing educational information on Pharmacy Benefits Managers right at the pharmacy counter for consumers and patients. ■





# The West

## A global player on the move

California is more than the birthplace of the internet and the latest AI technologies. Life sciences represent a US$450 billion economy, and the state is increasingly relying on an integrated cluster model, rather than single powerhouses.

**San Francisco and San Diego: Strides in public/private funding**
No wonder why thousands of executives, investors, and scientists fly to San Francisco every January. Beyond the pristine weather at that time of the year, the "Golden Gate City" is also home to the JP Morgan Healthcare Conference, one of the most anticipated events of the year, strategically located in one of the hearts of the VC and biotech communities of the US.

Despite the economic headwinds of the past 18 months, the San Fransisco life sciences cluster, with its over 2,400 biotechs, fared relatively well. In life sciences, the number of leases, megaleases, and square feet used in labs are often good indicators of a hub's health. In that sense, the Bay Area is not just the tech capital of the world, it is home to thousands of students, VCs, and entrepreneurs that cumulatively occupy 38 million square feet of lab space, a figure that is set to grow by close to 10% in 2024 according to CBRE. Among those players, drugmaker Horizon, stroke startup Imperative Care, and cell-sorting firm Nodexus all announced plans to expand in the Bay in 2023. Lab vacancy remained low compared with other sectors, and new leases and expansions point to the resilience of the sector.

The cluster also remains an investor-favorite at both governmental and private levels. The Bay Area received US$1.3 billion in NIH funding in H1 2023 alone, ranking it third in the country. A decade-long culture of entrepreneurship and risk-taking has made the Bay Area the Eldorado for VC funding in the country, and, boosted by both the AI boom and the biotech revival of H2 2023, San Francisco startups pooled a cumulative US$49 billion in seed financing through growth funding in 2023. That represented 41% of the total US investment, and the highest share in years. Interestingly, sustained record investment in the past years has pushed more science from the early stages to the clinical trial stage, suggesting the potential for future scientific and capital growth.

Despite employment headwinds felt throughout the country amidst fears of a recession, job growth saw a positive growth trajectory in San Diego in 2023, according to Biocom California's 2023 Economic Impact report. The cluster felt the pinch mostly in the notable decrease in VC funding, with the industry attracting US$2.5 billion in 2022, less than half compared with the year before. Yet, there are early signs to point to a positive 2024 for the other end of the "biotech beach".

**Los Angeles: Materializing hopes**
Compared with its Californian peers, the LA area has been in dire need of a boost to unlock its biotech activity for years. Recent months saw major developments in the cluster's potential to become a leading biotech hub.

In 2018, the creation of BioscienceLA acted as a catalyst for investment to flow in the greater LA region. Now known among the investor community behind the iconic Hollywood sign, LA grew to over 2900 life sciences establishments. Among them, firms like Kite, Capsida Biotherapeutics or Acelyrin, who registered positive results treating psoriatic arthritis for its lead asset izokibep in March 2024 contributed to the growth of the ecosystem.

LA is also poised to benefit from the unique ecosystem of collaboration between academia, the state, and private investors in California. In early January, UCLA acquired an empty mall in a US$700 million deal to create the "Research Park" Southern California needed to bolster innovation, discovery, and economic growth. The 700,000 sq. ft property will house the California Institute for Immunology and Immunotherapy at UCLA and the UCLA Center for Quantum Science and Engineering. With this renewed capability, UCLA gave a credible boost to its ambitious goal of building the immunology equivalent of Silicon Valley in LA.

Looking ahead, new biotechs in the C&G, CRISPR, and immunology spaces are expected to sprout around university-funded incubators, such as QB3, again highlighting the positive relationship between the academic ecosystem, made up of UC Santa Cruz, Berkeley, and UCLA notably – and the private sector in California. Importantly, there seems to be a fresh approach to collaboration in California. Incubators are now working across clusters rather than behind their university walls, which reflects a trend seen across industry segments, summed up Joe Panetta: "We are now beginning to see California move forward as not two or three individual clusters, but rather as a powerhouse of integrated clusters." ■

Image by Reynand at Adobe Stock

> We are beginning to see California move forward as not two or three individual clusters, but rather as a powerhouse of integrated clusters, and this will continue to be our focus in the future.

## Joe Panetta

President and CEO
**BIOCOM CALIFORNIA**

**What were the main highlights for Biocom California in 2023?**
2023 was one of our most successful years in terms of growing our membership. We undertook some refocusing, specifically in our capital development programs, helping our companies find partners and raise money to be able to continue their research and move towards commercializing their products. Biocom California's investor conference in 2023 was one of the most successful in our history, drawing not only small companies looking for opportunities but also many large pharma companies looking for funding opportunities and partners. We were also busy on the policy side, helping our members interpret the IRA - working with partners to challenge not only the current stipulations of the drug pricing provisions of the IRA, but also to continue to defend against any further legislative action that could potentially impose a greater threat.

Overall, 2023 was one of the most challenging years the biotech industry has faced. We worked to accelerate the success of our 1,700-plus member companies whilst mitigating the significant challenges they confronted. These challenges include the regulatory challenges surrounding the drug pricing requirements under the IRA, which was a threat to the innovative open market system of researching, developing, and commercializing products in the US.

**To what extent will the future of life sciences be digital?**
From artificial intelligence and big data to wearable devices and implantable diagnostics and therapeutics, the future of healthcare is digital, and California's tech and life science ecosystems are uniquely positioned to lead this transformation. Converge by Biocom California is a new cross-sector community where the brightest minds in technology and life sciences gather to shape and navigate this new digital frontier in healthcare.

**How is California continuing to grow as a biotech center, and what will the state have to do to keep its leading position?**
California is unlike any other biotech cluster in the world. The state is the fifth largest economy globally, plays on an international level, and has a US$450 billion life sciences economy. We have continued to see the Los Angeles (LA) cluster thrive over the last few years, with the emergence of many sub-clusters in the region as well. LA is a mega powerhouse of business and can bring in funding and international connections. Biocom California is proud to continue to connect the clusters by actively creating programs that allow for the opportunity to partner, access capital, and purchase supplies and services. We are beginning to see California move forward as not two or three individual clusters, but rather as a powerhouse of integrated clusters, and this will continue to be our focus in the future.

Biocom California's 10-year strategic plan, launched in 2024, calls for positioning California's industry as a major global player in life sciences in a proactive manner – actively identifying partnership opportunities around the globe.

**How do you think the regulatory and policy environment in the US is affecting investment into the biotech industry?**
I believe that the regulatory environment is, unfortunately, creating less opportunity for investment, but I am optimistic that we are continuing to see new company incubation, robust pipelines within our biopharmaceutical companies, and our industry fighting back and exploring, within the limitations created by drug pricing controls in the IRA, ways to develop potentially lifesaving and profitable products. A major concern is why in the IRA small molecules are being penalized with a nine-year time limit before negotiation on pricing begins versus a 13-year time limit for large molecules. The small molecules that have been developed or are in development are every bit as promising as the large molecules out there, but due to this shorter time limit, we are already seeing companies financially cutting back on small molecules.

**What are Biocom California's growth strategy and priorities for 2024?**
Biocom California aims to enable our members to become more international by bringing international partnership opportunities to California. We also want to get our companies better funded and have built an online platform, which we will launch soon, for VCs and life sciences companies to connect. ■

# The States on the Rise

## A plethora of opportunities in emerging markets

What gives the US its competitive advantage on the global scene is, beyond healthy competition, the complementarity of its hubs. In that sense, seeing Tier 2 markets emerge alongside the country's "Big Four" (Boston, Philadelphia, San Francisco, and San Diego) is highly encouraging for the industry. Scientists and entrepreneurs looking to develop a novel generation of drugs can set foot in Boston, New Brunswick, or San Francisco and find a plethora of opportunities. Behind the country's powerhouses, researchers more comfortable in labs will feel welcome in North Carolina's Research Triangle Park, whereas manufacturers from all over the world can expand through greenfield and brownfield opportunities in Oklahoma, Ohio, or Indiana, the state with the highest concentration of advanced manufacturing jobs in the US.

**Made in America: The Biomanufacturing Advantage**

With the "Big Four" leading innovation in the biotech space, opportunities are to be grasped in the lengthy and demanding value chain from concept to commercialization. Investors and entrepreneurs looking at the square foot price of facilities, access to a skilled workforce, along with flexible tax and post-pandemic remote working policies, have options in the heart of the country; Oklahoma, Ohio, Indiana, North Carolina, Chicago, and Texas, to name a few. One common thread across those states is the presence of an established culture of biomanufacturing, namely the production of large molecule drugs, like antibodies and enzymes, from living cells. Biomanufacturing resilience across the country became a top public policy priority post-COVID, particularly for the supply chain of vaccines.

America's Midwest has been the heartland for manufacturing and farming for generations. Today, of the 12 states that make the region, Illinois, Indiana, and Ohio are in a leading position to reshape economic growth through life sciences manufacturing. INCOG and CMC Pharmaceuticals both listed their respective states' manufacturing capabilities and strategic locations as the leading factors for investment attractiveness. Mike Radomsky, CEO of CMC, shared: "Ohio's strategic location and supportive ecosystem for life sciences companies make it an attractive destination for businesses seeking to expand or establish a presence in the Midwest."

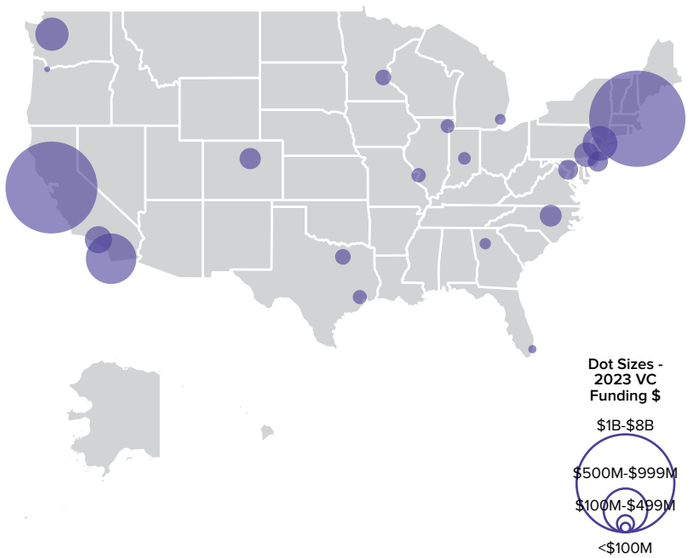
The influx of investment in manufacturing facilities in recent years in Indiana is unlikely to wane anytime soon. In October 2023, the state was designated a leading "federal technology hub" by the US Department of Commerce, which should allow the state to compete for millions of dollars in life sciences investment and further strengthen its position as a biomanufacturing hub. Indiana leads the US in pharma exports and has the second-highest concentration of life sciences jobs in the country, along with being the only state to manufacture all three COVID-19 vaccinations. Tedd Green, co-founder and COO of INCOG, shared: "Indiana and the Fishers area provide access to a skilled workforce with relevant experience in life sciences, which is crucial to our success. Moreover, Indiana's strategic location facilitates engagement with a global customer base."

The modest heaven of R&D that sits between Raleigh and Durham – the Research Triangle Park – certainly boxes above its weight class in the life sciences ecosystem. Close to 800 life sciences firms, along with 2,500 associated service providers, call the Triangle home. Among them are renowned pharmaceutical giants like Biogen, Novartis, Pfizer, and others. Every day, new biotech ventures are cropping up with an NC ZIP Code. And again, beyond Duke University and the University of North Carolina at Chapel Hill receiving the lion's share of the US$2billion+ NIH funding, the area distinguishes itself for its expertise in biologics manufacturing, with over 36,000 biomanufacturing employees across 108 sites. Its neighbor South Carolina is also a growing state for manufacturers. Out of the Netherlands, CurTec manufactures high-performance material for pharma firms. As the firm expands, it elected in 2023 Westminster, SC, as its US home. CEO Bart van Berkel explained: "South Carolina is a growing production hub, which means there is ample talent. From a logistics perspective, the state is geographically well-located to easily reach customers."

In the South, Oklahoma is carving itself a share of the development and manufacturing pie; particularly through a recent series of private loans and public grants. The Oklahoma Biotech Innovation Cluster Initiative received a US$35 million grant from the Federal government to bolster its growing life sciences industry. The grant will help launch six biotech projects in Oklahoma City, which, despite being lesser known on the pharma map, has significant potential for the expansion of emerging biotech as it is triple the size of Boston or the Bay Area. Touching on the city's competitive advantage in biomanufacturing, Stephanie Wickham, senior director of technical sales and technology at Cytovance Biologics, a homegrown CDMO, explained: "Oklahoma has a strong academic presence across the state, with many researchers focusing on different facets of biomedical research. There are a lot of technologies coming out of the universities, backed by VC firms, and recently, significant state and federal investment to build the biomanufacturing economy in the region."

The list of emerging life sciences hubs has not drastically changed over the years, but some areas are seeing their influence sustained more than others. Biotechs can now move out of the "usual suspects" to do business, and firms can attract funding even outside of the "Big Four." A recent CBRE report indicates that Chicago has 350,000 sq. ft. worth of demand, more than the city is building. Home to biopharma heavyweights and the world's largest stock exchanges, the Big Apple also has about 860,000 sq. ft. of new and converted lab space in the works. Across the US, there is room for growth. ■

### Life sciences market for funding




Source: Cushman & Wakefield Research, PitchBook





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# Drug Discovery and Development

"Oncology continues to be the number one category where R&D dollars are being spent, with CNS moving into the number two spot."

**MARK A. GOLDBERG**
CEO
**ALLUCENT**

GBR Series • UNITED STATES LIFE SCIENCES 2024

Image courtesy of Insmed

# Oncology and CNS Lead the Way

## Unprecedented strides mean growing hope for patients

Close to 250 oncology and CNS therapies are currently in development across the world, more than all other indications combined. In the US and much of the Western world endogenous and exogenous societal shifts, such as the use of tobacco, an aging demographic, and ever-growing obesity numbers are behind the patient-driven push to meet unmet needs in the oncology and CNS spaces.

2023 brought significant investment in oncology and CNS despite the market downturn. J.P. Morgan figures show that companies raised US$3 billion across 37 seed and Series A rounds, of which US$1.4 billion went to oncology-focused firms alone, nearly double the amount garnered by neuroscience biotechs. Oncology also led M&A investment, headlined by Pfizer's US$43 billion acquisition of Seagen, and AbbVie tapping Immunogen for US$10 billion to expand its solid tumor portfolio. On the neuro side, BMS scooped up Karuna Therapeutics and its schizophrenia candidate KarXT, while AbbVie acquired Cereve Therapeutics.

### Taking on a global killer

The global burden of cancer is growing. World Health Organization (WHO) data shows that about one in five people develop cancer in their lifetime, and approximately one in nine men and one in 12 women die from the disease. The disease – most common types being lungs, breast, and colorectal – is so spread globally that most people would likely know someone directly or indirectly affected by cancer. With cancer cases expected to grow by 77% at the turn of the century (up to 35 million in 2050, compared with 20 million in 2022) according to the UN's International Agency for Research on Cancer, it appears obvious why the leading indication for scientists, investors and patients alike remains oncology. Indeed, oncology is forecast to be the largest market by indication, with a projected market volume of US$214.10 billion in 2024, according to Statista.

J&J recently shared a paper in which the drugmaker expressed eliminating cancer moved from an out-of-reach goal to one "within our grasp". In 2023 alone, the leading oncology drugmaker presented new research in lung, bladder, and prostate cancers along with multiple myeloma, B-cell malignancies, and myeloid malignancies. In the US alone, the American Cancer Society projects over 2 million new cancer cases and 611,000 deaths in 2024, translating to 1,673 deaths per day. That said, survival rates have continued to improve in the country since the 1990s, following a blend of public policy initiatives targeting smoking, obesity, and pollution (the leading causes of cancer), and of course novel pharmaceutical therapies. Despite the pandemic causing a backlog in diagnosis and treatment, 2023 saw strides made in precision oncology, the "best new weapon to defeat cancer" according to Genetron Health CEO Sizhen Wang. The precision oncology approach identifies alterations in cells that may be driving the growth and spread of cancer, enabling the development of personalized treatment strategies.

Oncology is not ready to exit the spotlight. With patent cliffs looming, the trend of Big Pharma refurbishing its oncology pipelines is likely to sustain and strengthen. In the first half of 2024, BMS boosted its cancer pipeline by buying Mirati Therapeutics and completed the purchase of RayzeBio to enter the radiotherapeutics scene. AstraZeneca joined the radiopharmacy oncology waltz by announcing in March the takeover of Fusion Pharmaceuticals, while Novartis and J&J also bolstered their oncology pipelines. Gilead expanded its cancer cell therapy deal with biotech Arcellx late last year, with the collaboration now including two experimental drugs to treat multiple myeloma and will widen testing of one into lymphoma. Gilead can now co-develop and co-commercialize CART-ddBCM in the US. Arcellx's CBO Aileen Fernandes shared: "Overall, oncology remains a high priority, as evidenced by recent financing trends, where approximately a quarter of recent funding has been directed towards oncology. This influx of capital is likely to bolster funding opportunities not only for oncology but also for the broader biotech sector."

Image by alexraths at Depositphotos





### The ADC renaissance

After a true renaissance in 2023, an emerging class of biopharmaceutical drugs will undoubtedly keep getting attention in 2024 and beyond: Anti-Body Drug Conjugates (ADCs). Two decades after the approval of the first ADC, the established group of drugs are indeed late bloomers. The coming of age, materialized by Pfizer, AbbVie, and J&J's acquisition of ADC developers since H2 2023 helped push tri-fold the value of ADC deals compared with 2022. As momentum continues in 2024, highlighted by J&J's US$2 billion deal for Ambrx Biopharma, the significant investment underscores the rising value of a drug class that some advocates believe could eventually supplant certain traditional chemotherapy treatments. Currently, there are 11 approved ADCs in the US, with over half receiving FDA approval in 2019 or later.

The renaissance seen in pipelines is not due to an overnight success, but more to technical and scientific maturity, along with technological validation in recent years. ADCs got off to a bumpy start despite being labeled as "precision chemotherapy". Indeed, identifying the optimal combination of antibody, linker molecule, and toxic payload presents challenges. ADC designers aim to replicate the characteristics of a standalone antibody, such as specificity, clearance profile, and toxicity, as closely as possible. However, they also intend to incorporate a potent payload without compromising the antibody's pharmacokinetics. Many drugs are hydrophobic, which can lead to aggregation and limited tissue penetration. In recent years, the success stories of drugs like T-DM1 (trastuzumab emtansine), Enhertu, Padcev, and Trovelvy have demonstrated the potential efficacy of ADCs in treating cancer, hence raising the class' profile among investors and Big Pharma.

Innovation in scientists' ability to engineer linkers and novel payloads means we are seeing improved applications in the ADC space. Among the biotechs developing ADCs for oncology targets, MBrace Therapeutics is leveraging validated linkers and payloads to mitigate risks associated with drug development. The biotech's lead compound, MBRC-101, is an ADC targeting the EphA5 gene. MBRC-101 was manufactured using a conjugation platform with a cleavable linker and Monomethyl auristatin E (MMAE) payload with a Drug Antibody Ratio (DAR). MBrace's co-founder and CEO Isan Chen recalled those technological prowesses: "Over the past two decades, there have been notable improvements in conjugation methods, linkers, and payloads enhancing the stability and efficacy of ADCs. The advancements in linker design play a crucial role in ensuring the targeted delivery of cytotoxic payloads to cancer cells while minimizing off-target effects. Understanding and mitigating toxicity have also been paramount. Significant strides have been made in comprehending the drivers of toxicity, leading to the development of ADCs with improved safety profiles."

### Neuroscience's next frontier

For decades, researchers and scientists have been unsuccessful in their attempts to break the blood-brain barrier. The BBB, a selective semi-permeable membrane between the blood and the interstitium of the brain, allows cerebral blood vessels to regulate molecule and ion movement between the blood and the brain. Simply put, the system protects our brains from harmful chemicals. The issue is that molecules must cross that barrier and penetrate that system to treat neurological conditions such as Alzheimer's and Parkinson's. However, progress by researchers in 2023 bodes well for future breakthroughs.

The extreme difficulties associated with CNS drug development ought not to be understated. Under "normal conditions" (as defined by the NIH), the BBB prevents 98% of small molecules and 100% of large molecules from penetrating the brain. Making the BBB more permeable is therefore key, and researchers from Harvard Medical School might have made a

pioneering step in that direction. In July 2023, researchers identified a gene expressed in neurons that when mutated increases the permeability of specific regions of the blood-brain barrier. These findings could assist scientists in regulating the blood-brain barrier, which is vital for delivering drugs to the central nervous system or addressing damage caused by neurodegenerative diseases.

The partnership between academia and the private sector might be stronger in neuroscientific disciplines than for any other indications to try and overcome the BBB. According to a recent Deloitte report focused on sizing the brain, the neuroscience diagnostic market is primarily driven by medical imaging and next-generation sequencing technologies. As such, in 2023, a decade after the launch of the Brain Research Through Advancing Innovative Neurotechnologies (BRAIN) initiative, MIT and UCI received millions in NIH grants to develop the connections between the 86 billion neurons that form more than 100 trillion connections in our brains.

**The dementia landscape evolves**

Newly discovered treatments that have the potential to reverse Alzheimer's disease (AD) signs or remove toxic proteins from the brain are sustaining enthusiasm in the CNS market. In August 2023, the FDA approved Leqembi, a disease-modifying drug for Alzheimer's, the second only to address the progression of the disease. Leqembi functions by targeting amyloid beta, the primary component of the amyloid plaques present in the brains of Alzheimer's patients, impacting memory and cognitive functions. It labels these plaques for elimination by the body's immune system, thereby slowing the progression of Alzheimer's symptoms. Vaccines are among the treatments bringing hope to patients and investors. Companies like Elil Lilly and Prothena have expressed renewed interest as vaccines are easier to administrate and less frequent in dosing (Leqembi requires two injections per month). Firms like Prothena, AC Immune, and Vaxxinity all saw their AD-focused programs making strides in 2023. The efforts, however, continue to encounter setbacks. In January, Biogen dropped its controversial Alzheimer drug Aduhelm along with an FDA-ordered clinical trial deemed by a certain FDA regulator "the worst approval decision that the FDA has made that I can remember."


**Andreas Grassauer**
CEO
**MARINOMED**

> "In terms of biotech funding, the US remains ahead of the world, as the country is more innovative and moves faster. European investors are still slow to react on US stock exchanges. Biotechs are in a good place right now, I however do not expect a full-blown rally."

Now that Leqembi has proved that AD treatment works, the next step for drugmakers and biotechs will be developing shots that will not only generate response but also keep inflammation in control. Indeed, treating neurogenerative diseases like Alzheimer's or Parkinson's without side effects is a complex endeavor. The approval of Eisai and Biogen's Leqembi marked a pioneering moment for the approval of an early-treatment Alzheimer's drug on the US market. Yet, in terms of sales and adoption, the drug has been off to a slow start, notably due to potential side effects that include frequent infections, brain swelling, and bleeding. In a third-quarter earnings presentation, Eisai reported the drug had reached only 2,000 patients, below target as it aimed for 10,000 by the end of 2024. To mitigate side effects,which, like in the case of cancer, are sometimes worse for the patient than the disease itself, Aphios decided to go beyond what was available on the market and develop APH-1104, a novel α-secretase modulator and potential AD therapeutic. "This will not only help delay or prevent symptoms from becoming worse but will also increase memory by the regeneration of synapses or synaptogenesis," said the company's CEO, Trevor P. Castor.

Crossing the blood-brain barrier is a challenge that pertains to a natural dimension as the system was designed as part of our species' evolution. And like anytime humanity attempts to play with Nature, results are likely to take years to materialize. Nonetheless, Big Pharma, VC, and biotechs are increasingly pooling capital to smuggle drugs into the brain. Investment in the neuroscience market is perhaps more needed than ever: Beyond brain disorders being the leading cause of disability worldwide, an aging population (the number of people expected to live with Alzheimer's in the US is forecasted to more than double between now and 2050 to 13 million) dozens of psychological studies have emerged post-COVID-19 showcasing that the unprecedented stress test negatively impacted brain disorders across the world. ■





> "Aphios, which means virus-free, has the core mission to not only contain viruses but also to treat underlying infectious diseases."

# Trevor P. Castor

President and CEO
**APHIOS**

**What were the main highlights and achievements for Aphios in 2023?**

As the year evolved, Aphios focused on a few strategic approaches that are mission-centric. One of those approaches focused on ESG factors and how our approach to biotechnology fosters and assists in environmental sustainability. Additionally, the company also placed a focus on nanotechnology drug delivery – how to better deliver drugs to target therapeutic indications, whether it is for CNS, cancer, or infectious diseases. Nanotechnology drug delivery reduces dosing levels and frequency and improves efficacy and clinical response to the drug. Due to the complexity of biology, often a combination of therapies is required which can be facilitated by AI, and this was the third area of focus for us.

**What makes Aphios' technology platforms unique?**

Aphios' enabling technology platforms are based on environmentally friendly technologies where we use advanced scientific techniques to improve nanotechnology drug delivery, accelerate drug discovery and manufacturing processes, remove harmful pathogens from biologics and the human blood supply, and provide a viable biofuel solution for the future. We are exploiting the physiochemical properties of near-critical, critical, and supercritical fluids. When compressed, these fluids exhibit enhanced thermodynamic properties of penetration, selection, solvation, and expansion. We manipulate these SuperFluids on a cellular level to increase process selectivity and speed while reducing processing steps, toxic organic usage, and manufacturing costs.

**Can you elaborate on the work Aphios is doing in the Alzheimer's Disease (AD) space?**

Aphios wants to go beyond what is already available on the market and is developing APH-1104, a novel α-secretase modulator and potential AD therapeutic that will not only help delay or prevent symptoms from becoming worse but will also increase memory by the regeneration of synapses or synaptogenesis.

**Is the life sciences industry already adapting to climate shifts and mitigating that risk?**

Climate change, population increase, urbanization, deforestation, etc. will have an impact on our quality of life as well as our biology as there are effects on ecosystems and the habitats for viruses to which our bodies have no natural immunity. The industry will have to adapt by either creating better and quicker vaccines, or we will have to be able to rid those new viruses quickly from biologics and biotechnology products which can be a carrier of viruses. Aphios, which means virus-free, has the core mission to not only contain viruses but also to treat underlying infectious diseases.

As the climate in the northern parts of the US gets hotter, we will have problems with malaria, which kills more people than any other infectious disease in the world. To address the need for effective pathogen inactivation and removal techniques for human blood plasma and plasma-derived products, Aphios is now commercializing a green CFI (Critical Fluid Inactivation) technology that can inactivate enveloped and non-enveloped viruses with no residual contamination and negligible denaturation of proteins and enzymes. CFI does not damage proteins and enzymes since it is purely physical and does not involve the use of chemicals, heat, or irradiation, and it is a scalable closed system, fluid-liquid/solid contacting technique.

**Can you elaborate on Aphios' strategy to build partnerships, and what makes the company a compelling investment case?**

We have advanced several therapeutic products and technology platforms that are both ESG-sensitive and mature for establishing partnerships. For example, developing a technology that can improve the delivery and stability of mRNA vaccines and therapeutics, provides a platform for collaborations in several therapeutic areas. As we are in an election year, many investors are cautious and are waiting to see what happens before they invest. There is thus a significant amount of capital sitting on the side, inflation will go down, and interest rates will decrease, meaning the IPO market should be taking off soon. Aphios has a subsidiary, Zindol LLC, which we plan to take public, depending on market conditions, to develop our lead drug candidate for chemotherapy-induced nausea and vomiting, as well as for other indications of nausea such as GLP-1 medication-related nausea, hyperemesis in pregnancy, and postoperative nausea and vomiting. Aphios' key priority moving forward in 2024 will be to launch Zindol LLC as a company through private and/or public financing and work toward FDA approval of Zindol. ■

> We are dedicated to establishing proof of concept with our ADC targeting NPTXR.

# Peter Schiemann

CEO
**YMMUNOBIO**

**Could you provide some insights into the recent strategic shifts of Ymmunobio?**
One of the pivotal moments was our strategic decision to shift our focus toward a new lead compound. This shift was prompted by the tepid response from investors to our previous immune-oncology compound, despite its superior qualities. We realized that the investment climate, coupled with the perception of immune-oncology as 'old news,' was hindering our progress. Fortunately, our efforts were not in vain. We had been concurrently exploring a second compound, which yielded remarkable results. This compound targets a novel receptor, NPTXR, predominantly expressed in solid tumors while being absent in healthy tissue. This discovery injected fresh momentum into our endeavors.

NPTXR, a membrane receptor typically active during embryonic development, resurfaced in adult patients with gastric cancer, among others. Its presence in various solid tumor types, including ovarian, pancreatic, prostate, and lung cancers, presented a compelling opportunity for targeted therapy.

Our recent focus has been on developing an antibody-drug conjugate (ADC) targeting NPTXR. Unlike current ADCs, which may affect healthy tissue due to shared receptor expression, ours specifically homes in on tumor cells, minimizing off-target effects. Immunochemistry studies have identified NPTXR expression in 13 different solid tumor types, laying a solid foundation for further research and development. The enthusiasm surrounding our new direction has been palpable. Following our presentations at events like the JP Morgan conference, investor interest has surged. We have secured our first institutional investor, marking a significant milestone in our journey. This backing will propel our efforts to establish proof of concept for our NPTXR-targeting ADC through preclinical studies, slated for July or August.

In essence, while the past year has been marked by challenges, the emergence of NPTXR as a promising therapeutic target has reignited optimism and positioned Ymmunobio for a transformative year ahead.

**How has the recent fervor around ADCs helped in unlocking capital?**
Being the sole player working on NPTXR gives us a unique advantage. Unlike the crowded landscape of known targets in ADC development, our exclusive focus on a novel target means we have the entire field to ourselves. This significantly enhances our prospects and allows us to maintain control over the development process.

The recent fervor surrounding ADCs underscores the market's appetite for innovative approaches. While many companies are vying for a slice of the pie by targeting known receptors, our strategy of carving out a niche with a new target ensures that the entire cake belongs to us. This, coupled with the promising outlook for our approach, has garnered considerable attention from both investors and potential partners.

Overall, the landscape is evolving positively for targeted approaches like ours.

**What do you perceive as the key criteria investors prioritize when assessing biotech teams, especially against the backdrop of the approaching patent cliff and the imperative to revitalize pipelines?**

Investors recognize the importance of teams that not only possess technical know-how but also demonstrate adaptability and a forward-thinking approach. In an industry as dynamic and competitive as biotech, success often hinges on the ability to innovate, collaborate, and pivot in response to evolving market trends and scientific insights. Our recent nomination for the Prix Galien Best Biotech Startup award for 2024 is a testament to the recognition of our team's efforts and the promise of our novel compound. It underscores our commitment to excellence and innovation, qualities that resonate with investors seeking to partner with ventures poised for growth and impact.

**What will be the primary focus for you and your team in 2024?**
Our primary focus for 2024 revolves around achieving two major milestones. Firstly, we are dedicated to establishing proof of concept with our ADC targeting NPTXR. This entails rigorous preclinical studies to demonstrate its efficacy and safety profile. Concurrently, we are exploring the potential of a radio-labeled antibody, a project in collaboration with a partner company. Our first meeting is scheduled for early May to discuss the development of the linker and payload for the ADC. Secondly, we recognize the significance of companion diagnostics in ensuring precision therapy. ■





# Brian Frenzel

President and CEO
**TOSK**

**Can you re-introduce Tosk and the unmet needs that your pipeline products address?**
Tosk is a small-molecule drug discovery and development company, with a unique twist in pursuing the oncology space. Rather than developing entirely new therapies that often serve limited patient populations, we focus on blocking the adverse side effects of existing, widely used cancer therapies. While new therapies can be very expensive, our approach is intended to reduce the overall cost of care by making existing therapies more effective and by eliminating the need to treat side effects.

We have four products in the pipeline, the most advanced being TK-90, which has just completed a series of clinical studies in head, neck, and colon cancer patients. TK-90 addresses the mucositis and pulmonary fibrosis caused by several widely used cancer therapies.

We are currently performing a dose optimization study using a single dose of TK-90 in head and neck cancer patients receiving a combination of chemotherapy and radiation therapy. Results to date show that TK-90 can block virtually all of the mucositis caused by this therapy. Our goal is to initiate a Phase 2b/3 registration study for TK-90 in the US and other countries by the end of this year.

**Why choose the avenue of improving existing therapies rather than coming up with new ones?**
Anyone who has had cancer or watched a loved one suffer knows that the adverse effects of cancer therapy are often worse than the disease itself. Many patients do not complete the recommended course of therapy due to side effects. And because patients will not have to limit the dosing of their cancer therapy due to side effects, their treatments will have a better chance of overcoming the cancer.We think the combination of a better quality of life, lower cost of care, and more effective cancer treatment make a compelling argument for cancer therapy adverse effect prophylaxis. ■

# Isan Chen

Co-Founder and CEO
**MBRACE THERAPEUTICS**

**Can you introduce MBrace Therapeutics?**
Our primary objective is the development of ADCs targeting novel and promising receptors. We have consciously steered away from conventional approaches, emphasizing innovation over replication. Using our proprietary discovery platform, SPARTA, we can efficiently identify and validate unique targets that show promise in combating cancer. Among these, EphA5 emerged as a standout candidate due to its compelling profile in various cancers, notably non-small cell lung cancer (NSCLC) and breast cancer. EphA5 expression is particularly prevalent, ranging from 80% to 90% in these cancer types, encompassing adenocarcinoma, squamous cell carcinoma, and different subtypes of breast cancer, including triple-negative and hormone receptor-positive.

Additionally, EphA5 exhibits significant expression in other challenging-to-treat cancers such as gastric, pancreatic, and colorectal.

Our lead compound, MBRC-101, is an ADC targeting EphA5. MBRC-101 was manufactured using a site specific conjugation platform with a cleavable linker and Monomethyl auristatin E (MMAE) payload with a Drug Antibody Ratio (DAR) of 4. Preclinical studies have demonstrated exceptional tolerability, enabling us to progress swiftly through regulatory milestones. Notably, our preclinical toxicology studies have shown remarkable tolerability, with the ability to dose up to 30 mg/kg in rats and 10 mg/kg in cynomolgus monkeys.

**What is the difference between success and failure for a biotech in 2024?**
The outlook for biotechs improving. However, it remains contingent upon factors like US inflation, Federal Reserve interest rates, and the ongoing conflict in Europe, and potential developments in Asia. During our fundraising efforts for Series B, which extended into May 2023, there was considerable skepticism about the timing. We ultimately secured US$85 million, a feat given the financial drought earlier in the year. Notably, our valuation increased, defying the trend of flat or decreased valuations seen elsewhere. ■

# Aileen Fernandes

CBO
**ARCELLX**

**Can you introduce Arcellx and the firm's pipeline?**
Our mission is to pioneer transformative technologies. Central to our approach is our proprietary D-Domain, a synthetic binding domain that serves as the foundation for our innovative therapies.

Our leading drug candidate, anitocabtagene autoleucel (anito-cel), represents a significant advancement in CAR-T therapy for relapsed or refractory multiple myeloma (rrMM).

In addition to anito-cel, we are excited about our ARC-SparX program. ARC-SparX offers a modular approach to cell therapy, enhancing controllability and adaptability as a dosable CAR-T therapy. We have ongoing clinical programs, including ACLX-001 for rrMM and ACLX-002 for relapsed or refractory acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome.

From a business perspective, we are listed under the Nasdaq ticker symbol "ACLX" and in December 2022, we entered a strategic partnership with Kite, a Gilead Company, to co-develop and co-commercialize anito-cel in the US. This past November, we were excited to announce an expansion in that partnership.

**Can you elaborate on the D-Domain technology and its potential to revolutionize cell therapy?**
It is a novel synthetic binding domain scaffold, distinct from traditional ScFv used in CAR-T therapies. The D-Domain is smaller and more stable, offering unique advantages in both manufacturing and clinical efficacy. In manufacturing, we observe high CAR positivity, leading to potentially improved efficacy and safety profiles. Additionally, there is remarkable consistency across all patients, which is critical for scaling autologous cell therapies.

**Can you discuss the future of your lead drug candidate?**
We are focused on completing enrollment in iMMagine-1, our pivotal Phase 2 study of anito-cel. Our plans include presenting preliminary clinical data from iMMagine-1 by year-end. ■

# Will Lewis

Chairman and CEO
**INSMED**

**What have been the main milestones from Insmed in 2023, and what are the catalysts ahead after the successful completion of the Phase 3 ARISE and ASPEN studies?**
In 2023, we experienced the strongest year of commercial performance for our first approved therapy, five years after its initial US launch. Currently approved in the US, EU and Japan for a rare and serious lung disease, we are also investigating it in a broader patient population in two Phase 3 studies—ARISE and ENCORE. Last September, we reported positive topline data from ARISE. ENCORE remains ongoing, and we are working to finalize enrollment goals. We anticipate sharing topline data from ENCORE in 2025.

Last March, we announced enrollment completion of more than 1,700 adult patients in our Phase 3 ASPEN study assessing brensocatib, our lead pipeline candidate, in non-cystic fibrosis bronchiectasis. We plan to share topline data from ASPEN in the latter part of Q2 2024.

Beyond bronchiectasis, we are studying brensocatib in chronic rhinosinusitis without nasal polyps (CRSsNP) and hidradenitis suppurativa (HS). We initiated the Phase 2 BiRCh study in CRSsNP in late 2023 and plan to initiate a Phase 2 study in HS in the second half of 2024, pending positive results from the ASPEN study.

In October 2023, we announced encouraging blended, blinded data from our two ongoing Phase 2 studies of treprostinil palmitil inhalation powder (TPIP), the next candidate in our pipeline, in pulmonary hypertension associated with interstitial lung disease (PH-ILD) and pulmonary arterial hypertension (PAH). We plan to share topline data from the PH-ILD study in Q2 of this year, with topline data in PAH in 2025.

Lastly, in 2023, our research teams continued to advance pre-clinical studies across a range of devastating rare diseases by leveraging our novel gene therapy, AI-driven protein engineering, and proprietary manufacturing technologies. Additionally, last June, we acquired Adrestia Therapeutics out of Cambridge, UK, adding a world-class team and a leading synthetic rescue platform to our internal capabilities. ■





# Michael Ehlers

CEO and President
**ASCIDIAN THERAPEUTICS**

**Can you introduce Ascidian Therapeutics, the firm's pipeline, and its mission of redefining the treatment of disease by rewriting RNA?**
We founded Ascidian to solve some of the most pressing problems in gene editing and gene therapy, such as the fields' inability to address large genes or genes with high mutational diversity. Editing exons at the RNA level, without using foreign enzymes or touching DNA, addresses those challenges. Our approach enables precise post-transcriptional editing of gene products at an unprecedented scale, resulting in full-length, functional proteins at the right levels, in the right cells. Now, we've reduced that approach to practice and are successfully translating it into the clinic with ACDN-01, the first-ever RNA exon editor to enter clinical development.

At the same time, we are committed to realizing the full therapeutic potential of RNA exon editing. By rewriting entire chapters of the transcriptome with a single therapeutic, RNA editing at the kilobase scale has the potential to dramatically expand the reach of genetic medicine.

**Can you present ACDN-01, discuss the latest FDA approval and fast-track designation, and the catalysts ahead for your candidate?**
ACDN-01 is the only clinical-stage therapeutic targeting the genetic cause of Stargardt disease, which is the leading genetic cause of blindness.

This FDA IND clearance was also a big moment for the field. ACDN-01 is the first-ever RNA editor IND to be accepted by the US.

What are the main challenges and opportunities you anticipate in the biotech space in the US in 2024?

Biotech in 2023 was a tale of two worlds: unprecedented scientific advancements, such as the first gene editing approved therapy, tempered by once-in-a-generation financial constraints, even austerity. I expect 2024 will be more moderate, with investors continuing to prioritize discipline and translational potential, but the worst is probably behind us. ■

# Greg Bosch

CEO
**PANAVANCE THERAPEUTICS**

**Can you introduce Panavance and the firm's pipeline?**
Panavance Therapeutics Inc. is a privately held, clinical-stage pharmaceutical company developing a novel oncology asset, misetionamide (also known as GP-2250). Panavance was formed in 2021 as a carve out of the Geistlich group, to focus on misetionamide. Misetionamide is a tumor cell selective and broadly active small molecule with a unique dual mechanism of action which selectively disrupts the energy metabolism of cancer cells leading to cancer cell death as well as impacts nuclear factor-κB ("NFκB") to affect cancer cells' ability for protein synthesis and DNA transcription thereby restricting cancer cell growth and proliferation. The company is advancing towards two registration directed clinical studies: a Phase 2/3 for the treatment of ovarian cancer and a Phase 3 trial as a first-line maintenance in pancreatic cancer. Extensive preclinical studies have demonstrated that misetionamide's broadly anti-neoplastic MOA has the potential to be effective in many cancers.

**What are the catalysts ahead for misetionamide?**
Panavance has multiple key events in 2024. This includes conducting a pre-IND meeting with the FDA to review the company's clinical trial strategy for the development of misetionamide in platinum-resistant ovarian cancer. We plan to initiate our first ovarian cancer trial in late 2024/early 2025.

A second major catalyst is the completion of patient enrollment in our Phase 1 clinical trial in pancreatic cancer with a goal to establish safety, tolerability, and preliminary efficacy. The trial includes patients with advanced unresectable or metastatic pancreatic adenocarcinoma, and we are studying misetionamide as a second line therapy for patients who have progressed on first line therapy with Folfirinox. We expect to establish dose selection by the end of this year, so we can move forward with the ovarian and pancreatic clinical registration studies.

Looking into 2025, we are planning to initiate a Phase 2/3 clinical trial in pancreatic cancer with misetionamide as a first line maintenance treatment to extend progression-free survival and maintain quality of life for patients. ■

# Cell and Gene Therapies

## An immense potential left to unlock

From genetic conditions to cancer, the full power of cell and gene therapies (CGTs) is yet to be harnessed. But 2023 saw remarkable progress in that direction, with the momentum continuing into 2024. Despite not yet holding a lion's share of the market, no therapeutic area is growing as rapidly as cell and gene therapies. Worth US$15 billion in 2022 according to Precedence Research, the global CGT market size is forecasted to be worth US$82 billion by 2032. The overlapping fields of biomedical treatment aim to treat, prevent, or cure diseases, and both approaches have the potential to alleviate the underlying cause of genetic diseases and acquired diseases. The last years have seen considerable progress in cell therapies, particularly mRNA. While the focus on mRNA has somewhat subsided, the field continues to evolve.

As the scientific case for CGTs keeps improving, and with investor support, more products are likely to hit the market in the short term. Of the 14 CGTs that were approved across various therapeutic areas by the FDA over the past decade, 70% were given the green light between 2019 and 2023. There currently are over 694 CGTs in development in the US according to GlobalData's Drug database. Of these CGTs, 48 assets are in late-stage development (preregistrations and Phase 3).

Oncology will undoubtedly remain the top area of CGT development in the short term at least. Due to high unmet medical needs, oncology is poised to represent 44% of the US$82 billion CGT market by 2032. In oncology, the fundamental concept of adoptive cell transfer involves infusing modified immune cells into patients, empowering their immune systems to effectively combat and conquer a growing range of cancers. Chimeric antigen receptor (CAR) T-cell therapies have pioneered significant advancements in oncology, offering targeted and efficient treatments for certain blood cancers and leukemia. As of 2024, the FDA has approved eight CAR T-cell therapies. Importantly, several of these potentially curative treatments are now being used as second-line therapies. Arcellx is pursuing a cure for cancer through cell therapies. The firm's lead asset, anitocabtagene autoleucel, is currently in a Phase 2 pivotal trial for patients with relapsed or refractory multiple myeloma. Speaking of the breakthrough potential of the candidate, the firm's CBO Aileen Fernandes explained: "92% of evaluable patients had a very good partial response or higher, indicating the potential for anito-cel to be a best-in-class autologous CAR-T therapy. Importantly, our therapy demonstrated a unique safety profile with no instances of delayed neurotoxicity or Parkinsonian symptoms, setting it apart from existing CAR-T therapies on the market."

On the horizon, a highly promising phase 1 clinical trial in Pennsylvania completed in December stands out as the world's first to utilize CAR T cells targeting two proteins linked to the most aggressive form of malignant brain cancer. CAR T cell therapy has revolutionized treatment for many people with blood cancers who had run out of other treatment options, therefore the results of the planned phase 2 portion of the study will be fundamental to understanding how designing CAR affects the way T cells work.

Beyond oncology, cell and gene therapies hold promises in other indications. Non-oncology indications continue to be the most targeted rare diseases by RNA therapies (81%), amongst them Duchenne's muscular dystrophy, amyotrophic lateral sclerosis, and cystic fibrosis. With three therapies based on RNA editing having entered clinical trials or received the green light to do so in recent months, RNA-editing therapies are picking up steam. Boston-based Ascidian's RNA exon editing platform is designed to expand the therapeutic possibilities of RNA medicine and treat diseases not addressed by today's gene editing technologies. As the field cannot (yet) address genes with mutational diversity, Michael Ehlers, CEO and president, explained the firm's progress: "Our approach enables precise post-transcriptional editing of gene products at an unprecedented scale, resulting in full-length, functional proteins at the right levels, in the right cells. Now, we have reduced that approach to practice and are successfully translating it into the clinic with ACDN-01, the first-ever RNA exon editor to enter clinical development."

Introducing new genes into existing body cells while keeping them working is a challenging endeavor. Insmed's RNA end-joining technology allows for the delivery of large genes that traditional gene therapy methods cannot handle. The new platform unveiled in 2023 holds promise for addressing conditions like Stargardt disease, a hereditary retinal condition leading to vision loss usually starting in childhood, which was previously untreatable with gene therapy. In the words of Insmed CEO Will Lewis: "Our research teams continue to advance pre-clinical studies across a range of devastating rare diseases by leveraging our novel gene therapy."

### Democratizing scientific prowesses

Despite the robust CGT pipeline in the US, translating scientific progress into commercial success will remain a challenge. The limited prevalence of certain conditions under study leads to a small patient pool, making it challenging to attain a sizable sample size. Additionally, the view that CGTs serve as treatments only when all other options have failed can deter potential participants. Risk of clinical trial failures – most recently highlighted by the failure of Cleveland-based Athersys' stroke cell therapy at phase 3 – coupled with high production costs will place further stress on these innovations. On the consumer end, CGTs are amongst the most expensive: the Institute for Clinical and Economic Review (ICER) estimates the average cost of such therapies between US$1 million and US$2 million per dose, with some like Hemgenix (a one-off infusion to treat hemophilia B) costing up to US$3.5 million.

The US government recently established the Cell and Gene Therapy Access Model within the DHHS' Centers for Medicare & Medicaid Services to help lower drug costs. Effective in January 2025, the Model will test outcomes-based agreements for cell and gene therapies, first focusing on sickle cell disease, which affects 100,000 Americans. Gene therapies for sickle cell disease could be a game-changer for people affected by the condition, along with leading to reducing the hefty costs of treating the disease for both states and taxpayers.

Gene therapies represent a groundbreaking shift in medicine by targeting the root causes of diseases rather than just managing their symptoms. This approach holds the promise of potentially curing previously untreatable diseases, offering hope to millions of people worldwide. ■



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# Contract Manufacturing, Services and Chemicals

> Geopolitical developments such as the tensions between China and the USA have been driving change in the procurement strategies of pharma companies. Clients have been withdrawing from China and are looking for a European partner.

**Eelco Ebbers**
CEO
**SYMERES**

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Image courtesy of Pfizer CentreOne

# Adapting to Support the Resurgence in R&D

## Back to business, differently

The CDMO segment remains one of the industry's buzziest fields in life sciences. Data from analytics firm Evaluate supports this statement, showcasing that the segment is poised to outperform the rest of the life sciences industry through until 2028. In recent months, clinical studies have ramped up across many indications, as regulators, innovators, and manufacturers move on from the COVID-19 focus. The numerous phase 2 and 3 trials that were delayed by a couple of years are now live, with drugs nearing the approval stage, representing a formidable growth opportunity for the CDMO segment. Overall, 2021 and 2022 were dormant years for clinical trials and coincided with sluggish years for biotech funding. The robust innovation pipeline, along with the uptick in both scientific progress and investor appetite seen in early 2024, are great markers for a positive outlook ahead for CDMOs.

As the COVID induced innovation freeze begins to thaw and pharma firms rebuild their capacity, CDMOs will undoubtedly see diverse (and plenty) of work coming their way. Jeff Butler, head of small molecule, North America, SK pharmteco, said: "Companies that were severely exposed to COVID therapies certainly had a soft year in 2023, and I see them using 2024 as a realignment and rebuilding of some of the capacity that was used for COVID drugs. There is still the COVID bubble rolling through the clinic, but we are seeing strong demand for new clinical materials, and biotechs starting to bring on more pipelines, which certainly benefits the CDMO space."

**Arthur Kesisyan**
Sector Lead Life Sciences
**ATKINSRÉALIS**

"We are seeing a need for modular/flexible facilities that can make small-scale runs of diverse drug products that may be personalized. We are also seeing some overlap with medical devices and drug products, which could prove to be a new frontier, with combined therapies to treat different types of ailments and diseases."

**Raul Cardona-Torres**
Chief Quality and Regulatory Officer
**SIMTRA BIOPHARMA SOLUTIONS**

"Digital and automation advancements have brought about better management tools in terms of analyzing data and trends. The technological tools available on the market today are superior and allow for increased efficiency and insights - the industry must embrace and adopt these technologies going forward."



Image courtesy of Kindeva Drug Delivery



**Large molecules driving large *capex* investments**

Biologics and advanced therapeutics (ATs) are emerging as a dominant force, estimated to be valued at over US$500 billion by 2030. The latter field encompasses targeted drug delivery, CGTs, and personalized medicines aimed at improving patients' quality of life. The swift development and launch of COVID-19 vaccines significantly impacted the biologics and ATs sector by accelerating momentum for the regulatory approval of innovative therapies unrelated to COVID-19, and deal making has gathered momentum. Since 2022, several deals occurred in the AT space, with Resilience producing gene therapies for Opus; WuXi Advanced Therapies manufacturing CAR-Ts for Chimeric, and Fujifilm producing RNA oncology candidates for Chimeron. As summed up by Dipharma's Catalogue APIs BU leader, Roberto Fanelli: "The growing demand for personalized medicine and specialty drugs presents avenues and opportunities for innovation."

CDMOs and CROs are making the large *capex* investments needed to grow their biologics business. Aragen invested in a manufacturing facility that will come online at the end of 2024 and will allow customers to go all the way to Phase 2 and beyond, with the end of becoming an "end-to-end service provider from gene to GMP". Cytovance Biologics invested in a 200-liter stainless steel vessel to provide more capacity for microbial clients, while Lotte Biologics entered the US market with its first CDMO plant (which includes BMS' facility in New York) in 2024. Jueon Kang, Lotte's chief strategy officer, explained the US$80 million strategic move would allow the Korean firm to expand its ADC offering before being GMP-ready by 2025.

Such growth is likely to drive more consolidation for production juggernauts eager to dominate the next-generation medicines space. Protein-based biologics are projected to remain dominant, capturing 80% of the market, while ATs are anticipated to expand to 9%. A significant trend is the increasing demand for viral vector manufacturing, leading to substantial investments by CDMOs and impactful acquisitions reinforcing strengths in cell, gene, and oncology segments notably. In November 2023, Ajinomoto acquired Forge Biologics for US$620 million, leveraging the latter's expertise in gene therapy manufacturing to bolster its regenerative medicine, ADCs, and oligonucleotide drug capabilities. In March 2024, Lonza picked up one of the largest biologics manufacturing facilities from compatriot Roche for US$1.2 billion to enhance large-scale capacity for biologics manufacturing, encompassing commercial-scale mammalian contract manufacturing and clinical-stage projects.

Looking ahead, the growth of personalized medicine and advanced therapies will increase the need for specialized CDMOs capable of managing complex modalities like mRNA, lentiviral vectors, and plasmid DNA. The R&D landscape might even shift further towards biologics with the repercussions of the IRA, which could be harmful to small molecule development as detailed in the previous "Regulatory Landscape" article. Tom Ross, president and CEO of CDMO GRAM, witnessed the change: "Our clientele demonstrates a diversified portfolio, with a discernible inclination towards biologics and a diminishing emphasis on small molecules."

Roth, PBOA's president, expressed in early 2024: "The R&D landscape might strongly shift toward biologics at the expense of small molecules, to extend product lifespan before price negotiations."

**A marriage in tune with the times: The new CDMO model**

To meet the new requirements of their pharma and biotech clients, CDMOs are adapting beyond being classic service providers, to become technology partners at the forefront of pharmaceutical innovation. Aside from technological help at the earlier stages of molecule development, pharma firms now expect CDMOs to provide expertise along the entire manufacturing process, including commercial launch, according to an EY study. This trend further strengthened in 2023-2024, notably as the customer base

## Anil Kane

Executive Director and Global Head of Technical & Scientific Affairs, Pharma Services
**THERMO FISHER SCIENTIFIC**

**Can you touch upon the latest investments made by Thermo Fisher in the field of R&D and innovation?**
The company has expanded our capabilities to support the accelerated demand for our global sterile drug products and biologics manufacturing, increasing the scale of our operations as well. Thermo Fisher has expanded our capabilities in the Asia Pacific region and can now support our pharma partners in sterile drug product manufacturing from our new Singapore facility. The company's Italian site in Monza recently received GMP approval for RNA-based products, enabling us to support our partners not only from a drug substance perspective but also from a drug product perspective. These are mRNA-based products including LNPs that have shown success in a variety of indications beyond oncology and immunotherapy.

Our new cell therapy development and cGMP manufacturing collaboration center at the University of California in San Francisco helps our partners to accelerate advanced cell therapy for difficult-to-treat conditions including cancer, different immune conditions, etc. Thermo Fisher's newly constructed 300,000-square-foot viral vector manufacturing facility in Plainville, Massachusetts was commissioned in 2023 and supports taking complex viral vectors through development and clinical phases to commercial manufacturing. Beyond these new technologies, we have also supported our partners with their sterile drug products, prefilled syringes, and clinical supply chain services.

**What is your analysis of the main trends ahead for the pharma industry in 2024?**
Today, a lot of effort is put in to make medication administration easy for patients, not only from an oral solid format perspective but also from a sterile injectable format perspective in the form of prefilled syringes.

Digitalization is also a major trend. We are going to see AI and machine learning being applied to utilize data more effectively, enabling data-driven decisions. ■

## Tom Wilson

Global Business Development Lead
**PFIZER CENTREONE**

**What have been the main achievements for Pfizer CentreOne in 2023?**
Pfizer CentreOne has been able to establish our credibility within the cell and gene space. Antibody-drug conjugates (ADC) continue to grow, and this field has certainly kept us busy. We are seeing a continuation of regionalization coming out of the pandemic where companies are localizing their supply chains and establishing a series of hubs.

**How has the role of CDMOs and their relationship with customers evolved post-pandemic?**
We are seeing a continued push of companies looking for CDMO services, however, they are not necessarily looking for a transactional relationship and are rather pressing for a deeper relationship – a collaboration partnership.

**In what therapeutic areas do you see the most growth for Pfizer CentreOne going forward?**
We anticipate significantly more growth in ADC than we would have thought five years ago. In terms of gene therapy, we are still seeing a developing marketplace and there is a tremendous amount of sophistication on the part of the innovators, more so than what I have ever seen previously in a platform. We are early in the cycle, and we need to continue to let that pipeline flow through. Looking at biologics, we are seeing significant opportunities in both the mammalian and microbial space. Most of it is going into injectables, and it is about trying to figure out how do we risk mitigate the supply chain, what is the right scale to produce at, what is the most efficient way to package - whether it is in vial, frozen bag, or room temperature prefilled syringes – and how do we optimize it for administration.

**What are Pfizer CentreOne's main priorities in 2024?**
Big focus of the company will be finding ways to tackle drug shortages, bringing our capabilities to the table to assist companies in getting medicines to market and patients. ■



**Himanshu Gadgil**
CEO
**ENZENE BIOSCIENCES**

> "The US presents a challenge: The need for local CDMO manufacturing, especially post-COVID, with disruptions in global supply chains."

of CDMOs broadens from big pharma to small biotechs. In that sense, the future will likely resemble one of an integrated model for CDMOs, with "one-stop-shop" slogans at the heart of their manufacturing mission.

Pharma companies are outsourcing more, not less, and this trend only shows signs of continuing. With the recent market downturn and efforts to bring drugs to market cheaper and quicker, drugmakers are focusing on drug discovery and marketing, while increasingly entrusting CDMOs with the development and manufacturing of their product. The sixfold growth in the global value of pharmaceutical goods in the past decade is pushing drugmakers to focus on their core competencies and in turn, is driving opportunities for CDMOs. The coming years are therefore likely to see a "natural selection" in the extremely competitive CDMO space, and firms that are at the cutting edge of technology are those that shall survive. Tim Tyson, CEO of TriRx Pharmaceuticals, noted: "There is a significant growth in demand for CDMO services, mostly driven by the trend of companies outsourcing development and manufacturing capabilities to focus on their core competencies."

Going forward, the CDMO-drugmakers relationship will move from a rather transactional (or fee-for-service) relationship to one resembling a long-term marriage. Today, over 50% of products developed and commercialized are being outsourced in the US pharmaceutical industry, which is leading to a change in the relationship between drugmakers and their CDMO partners. As put by Anil Kane, executive director, and global head of technical & scientific affairs at Thermo Fisher Scientific: "The expectation is now that CDMOs must deliver transformational value, have access to cutting-edge technologies, have critical data-driven insights, have access to advanced materials, have innovative manufacturing processes, and also invest in resources and skilled individuals in different fields of science."

In finding the perfect marriage partner, pharma companies are now putting more effort into the earlier stages of the dating process. Leaders of the 40+ CDMOs interviewed in recent months have noted a more rigorous due diligence process for the CDMO selection. "This involves multiple on-site meetings and audits, fostering a deeper understanding of expectations, and cultivating trust from the outset" explained PCI's COO Brad Payne.

Pfizer CentreOne's global business development lead, Thomas Wilson noticed the same trend in the earlier stages of the relationship: "The dating period is significantly more exploratory than it used to be and the engagement period – setting up the contract - is greatly focused on collaborative approaches, balance and alignment, and fairness in both directions. Companies are picking a partner in their early stages, but recognize that you can only afford to pick a partner once."

As funding, innovation, and clinical trials recover post-pandemic, contract manufacturing and research organizations will only get busier in the years to come. The growth in biologics is likely to drive investment along with organic and inorganic growth in the future. More than ever, choosing the right partner from the onset will be fundamental for Big Pharma firms and biotechs alike. As concluded by Ramesh Subramanian, Aragen's CCO: "We expect the segment to be in a growth mode and to do a lot better than in 2023. We are convinced that externalization and CROs/CDMOs are going to be ever more present." ■


CRC


AH

## Cindy Reiss-Clark and Anya Harry

CRC: CCO
AH: CMO
**WEST PHARMACEUTICAL SERVICES**

**Can you introduce West Pharmaceutical Services?**
CRC: For over a century, we have been a global leader in providing primary packaging for injectable drugs.

Injectable drugs are the fastest-growing drug segment within medicines today, with biologics being the biggest driver of that growth and West maintains a high participation rate with these molecules. Notably, our elastomer portfolio plays a significant role in securing the safety and sterility of vials, cartridges, and prefilled syringes. Additionally, we have diversified our offerings to include the development of drug delivery devices, both for our customers' intellectual property and our own.

**What trends are West Pharmaceutical Services observing in the marketplace?**
AH: Across all markets, patients and prescribers express strong support for managing chronic diseases with medication that can be self-administered. Indeed, nine out of ten patients and HCPs say the ability to administer injectable medicines at home helps patients lead more independent lives and stay on track with treatments.

West recently sponsored a global survey of adults with chronic conditions to understand how patients and healthcare providers perceive and consider using self-administered injectables and on-body delivery systems to manage chronic conditions. It assessed several key areas including openness to using self-injectables and on-body delivery systems for the administration of prescription medicines. Across all markets, patients and prescribers express strong support for managing chronic diseases with medication that can be self-administered.

**What is your take on the health of the life science industry in the US in 2024?**
CRC: We remain long-term positive in the injectable industry. From an overall industry trend, acquisitions and pharma M&A are picking up, and projects are resuming, indicating investment. ■

## Jeff Butler

Head of Small Molecule, North America
**SK PHARMTECO**

**What have been the main highlights and achievements of SK pharmteco in 2023?**
SK pharmteco has consolidated our five separate business units under a single marketing entity to support both our small molecules and cell and gene interests globally. The company has made large investments in small molecules and cell and gene therapy. Our customers are agnostic from how they treat disease from a modality perspective, and we continue to work to reflect that as much as possible in our offerings.

**What do you forecast will be the main areas of growth for SK pharmteco in the coming year?**
SK pharmteco is still heavily involved in oligonucleotides and has brought on laboratory-scale capabilities in this space. The company has expanded our chromatography capabilities from a batch perspective, which is key in the more complex chemistries and modalities, whether it is oligonucleotides, ADCs, or lipids. We also see a strong demand for our ability to solve complex chemistries through continuous processing.

SK pharmteco has made key investments around micronization. Historically, our customers have put milling and particle size manipulation on the drug product side, but in more recent years, it has been the expectation that the work should be done by the drug substance manufacturer. One of the key areas that continues to come up with some of the new small molecules is around rotational isomers.

**What do you forecast will be the key points of conversation in the CDMO space?**
There has been great M&A activity over the past four months with large innovator companies having a strong appetite for buying pipeline, but it will be exciting to see the next round of innovation coming through with biotechs receiving the funding they require to develop their technologies. ■






MB


DS

## Milton Boyer and David Stevens

MB: CEO
DS: CCO
**KINDEVA DRUG DELIVERY**

**What have been the latest developments and achievements for Kindeva over the past 12 months?**
MB: At the end of 2022, Kindeva merged with Meridian Medical Technologies to create a market-leading global CDMO focused on drug-device combination products. Over the past year, we have integrated the two companies with a focus on commercial structure and the necessary internal support to take our product offerings to market.

DS: Kindeva made tremendous progress on our new aseptic injectable fill-finish facility in Bridgeton, Missouri. We made significant strides on our green propellant projects and enabling capital investment programs, which will significantly reduce the Global Warming Potential (GWP) of inhalers. We also launched Breyna™, the first FDA-approved generic version of Symbicort, with our partner, Viatris. Finally, Kindeva also began 2024 with the acquisition of Summit Biosciences, a nasal drug-delivery CDMO.

**Can you elaborate on the launch of Kindeva's Analytical Services Global Business Unit?**
DS: When we considered the accumulated experience and capabilities across Kindeva and Meridian, it was clear there was incredible depth and breadth of analytical expertise, equipment, and institutional knowledge that had been accumulated during a combined century of developing and supplying combination products. We wanted to open this value to the wider pharmaceutical, biopharmaceutical, and medical device sectors through stand-alone analytical support, whether customers are doing a full program with us or not. Our 32,000-square-foot best-in-class laboratory infrastructure in Minnesota will serve as the central hub for these expanded services.

**What are the main trends driving the drug delivery market?**
MB: There is a lack of capacity in many of the areas Kindeva serves, such as injectables, specifically Annex 1 compliant and newer technologies. In the pulmonary & nasal drug-delivery space, we believe that green propellants are the future for pressurized metered-dose inhalers (pMDIs) and as regulations and legislation around sustainability evolve, demand will increase. These trends correlate to tremendous opportunity as we continue to invest in these key areas.

**How do you assess the current operating environment for CDMOs in the US?**
DS: The biotech funding crunch has driven a more risk-averse approach to early-stage work with innovators who have been forced to conserve cash to extend their runway. This has created headwinds for CDMOs as product development has slowed down.

Increasingly, Chinese and Indian CDMOs have started competing on higher-value parts of the outsourcing supply chain, such as biologics and sterile fill-finish, creating additional pressure on US CDMOs.

The Inflation Reduction Act (IRA) undoubtedly contributed to investors being more circumspect. Any threat to future pricing creates a trickle-down effect for CDMOs, either through fewer development programs or other cost-control measures. CDMOs have already seen greater pressure on generic product pricing due to end market channel consolidation squeezing margins. A cursory look at the FDA's drug shortage list illustrates it is becoming difficult to produce certain generic products sustainably for several reasons, most of which stem from price pressure.

**How does Kindeva leverage AI and automation technologies?**
DS: We adopt AI to accelerate the way we model formulation, molecule, and device interactions. This reduces time and cost, expediting development and commercialization. Our new sterile fill-finish injectable facility utilizes automation to engineer out inefficiency and risk where possible, with the goal of manufacturing injectable medicine while prioritizing patient safety.

**What are the key priorities for Kindeva to continue growing in 2024 and beyond?**
MB: The investments and partnerships Kindeva made in 2023 put us on a great path for 2024. The company will continue to focus on being a premier drug-device combination CDMO across multiple platforms. Our key priorities will be to continue making investments and acquisitions in the drug-device space while forming key industry partnerships.

DS: Scalability is key for Kindeva in 2024. While we are very pleased with the progress to date and believe we have a strong foundation, we also have much we want to further improve. ■

> Great innovations and new medicines are emerging in the animal health space, especially in terms of biologics and monoclonal antibodies, and we saw great opportunities in this developing area.

# Tim Tyson

Chairman and CEO
**TRIRX PHARMACEUTICALS**

**What were the main highlights for TriRx in 2023?**
TriRx had a fantastic 2023 and experienced tremendous growth in new business, as well as our technologies and capabilities. It was exciting to see the marketplace coming out of all the pressures and inflationary periods after COVID-19. In 2023, TriRx became the largest CDMO in animal health in the world, and we have focused our attention on this segment. Today, our business is approximately 85% animal health and 15% human health.

**Can you elaborate on TriRx's partnership with Liverpool City Region, and what it will mean for the company?**
Great innovations and new medicines are emerging in the animal health space, especially in terms of biologics and monoclonal antibodies, and we saw great opportunities in this developing area. TriRx already had a large amount of biologics capability, but to enable our ability in monoclonal antibodies, we decided to create a development laboratory, commissioned in 2023, which allows us to do full-scale monoclonal antibody development. We are also investing in upstream facilities to enable our mAb's manufacturing capability. The UK Government, through the Liverpool Investment Zone, agreed to support this project and provided a minor investment grant to enable us to develop this monoclonal antibody capability.

**How important is the US market for TriRx, and what is the company's growth strategy here?**
TriRx has three facilities in the US, one in France, and one in the UK. We invest equally into these facilities as there is a huge opportunity in all of these markets. Our US facilities all saw major growth in 2023 and the US market is a very important market to TriRx and the industry.

**What will be the key catalysts for CDMOs in 2024 and beyond?**
The key catalysts will be new technologies and the growth of the market. There is a significant growth in demand for CDMO services, mostly driven by the trend of companies outsourcing development and manufacturing capabilities to focus on their core competencies. There is also an increasing and aging population in both the animal and human health worlds, which also drives demand. A focus on reshoring is also a major opportunity and is being accelerated by the BioSecure Act in Congress.

**Can you elaborate on TriRx's innovation culture, and how that is a competitive advantage for the company?**
Innovation is key in the pharmaceutical and life sciences industry, and bringing new technologies and products to market is critical to the growth and value of the industry. TriRx's position is to apply technologies to improve efficiency and generate the capability to produce products for the marketplace. In 2023, the company invested in capabilities and technologies in three areas - sterile injectables, liquid creams and ointments, and monoclonal antibodies.

**The US is known as the innovation hub of the world. What is your take on the US' capacity to continue innovating?**
Innovation in the pharma world has historically come from Western Europe and North America. Innovation will continue to be critical and will continue to be led out of the places where there are thriving economies and strong technical knowledge and capability. I believe we will continue to see significant innovation in the US, as well as Europe.

**What is your take on the health of the life sciences industry in 2024 compared with 12 months ago?**
The health of the life sciences industry in 2024 is very favorable. There are some countermanding pressures due to the cost of care and medicines and the number of people in need, and there is this constant dynamic with pricing pressures and innovation. Innovation costs money, and trying to figure out how to balance the investment needed to generate and advance technology for efficiency and new medicines will be critical. People finding a way to achieve this balance, as they always have, will be the solution. There is a positive attitude and dynamic towards the capability and ability of the life science industry to continue to innovate and continue to make a difference.

**What are TriRx's key priorities to sustain company growth?**
We want to deliver an exceptional experience, and it is our focus to be the preferred CDMO that can be trusted to continuously and reliably deliver on its commitments. ■





# Roger Erickson

CEO and Founder
**INTERBIOME**

**How is the unique Interbiome franchise model being received by the biopharma industry?**
Awareness is just beginning. There is growing public as well as private awareness of the need to generate additional surge capacity since we still cannot make adequate volumes of novel drugs on demand when emergencies, disasters, or political squabbles impair existing production streams. Sustainable health resiliency is replacing industrial colonialism at an accelerated pace, domestically as well as internationally. The bigger the blockbuster drug market, the more critical it has become to have reserve production capacity, even in the commercial supply chain. Interbiome has partnered with innovative developers, builders, industrial engineers, and architects to define a novel franchise CMO approach. Domestically, that is extremely important for all aspects of reserve capacity, and it is even more important for emerging economies. This is why Interbiome is continuing to evolve our franchise model for advanced economies. For developing countries around the world that do not want to suddenly run out of any product - whether aspirin, insulin, or critical drugs - due to the unreliability of international supply chains, we pitch our franchise model for the launch of a Sovereign Pharma industry.

**How do you assess the current state of the pharmaceutical industry?**
There is a growing divide between the mission-oriented uses for inventions and the investment and policy communities. In the bio-pharma world, people are getting lost in molecular mechanisms, biomarkers, and platforms, and oftentimes are disconnected from the actual diseases targeted and the populations the methods are being developed for. There is growing demand for all industries and policy systems to become more mission-driven, and this can only be achieved by continuously rewiring our interaction patterns. For that we need better/faster/cheaper methods for re-mapping, re-modeling, and then re-wiring interaction patterns. Teamwork lags when the definition of team keeps changing at an accelerating pace. ■

# Anwar Daud

Managing Director
**ZIM LABORATORIES**

**What will be the main priorities for ZIM Laboratories in 2024?**
ZIM will continue to focus on adding new business and increasing revenue through the Developed and Pharmerging markets aiming to increase operating margins and fortify the balance sheet. We will actively expand our global presence and execute multiple filings for NIP and Oral Thin Films in regulated and Pharmerging markets. We anticipate a significant milestone with the impending receipt of our first Marketing Authorization (MA) for NIP and once received, our focus will be on commercialization and supply. We will continue to focus on strategic partnerships, both local and global, as it plays a pivotal role in our growth strategy. These collaborations enhance market access, improve distribution capabilities, and may include joint ventures, leveraging synergies for mutual benefits.

**What are the main challenges and opportunities you anticipate for pharmaceutical companies in 2024?**
Some of the challenges that pharmaceutical companies may have to face in 2024 include pressures on pricing because of affordability drives, increasing localization by governments to promote homegrown companies, regulatory tightening, and buyer consolidation which will result in fiercer competition. Additionally, topics to monitor will be changing disease profiles and the emergence of "cures" for chronic conditions like diabetes, as well as geopolitical instability due to increased political polarization, and an aging population with increased mobility and a move towards an emphasis on convenience in healthcare.

**Which measures are necessary to drive innovation forward within the industry?**
First, the use of AI, Data Analytics, and Nanotechnology in rediscovery and repurposing of known pharmaceutical substances for new indications. The industry will also likely witness an acceleration in the discovery of new target sites for hitherto unsolvable aging and metabolism-related conditions presently treated through "management" therapies and the move toward their cures such as cancer, diabetes and alzheimer's. ■

# American Dream for Foreign Contractors

## A confluence of factors attracting new players

Whether you are a large East Coast pharmaceutical company with millions in R&D budget, or a modest biotech testing out a few compounds from the Bay Area, you will more likely than not have noticed that the partners you need to develop your product have flown in from all over the world. The past two years have seen an unprecedented shift in the US pharmaceutical landscape, as the emphasis on domestic production, the repercussions of the China+1 strategy, and the demand for specialized services have attracted players from Europe and Asia looking to compete in the world's largest and fastest-growing pharmaceutical market.

**The geopolitical dimension: The BIOSECURE ACT**

If it has not been made sufficiently clear in recent years, biotech is at the heart of national security. China's aggressive strategy to become the global biotech leader is having legal, political, and economic repercussions along the pharma value chain in the US. In February 2024, four US lawmakers called China-based biotech Wuxi a "giant that threatens US intellectual property and national security" after allegations that the firm transferred a US client's IP to the Chinese government without consent. And in its annual threat assessment released the same month, the Office of the Director of National Intelligence (ODNI) cautioned that Beijing is focusing on advancing its biotech sector, and highlighted Beijing's efforts to expedite its scientific and technological development through intellectual property theft and other methods to gain economic, political, and military advantages.

The earlier months of 2024 marked a clear escalation in the decade-long pharma cat-and-mouse game between the US and China. In March, the US Senate and House of Representatives put forth the BIOSECURE Act, intended to "stop funding foreign adversaries' hostile actions and to stop the flow of genomic data of Americans to the Chinese government." After this bill set the tone, the Prohibiting Foreign Access to American Genetic Information Act followed. Importantly, China has expressed its ambitions of being a biotech leader particularly in precision medicine and biologics. And as reminded by Gian Paolo Negrisoli,

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Image courtesy of Procos SPA





AC

RF

# Andrea Confetti and Roberto Fanelli

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

**What have been the main highlights and milestones achieved for Dipharma in 2023?**

AC: Dipharma was able to deliver our forecasted revenue for our consolidated products and services in 2023, delivering on significant critical milestones which were instrumental for our growth and success. One of these milestones was the completion of the expansion of our Kalamazoo site where we now have additional manufacturing capacity and API production capabilities. Another important highlight in 2023 was that Dipharma obtained its second GMP certification from the Regulatory Authority of Brazil, ANVISA, for our Caronno Pertusella site.

The company also expanded our small molecule R&D Center at our headquarters located in Baranzate, Italy, which more than doubled the area dedicated to analytical R&D activities. This strengthens our analytical capabilities and broadens our expertise for the development of new organic analysis methods and technologies allowing us to offer a wider range of new APIs and advanced intermediates.

Overall, the US market plays a pivotal role in Dipharma's business and contributes approximately 40% to the company's overall turnover.

**How is Dipharma expanding its API portfolio and growing in different markets?**

RF: We market our generic APIs worldwide depending on the patent situation and our regulatory compliance in each country. An important element in selecting new generic APIs is the PIV strategy, which helps enhance readiness to be the first filer or supplier in the market. Our experience in developing proprietary chemical processes and alternative solutions to support the generic API industry has been instrumental in our growth and to rapidly expanding our CDMO activities, particularly in the US and European markets. We continue to execute on our strategy of extending our API portfolio and growing in new markets. In 2023, we actively pursued partnerships and collaborations to broaden our product offering seeking to enter new therapeutic areas.

**What are the demand trends for Dipharma's products and services in the US?**

RF: The US pharmaceutical industry continues to rely on Italy as the leading European source of high-quality APIs, and there is a growing need for innovative manufacturing processes that allow for increased efficiency, reduced costs, ensured regulatory compliance, and overall sustainability. Dipharma's technology is backed by our strong track record of commitment to quality, and we are in a position to meet these demands.

**How do you forecast the operating environment to look like for CDMOs in 2024?**

AC: The operating environment for CDMOs in the US has been highly variable over the last decade, and in 2022, the CDMO industry faced significant uncertainty mostly due to disruptions at different levels of the supply chain. However, we are seeing positive signals for recovery in 2024, including collaborations between tech and biopharma companies and increased M&A activity. The regulatory framework in the US also supports the growth of CDMOs.

RF: The life sciences industry is expected to be robust in 2024, driven by advancements in medical technology and the ongoing focus on new drug development and innovation. The growing demand for personalized medicine and specialty drugs presents avenues and opportunities for innovation and new collaborations directly with Innovators, allowing Dipharma to leverage its expertise in developing and manufacturing complex APIs.

**As the firm celebrates its 75th anniversary, what are Dipharma's main objectives for 2024?**

AC: Dipharma aims to continue to enforce our position, both in the European and the US markets, by leveraging and expanding our technological capabilities. We have a multi-phased global expansion strategy focused on being a trusted partner to our customers and helping them to materialize their goals in a timely fashion. We will continue to invest in our manufacturing capabilities and capacity to meet the growing demand with our API and advanced intermediate services.

RF: Dipharma is proud to have been reliably serving the life sciences industry for decades and will continue to do so for many years to come. The company will continue to actively seek partnership and collaboration opportunities to be able to meet the demands of the industry and offer tailored solutions to our customers. 2023 was an extraordinary year for innovation. The FDA approved 55 new drugs in 2023, of which 34 were small molecules, which is an over 50% increase compared to 2022. This opens new opportunities for Dipharma in the years to come. ■

> Although the US may have been ahead in technology adoption initially, India has been catching up rapidly.

# Ajay Tandon

CEO

**VEEDA CLINICAL RESEARCH**

**Can you provide the main highlights from Veeda Clinical Research (Veeda) in 2023?**

In 2023, Veeda continued its strategic trajectory toward becoming a comprehensive integrated contract research organization. This journey over the last four years has involved expanding our service offerings to cater not only to traditional clinical research but also to the broader needs of biopharma and innovative companies across a broader spectrum of their preclinical and clinical development needs.

A key highlight of 2023 was the substantial expansion of our integrated biopharma laboratory capabilities. This expansion enables us to provide comprehensive development support, from discovery biology to clinical bioanalysis, across diverse modalities within the biopharma space including biosimilars, peptides, vaccines and biologics. Bioneeds, our group company providing preclinical solutions, further enhanced capabilities in specialized inhalation and ophthalmology studies, complex tissue distribution studies, enhanced AMES testing, neurotoxicity, and immunotoxicity assessments, besides expanding synthetic chemistry capacities to support higher volume reactions.

Alongside this, we made significant investments in technology adoption to optimize operational efficiency, strengthen quality assurance and regulatory compliance, and expedite project timelines.

**Could you discuss Veeda's global focus and expansion strategy in the US?**

While our operations are primarily based in India, we serve a global clientele, with the US and European markets contributing to around 50% of our revenues. The US market is crucial to us strategically, given its size and the opportunities it presents for our services across different stages of drug development. We believe there is untapped potential, especially in engaging with small and emerging pharmaceutical and biopharmaceutical companies that seek outsourcing support. These companies often lack in-house capabilities and attention from larger CROs. Leveraging our scientific, technical, and regulatory expertise, coupled with our cost advantages from operating in India, we aim to bridge this gap and form strong partnerships in the US. Looking ahead, we remain open to both organic and inorganic growth opportunities in the US market, evaluating potential acquisitions to better serve client needs onshore.

**Have you witnessed more interest in India-based CRO services from Western firms than pre-pandemic?**

Indian CROs have significantly evolved, showcasing improved capabilities in both biopharmaceutical and small-molecule segments. This evolution has led to heightened interest from US companies in partnering with Indian CROs. With a robust ecosystem of scientific talent and a large patient pool, India is well-positioned to meet the evolving needs of pharmaceutical companies. Additionally, India's diverse population makes it an attractive destination for clinical trials aiming for global representation.

**How does Veeda adapt to different infrastructure requirements and regulatory frameworks globally?**

For the past two decades, we have focused on meeting global regulatory standards for our clients, including those set by agencies like the US FDA, EMA, WHO, MCC Canada, and Brazil's ANVISA, among others. Our preclinical operations also have global GLP, the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC), and Office of Laboratory Animal Welfare (OLAW) accreditations. We are tracking the regulatory trends, such as towards increasing adoption of in-vitro and in-silico research, and are informing our capability strategies accordingly.

In terms of technology adoption in clinical trials, we are very focused on integrating technology across our operations for study monitoring, data quality, speed, and cost-effectiveness. We are also embracing data analytics and AI, recognizing their transformative potential in the near and medium term. We are actively engaging with partners to ensure we stay ahead in this rapidly evolving landscape. Although the US may have been ahead in technology adoption initially, India has been catching up rapidly.

**What do you foresee as the main challenges and opportunities for CROs this year?**

There is a continual quest for the next generation of drug candidates, whether they are generics or novel compounds. Companies are striving to set themselves apart through scientific and technological advancements in the search for specialized and personalized healthcare solutions. Additionally, there is a rapid evolution in technology across the board. The conversation globally underscores the importance of robust evidence generation before and during clinical trials. ■

# Paolo Paissoni

Director of Innovation and Business Development
**PROCOS SPA**

**Can you introduce Procos and give an overview of the company's milestones achieved in 2023?**
Procos is active in both the custom synthesis and generic API manufacturing areas, where our custom business is focused on the US, European, and Japanese markets, and our generic business is worldwide. 2023 was a brilliant year for Procos as the company achieved a record turnover of over €200 million.

**Can you present Procos' facilities and capabilities and elaborate on the company's expansion strategy?**
In 2023, Procos announced an expansion of our existing HPAPI area by adding two new cGMP units, which were approved by authorities in January 2024. We now have four manufacturing units, as well as dedicated R&D and Quality Control laboratories. Procos is particularly active in the antibody-drug conjugates (ADC) area, and we are mainly manufacturing highly potent drugs, specifically drug linkers. This part of our business is significantly growing, and we are supporting both clinical trials and the commercialization of ADCs.

**What will be the main challenges and opportunities for CDMOs in 2024?**
Companies trying to nearshore or onshore their supply chains create opportunities for CDMOs in the US, and Procos can significantly benefit from these localization efforts. In the current competitive environment where many CDMOs have the capabilities, technology, and capacity, it is crucial to offer added value by having highly skilled people who can provide the right support to the customer throughout their project timeline.

**What are Procos' key priorities and growth strategy in 2024?**
Procos will continue to invest in our capabilities and capacity. We are currently building a new workshop in which we are specifically going to add small-scale lines to support clinical trial supply and generic product manufacturing. We expect to continue growing in the US market and plan to increase our capacity from 560 cubic meters to 700 cubic meters. ■

**Franco Stevanato**
Executive Chairman
**STEVANATO GROUP**

> "The US market will be Stevanato Group's main focus for the next 10 years. In 2021, Stevanato invested in a state-of-the-art greenfield plant in Indiana to support the expansion and production of the company's EZ-fill solutions and pre-sterilized drug containment systems."

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CEO of Flamma SpA, an Italian CDMO with operations in both countries: "Approximately 20% of new pharmaceutical molecules entering phase one of studies now originate from China, a substantial increase from the 8% two decades ago."

Such conditions create a ripe environment for foreign CDMOs outside of China to increase their presence in the US.

Decoupling Wuxi AppTec and its affiliate WuXi Biologics (along with three other Chinese contractors) would create a hole in the US medicine chest that pharmaceutical companies are not confident domestic CDMOs could fill. Over the years, the Chinese firm grew rapidly through billion-dollar investments in the US, also receiving billions in tax incentives to build research and manufacturing sites in Massachusetts and Delaware. WuXi is so embedded in the US medicine landscape that the firm makes all or most of the ingredients for therapies seeking to treat cancers ranging from leukemia to lymphoma as well as obesity and HIV. The CEO of a Seattle-based biotech who has been working with WuXi for 16 years said the bill could set his firm back two years by the time he finds another contractor, and shared with the NY Times: "What I don't want to see is that we get very anti-Chinese to the point where we are not thinking correctly."

Calmer minds will most likely prevail as almost all Big Pharma firms have contracts with China, and both countries have advanced cooperations in several areas, particularly the promising ADC space.

Drugmakers and biotechs are accelerating their contingency plans, offering broader opportunities for foreign CDMOs and CROs. Already, firms like ArriVent Biopharma and Dianthus Therapeutics announced that they were looking for alternative manufacturers to WuXi. The loud threat of prohibiting US drugmakers from receiving federal grant dollars should they select the aforementioned Chinese contractors has undoubtedly accelerated the pace with which pharma and biotechs were finding alternative suppliers. Increasingly, drugmakers have set their sights on European and Asian contractors. Japanese and German contract manufacturers expressed during talks





at DCAT – the segment's main yearly gathering in New York – having received exploratory inquiries and growing engagement from US firms. Krishna Kanumuri, CEO and managing director of SAI Life Sciences said: "Traditionally, China has been a dominant force due to its scale and capacity. Presently, the prevailing sentiment among Western companies is to diversify their manufacturing sources beyond China without necessarily abandoning it entirely."

**Foreign expertise for domestic advantage**
More than an isolated geopolitical event, the recent national security-related escalations ought to be analyzed as part of a broader long-term trend of bringing manufacturing back to the US after decades of externalizing the supply chain. While the challenges of such an endeavor will be tackled in a separate piece, the push towards domestic production of APIs, chemicals, and drugs further accelerated in 2023-2024 and offers opportunities for contractors eyeing growth in the US market.

Pharma and biotech firms' need for expertise in growing therapeutic areas along with efforts to manufacture domestically means the trend of billion-dollar contractors making major capex moves in the US is unlikely to wane anytime soon. Samsung Biologics and Lotte Biologics both opened offices in the US this year, eager to join the booming biologics CDMO market (forecast to grow from US$6.6 billion in 2023 to US$12.4 billion by 2028). In 2024, Fujifilm Diosynth Biotechnologies, Japan's leading CDMO, announced it intends to invest an extra US$1.2 billion in its operations to further enhance its biomanufacturing facility in California. Out of Europe, Lonza announced in March it would purchase Roche's Vacaville, CA, facility for US$1.2 billion.

With the rise of complex biologics, gene therapies, and HPAPIS, there is a growing demand for specialized manufacturing and development capabilities that many foreign contractors excel in. Most players interviewed this year out of India indicated that the US market represented the larger chunk of their revenue and that they had strategic plans to grow in the country by either setting up shop there or expanding their current footprint. That mutual attraction between pharma firms and Indian contractors is the result of the latter's highly sought-after technical expertise and understanding of complex regulatory environments globally. For example, beyond expertise in clinal research, Veeda, an integrated CRO out of Ahmedabad, focused on meeting US FDA, EMA, WHO, MCC Canada, and Brazil's ANVISA regulatory standards to meet client requirements globally. Its CEO, Ajay Tandon, explained the competitive advantage: "Indian CROs have significantly evolved, showcasing improved capabilities in both biopharmaceutical and small-molecule segments. This evolution has led to heightened interest from US companies in partnering with Indian CROs."

European CDMOs are also penetrating the US market at an aggressive rate. Benefiting from a world-renowned reputation for quality, established contractors and newcomers from Germany such as CordenPharma, Aenova, or Axplora, and from Italy, including Dipharma and Procos have seen their portfolio of US biotech and pharma customers grow in recent years. Paolo Paissoni, director of innovation and business development at Procos SPA, said: "Companies trying to nearshore or onshore their supply chains create opportunities for CDMOs in the US."

Nicola Cadei, general manager of Italian CDMO Fisiopharma, concurred: "The political tensions and strained US-China relations are not favoring business opportunities in the CDMO sector between the two countries, which is benefiting Europe instead. In our cooperation with US customers and partners, we experienced a preference for US markets for EU-based companies, which proves the reliability high quality, and technological standards of the European CDMOs."

The ever-so-competitive CDMO landscape just became even fiercer. Market growth, demand for technological and regulatory expertise, and the payback of past manufacturing policies mean addressing widespread drug shortages in the US will undoubtedly require a global effort. For US drugmakers and biotechs, the road ahead might separate them from Chinese contractors, and redirect their outsourcing towards other foreign and domestic firms. The latter are feeling the pinch brought by the increase in foreign competition. David Stevens, CCO of Kindeva Drug Delivery, a leading combination product CDMO, shared: "Increasingly, Chinese and Indian CDMOs have started competing on higher-value parts of the outsourcing supply chain, such as biologics and sterile fill-finish, creating additional pressure on US CDMOs." ■

# Krishna Kanumuri

CEO and Managing Director
**SAI LIFE SCIENCES**

> I anticipate a continued trend of Western companies exploring India as an attractive manufacturing destination.

**Can you highlight the main achievements of Sai Life Sciences (Sai) in 2023?**
In 2023, Sai Life Sciences experienced significant expansion across all business lines, prioritizing the enrichment of higher-value services in discovery, transitioning to integrated services, and broadening the CMC portfolio with a focus on API offerings. With approximately 70% of discovery programs now integrated, spanning biology to toxicology and medicinal chemistry, and a commercial portfolio growth from five to 35 molecules in three years, our involvement in around 10% of all small molecule launches underscores our progress. Despite industry-wide challenges, such as destocking, we have maintained robust growth rates, with a 30% annual increase in the discovery segment and overall company growth surpassing 20%, positioning us ahead of market trends and poised for continued expansion.

**How does your recent expansion of end-to-end drug metabolism and pharmacokinetics services reflect your commitment to accommodating larger programs?**
We have always aimed to provide high-quality DMPK services, but in response to the guidance from our large pharma customers, we have significantly ramped up our efforts over the past year. This involved enhancing our throughput to handle increased compound volumes and improving asset reliability through automation. Our expansion strategy encompasses three key aspects: Broadening our service range, implementing automation to minimize human intervention in experiments, and enhancing compound management for improved data tracking and management for our customers. This expansion also involves nearly doubling the size of our portfolio footprint, covering technology, personnel, and physical space.

**Can you elaborate on the growth Sai Life Sciences experienced in the US market recently?**
2023 was particularly successful for us in the US market. We are currently assessing whether it is more advantageous to further expand in the US or enhance collaboration between our US and Indian sites. Our US facilities primarily focus on introducing new technologies and closely engaging with customers, while the Indian sites handle scaling up operations. We are considering bolstering the capabilities of our Boston labs to tackle more complex and innovative technologies, which we can then implement at scale in India.

**What are the factors attracting Western firms to foreign contract manufacturers?**
Traditionally, China has been a dominant force due to its scale and capacity. Presently, the prevailing sentiment among Western companies is to diversify their manufacturing sources beyond China without necessarily abandoning it entirely. India stands to benefit significantly from this trend, particularly in the realm of manufacturing, as evidenced by the increased attention Sai Life Sciences is receiving. Our investments, facilities, and team in Manchester have positioned us ahead of the competition, enabling us to capture a substantial portion of this shifting demand. Looking ahead, I anticipate a continued trend of Western companies exploring India as an attractive manufacturing destination. Our strength in the UK market further distinguishes us in the industry.

**How do you assess the operating environment for CDMOs globally?**
The evident catalysts for change are reflected in recent funding cycles, signaling a shift towards streamlined operations in response to an unprecedented surge in resource allocation over the past five years, alongside regulatory changes like the IRA, prompting companies to expedite processes for funding acquisition. This dynamic environment emphasizes the need for companies to strive for 'first in class, best in class' status, driving a trend towards faster operations and larger clinical trials with a focus on multi-indication approaches, demanding agility, and a robust R&D foundation for success. While new modalities such as ADCs and peptides present both challenges and opportunities, companies must diversify offerings, invest in high-end talent, and develop new technologies to remain competitive in the evolving CDMO space, where adaptability and innovation are key to thriving amidst a positive market outlook. ■





> Since the establishment of our facility in the US, we have felt the appreciation of the market in being able to have a local partner, especially in light of many companies trying to localize their supply chains.

# Bart van Berkel

CEO
**CURTEC**

**Can you introduce CurTec to our readership?**
CurTec is a GMP-certified high-performance packaging company manufacturing plastic screw top drums, pails, and jars for high-value materials industries, including pharma and specialty chemicals. In 2023, the company expanded our production capability into the US and opened a GMP and FSSC-certified facility in Westminster, South Carolina. We are primarily a bulk packaging supplier that specializes in keeping the products of pharmaceutical, specialty chemicals, and food ingredients companies safe during transport and storage while also having the safety of the humans interacting with the product in mind. Our development, production, and logistic processes are certified and comply with the high-quality requirements of our customers.

**How important will the US be for CurTec moving forward?**
As many of the development of new medicines and drugs are happening in the US, this market will remain extremely important for CurTec. We already supplied a large US customer base from the Netherlands, but to be closer to our customers, cut down on delivery time, and reduce transportation needs to make the logistics chain more sustainable, we decided to establish a manufacturing facility in the US. Since the opening of the facility in May 2023, we have seen great traction, and we look forward to partnering with new customers. CurTec has a unique product that fits the unique needs of the market, and we see the US as our main market for growth. South Carolina is a growing production hub, which means there is ample talent. From a logistics perspective, the state is geographically well-located to easily reach customers.

**What is CurTec's approach to ESG?**
In 2023, Ecovadis again awarded CurTec a gold sustainability rating, and SBTi accepted the company's 2023 and 20250 climate goals to reduce our GHG emissions.

We are focused on truly understanding our own footprint and have mapped out our scope 1, scope 2, and scope 3 emissions. Where we see the biggest impact is in raw materials production and the end of life of the products, which is why our actions are primarily focused around these two topics. Circularity is becoming increasingly important in the packaging industry, and we contribute to a circular economy by having introduced recycled and biobased materials into our products. CurTec's sustainability goals are divided into three pillars – Climate, where the ambition is to bring emissions to net zero across our entire value chain; Health and Well-being where we are focused on having a positive impact on the health, safety, and well-being; and Circularity and Partnerships where the focus is on working with partners on the transition to a circular packaging industry through new products and materials.

For the pharma industry to reach the level of sustainability it wants and needs to, there has to be industry collaboration and it will have to start at the top. We are already seeing big pharma pushing from the top, researching alternative packaging solutions or materials like biobased and working only with companies with a strong and active ESG policy, in efforts to make their supply chain more sustainable. These efforts will ultimately trickle down throughout the industry, making entire supply chains sustainable.

**What makes you excited about the life sciences industry in 2024 and beyond?**
There is optimism in the market, and we are seeing much more activity in terms of new projects coming online. There are efforts to eliminate cost and quality issues in the supply chain, as well as to work towards a more sustainable supply chain, and the level of opportunities that are arising is much higher than in 2023. CurTec has expanded our sales and support team in the US to meet increased customer demand, and since the establishment of our facility in the US, we have felt the appreciation of the market in being able to have a local partner, especially in light of many companies trying to localize their supply chains.

**What are CurTec's main priorities for the next year?**
CurTec hopes to significantly grow our market presence in the US. Furthermore, realizing that the companies we work with are often globally organized, we have in Q1 2024 opened a new sales office in Singapore, supporting the Asia-Pacific markets. Lastly, we will continue to innovate and make further bold steps forward in terms of sustainability through collaboration with industry partners. ■

INTERVIEW

## Peter DeYoung

CEO
**PIRAMAL PHARMA**

## Robert Bloder

Director, Board of Developers and CBO
**ASCENDIA PHARMACEUTICALS**

MM

AR

## Martin Meeson and Arul Ramadurai

MM: CEO
AR: CCO
**AXPLORA**

**Could you highlight the main milestones of Piramal Pharma in 2023?**
We expanded our API and HPAPI facilities in Riverview, Michigan, and Aurora, Ontario. Additionally, we made significant strides in our capacity expansion efforts, particularly in ADCs (antibody-drug conjugates) production at our Grangemouth, UK, location. Another achievement is the enhancement of our discovery chemistry capabilities at our Ahmedabad, India, site. By adding in vitro biology capabilities, we now offer a comprehensive package for early-stage discovery efforts. Furthermore, we initiated our first fully integrated program, starting with mAbs (monoclonal antibodies) and expanding into conjugation and fill-finish processes.

**How does Piramal Pharma plan to boost its programs in oncology and ADC?**
With the addition of the Lexington site, we began offering integrated solutions, encompassing conjugation and fill-finish processes. Additionally, at our Aurora and Riverview sites, we have conducted linker or payload work for clients. However, one missing component for us was the mAb aspect. Recently, with our investment in Yapan Bio, we now offer this component as well. We have introduced a branded offering called ADCelerate, aimed at speeding up ADC efforts by combining all necessary components into a single, integrated package. ■

**How has the market responded to the launch of LipidSol?**
Ascendia's newest technology platform, LipidSol, compliments our existing three technologies – EmulSol, AmorSol, and NanoSol – and is the technology the market has been waiting for as it encapsulates genetic material and drugs and delivers it intracellularly using lipids which the body perceives as not a problem. When Ascendia first entered the market, demand was approximately 50% for sterile products and 50% for non-sterile products. Today, the curve has skewed much more to sterile injectables, prefilled syringes, auto-injectors, and cartridges.

**How do you assess the health of the industry entering the year?**
Now that we are again seeing more funding flowing into the life sciences space, we will see more drugs entering clinical trials and more products being developed, and it is going to be about who is executing the best that will make the difference. Many companies come to the US to innovate as there is a tremendous amount of talent and expertise.

**What are Ascendia's main priorities and growth strategy for 2024?**
Our colleagues will continue being the best solutions partner for our clients, especially on the LNP (Lipind Nano Paricels) and sterile products including prefilled syringes, vials and cartridges. ■

**What will be the main opportunities and challenges for CDMOs in 2024?**
MEM: Capital flows for new and early phase biotechs have slowed down and we have seen the impact on CDMOs, in particular those with earlier phase pipelines.

Then there are the twin topics of ADC's and GLP-1's. Both areas are showing such exciting positive impacts on large patient populations. At Axplora we are extremely pleased to be able to bring our expertise in the ADC space to support our partners' programs and in GLP-1's we have some world-leading technologies, particularly in purification that we are bringing to meet the surging demand.

**What are Axplora's key priorities for 2024 and beyond?**
MEM: There are many molecules in our pipeline for which we will use our deep technical and regulatory skills to advance through the clinic to commercial.

AR: The pharma game is about getting molecules to the market as soon as possible, and Axplora offers speed with unbeatable quality. ■



INTERVIEW

## Brad Payne

COO
**PCI PHARMA SERVICES**

## Tom Ross

President and CEO
**GRAND RIVER ASEPTIC MANUFACTURING (GRAM)**

## Andrew Mears

CEO
**LEAD CANDIDATE**

**Can you highlight the key activities that have occupied PCI Pharma Services over the past year?**
Over the past year, PCI has been deeply engaged in expanding our integrated service offerings across commercial packaging technology, clinical trial services, and drug product development and manufacturing. With a global footprint of 30 sites, our focus has been on strategic growth while reinforcing our existing foundation. We have deployed capital towards constructing new facilities and integrating advanced technologies, with notable projects including building a 400,000 square foot Advanced Drug Delivery Center of Excellence in Rockford, Illinois, as well as bringing commercial-scale, fully isolator contained aseptic vial filling and lyophilization capabilities to our Bedford, New Hampshire facility. We have also expanded our capabilities and capacities in Ireland, and our clinical centers in Berlin, Boston, and San Diego.

**Could you elaborate on some of your latest innovation-related investments?**
Innovation and technology stand as cornerstones of PCIs strategic vision, particularly highlighted by recent investments in automated assembly and packaging technologies as well as our digital supply chain management platform PCI|Bridge™. These initiatives exemplify our commitment to simplifying processes. ■

**Can you share the main highlights of Grand River Aseptic Manufacturing (GRAM) in 2023?**
Emerging from the challenges of the COVID era, we had a considerable portion of our capacity initially dedicated to producing COVID-19 vaccines. With the successful addition of new capacity, we made capacity available for vials, PFS, and cartridges. Our focus was on engaging with potential clients, which resulted in the acquisition of many new partnerships. Most of the products fall within the biologic space, specifically monoclonal antibodies and related biopharmaceuticals.

One notable project involved the production of the JYNNEOS vaccine for the prevention of mpox and smallpox. GRAM is currently the sole facility in the US manufacturing this vaccine.

**How does GRAM's approach to designing facilities give the firm an advantage for Annex 1 compliance?**
Our facilities, constructed in the last two to three years, were purposefully designed to meet Annex 1 compliance standards, emphasizing isolator technology, automated inspection machines, and automated loading systems. Our proactive approach, analyzing and implementing the necessary systems and processes for Annex 1 compliance during the initial facility build-out, provides a substantial advantage over competitors. ■

**Can you introduce Lead Candidate?**
Lead Candidate is a talent consultancy for the global life sciences sector. We partner with both customers who are hiring, and customers who are looking to be hired and provide them with the tools and support to fuel growth.

**What are life sciences firms currently looking for in candidates?**
There is a move away from predominantly looking at a candidate's academic background, and the more forward-thinking organizations are not only focusing on technical capability and experience, but also the cultural fit and values alignment to the business.

**What trends are you seeing in the recruitment sector heading into 2024?**
Lead Candidate did an analysis identifying the top 10 things driving talent away from companies, and in 2023, the primary reason for people leaving a company was related to career development and the lack of progression opportunities. Compensation was still in the top five, especially considering high inflation.

The life sciences industry has lost people to tech as companies in that industry are more innovative and embracing new ways of working. Life sciences are competing with these forward-looking sectors and need to adapt to the changing working landscape. ■

# The Year(s) Ahead for CDMOs

## An outlook of pain points and opportunities

Headed into the mid-decade, the CDMO segment remains prey to the same fluctuations and pressures impacting the broader biopharma sector. Recent industry shifts suggest CDMOs will have to execute on three main catalysts going forward: Talent, manufacturing, and technology.

**Human capital**

Amongst the biggest pain points for CDMOs since the pandemic and entering 2024 has been accessing talent. Felt across the industry, the talent shortage can be explained notably by potential candidates joining a "younger" tech industry, seen as more innovative. CDMOs have therefore multiplied internship opportunities, graduate and training programs to attract and retain talent. When asked about the catalysts ahead for the CDMO segment through 2030, Nick Shackley, Veranova's SVP and CCO, mentioned the pandemic was an eye-opener for firms regarding the value of human capital: "Post-pandemic disruptions and the evolving workforce landscape require a continued focus on recruiting, training, and retaining talent."

Faced with a talent drought, CDMOs have started to be less picky regarding candidates' academic experience. Previously, an industry-wide push of requiring four-year degrees and advanced technical competencies (less than 5% of employees at Charles River Laboratories have less than a two-year degree) has restrained access to a wider pool of talent. Andrew Mears, CEO of Lead Candidate, a Newcastle-based talent consultancy for the life sciences sector, who notably has been assisting INCOG in its rapid growth since 2021, shared: "There is a move away from predominantly looking at a candidate's academic background, and the more forward-thinking organizations are not only focusing on technical capability and experience but also the cultural fit and values alignment to the business."

Attracting talent is one thing, retaining it is another. With great technical abilities and comfortable with being client-facing, notably during the many tradeshows during the year, CDMO employees are highly marketable individuals. For CDMOs, not being able to retain their most senior people could represent nothing short of an existential threat going forward. In a study of the main factors causing retention issues in the industry, Lead Candidate found that more than compensation, the primary reason for people leaving a company was related to career development and the lack of progression opportunities. The CDMO of tomorrow ought to put the necessary investment onto creating new leaders to navigate an increasingly complex environment.

**The onshoring conversation loses steam**

COVID-19 exposed the weak supply chain structures of certain drugs vital for the US population. For the past two years, lawmakers, policy-makers, and life sciences stakeholders alike have called for the majority of manufacturing to take place in the US. This however poses at least two substantial challenges. First, that of capacity. As over 70% of drug manufacturing happens overseas, producing domestically products, APIs, and chemicals needed for drugs will require large manufacturing capabilities that very few CDMOs could absorb in the US. Capacity-wise, the US does not even manufacture certain chemicals needed as the outsourcing model has been established for decades. Chen Zhou, CEO and co-founder of ChemPacifc, said: "Currently, it is a daunting task to make a swift transition. Over the past decade or so, many big pharmaceutical companies have shut down their research and development centers and pilot plants in the US, opting to relocate operations overseas."

However, the hardest barrier to overcome to bring manufacturing back domestically is that of price. From biopharma firms to CDMOs, players have felt that the cost-efficiency calculation has still not tilted towards favoring onshoring supply chains. In 2023, API manufacturer Noramco launched the Noramco Group, a "North American pharmaceutical supply chain provider" aimed at addressing rising drug shortages and quality issues in the US through improved supply chain performance. Noramco's CEO, Lee Karras, explained: "While there is a clear mission to bring manufacturing back to the US, the feasibility of this largely depends on market demand and pricing dynamics."

Concerns over drug shortages and supply chain security will keep onshoring discussions going, but there remains uncertainty as to conversations turning into action. In November and December 2023, White House statements emphasized a national security approach to supply chain resilience. However, the hyperbolic conversations in conference rooms and political circles do not appear to match the reality on the ground. In a 2023 Cytiva report, less than 20% of executives questioned said that enhancing supply chain resilience was a top domestic priority for the upcoming two years. For CDMOs, the point will be to remain flexible and grow their international footprint to make their supply chains more robust in light of other possible disruptions. As concluded by Victor Swint, CEO of Florida-based Formulated Solutions: "Supply chain resilience has become increasingly important. The recent fluctuations in global supply networks have underscored the necessity for robust strategies to mitigate disruptions."

**The CDMO differentiator: AI**

One of the advantages of gathering business intelligence over repeated years is that one gets to see the evolution of phenomena into trends – or not. In 2020, during CPhI (contract manufacturers' largest gathering), a panel discussed for the first time "Introducing Artificial Intelligence and Machine Learning" in the contract manufacturing space. Fast forward three years and the panel topic has grown from introducing to "Loading (the) Potential" of AI. A few months after CPhI 2023, DCAT, the other leading CDMO event, organized as its "flagship event" a panel on the emerging role of AI in supply chain management. Separate from the hope AI brings in drug discovery, leveraging this tool at the supply chain level is where CDMOs will most likely make the greatest strides in the coming five years.

In the future, AI will likely change how biopharma firms and suppliers do business. The advantages are many: AI can facilitate the automation of production lines, visual inspection, quality control, processing, and proactive equipment maintenance. Specifically for CDMOs, it can enhance supply chain management by predicting demand, optimizing inventory levels, improving logistics efficiency, detecting anomalies for quality control, and automating routine tasks to streamline operations. "In essence, we anticipate AI to enhance efficiency, particularly in supply chain management, and play a pivotal role in advancing research and development," shared Saurabh Gurnurkar, managing director of Uquifa, a CDMO.

For CDMOs that are helping clients move into the commercial space, AI can be useful to repetitively produce high-quality products based on the data gathered and processed quicker and more efficiently. Aragen, the only CRO/CDMO with a Chief Digital Officer, recently embedded all its facilities with automation capabilities to support customers with AI-based assistance from discovery to manufacturing. Moving forward, the industry will likely see CDMOs getting even more serious about AI. ■



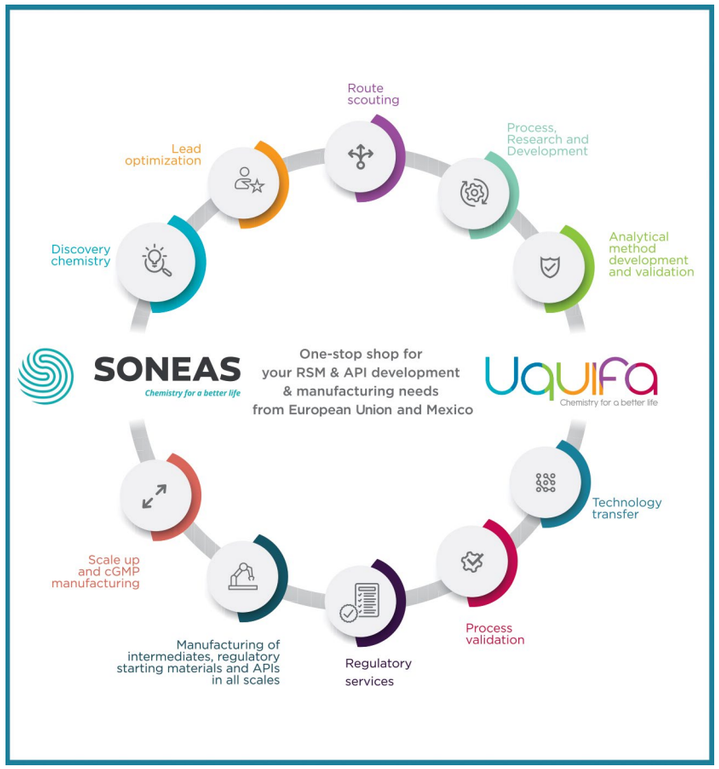


Image courtesy of Aragen Life Sciences

> There are hundreds of firms out there offering very specific services, and this will ultimately lead to more consolidation within the industry.

# Tom Sellig

CEO
**ADARE PHARMA SOLUTIONS**

**Can you share the main updates and achievements from Adare in recent months?**
Last year, Adare was one of the few CDMOs that experienced both top-line and bottom-line double-digit growth. We've seen that this growth was primarily due to our strategy of pursuing continual significant investments in new equipment and capabilities across our global network.

We are continuing to expand our existing high-potency capabilities across our network of sites. This enables us to serve a wider market by addressing high-potency requirements at various stages of the manufacturing process and across different scales. For example, we'll soon be offering commercial scale encapsulation, granulation, and packaging, in addition to our current milling, blending, and tablet compression capabilities. We are also seeing promising growth in our newer offerings and capabilities, especially in controlled substances. As part of our investment strategy, we've built a new Schedule II Vault in Philadelphia capable of storing up to 72 pallets of controlled substance material.

Our development pipeline is full of new opportunities. We are experiencing growth across numerous development areas, from supporting pediatric products to addressing challenges like nitrosamine mitigation, reformulation, and solubility issues. We have had record proposal volume in Q1 and we're seeing significant new opportunities.

**What are the specific areas driving growth for Adare?**
Pediatrics continues to be a growing portion of both our business and the market at large. There are numerous interesting challenges to overcome in developing a pediatric product: It has to be easy to administer, it can't be hard to swallow, and it can't be bitter. In the industry, Adare is seen as an expert in deploying strategies and technologies to overcome these challenges.
Another area driving growth for us is oncology. As I look at our pipeline, a large proportion of the products we're developing are cancer drugs. Oncology continues to be one of the largest development areas for the industry as a whole; almost half of the drugs in development are cancer drugs, and 75% of those are highly potent. This underscores how important our expanded high-potency infrastructure investments will be in proactively meeting the future needs of our customers.

**Adare has also recently been expanding its capabilities in Europe. Is this an important market for Adare?**
Europe is a very important region for us, and we're excited to expand our capabilities and market reach there. Initially, we're investing in upgrades and expansions for our Pessano site in Milan, Italy to offer greater capacity and capabilities throughout all of Europe.

In Europe, blister packs are generally preferred over bottles for oral solids, so we've added a purpose-built packaging hall capable of more than 50 million blisters a year. This expansion also provides a 1,000 square-meter warehouse with capacity for 900 pallets, as well as space to accommodate a second packaging line in the future.

We've also added a dedicated high-shear mixer granulation suite that allows us to provide even broader oral dose capabilities. The site's analytical and formulation laboratories are receiving high potency capabilities as part of the upgrades across our network.

**ESG is a growing topic for private equity, how is Adare making strides in that direction?**
Last year, we built out a comprehensive ESG strategy with nine pillars and we have specific targets for everything from our carbon footprint to waste reduction goals and DEI. We are pleased with the progress we've made so far; last year we were awarded an Ecovadis bronze medal rating.

**What will be the key catalysts for CDMO growth in 2024?**
Consolidation will certainly be an important topic in the industry this year. The CDMO landscape is highly diversified: For comparison, the top 10 CROs make up 80% of that segment, but within CDMOs, the top 10 make up less than 20%. There are hundreds of firms out there offering very specific services, and this will ultimately lead to more consolidation within the industry.

Looking ahead, oral solid versions of GLP-1s are an exciting opportunity and I believe there will be important technical breakthroughs that will enable these products to be reformulated into oral solid forms. Oral solids can provide many benefits including patient preference and scaling capacity, and can lower both production costs and pricing for patients.

**What is Adare's key priority for 2024?**
Execution. We have a great strategy in place, one that's already paid tremendous dividends. ■





SD

RS

# Subodh Deshmukh and Ramesh Subramanian

SD: CEO Biologics and President Development
RS: CCO
**ARAGEN LIFE SCIENCES**

**What were the main highlights from Aragen in 2023?**
RS: 2023 was challenging from a macro perspective, as biotech funding was low. Despite this, our overall performance has been good. We now have around 4,200 people across six global campuses and are working with 17 large-cap firms around the world.

During the year, we further strengthened our drug product service offerings by adding clinical capacity to drug product manufacturing. This will allow us to integrate our drug substance into a drug product. We have also seen strong growth in our Formulations and Analytical verticals. We invest where our customers' future needs are - biologics, peptides, oligonucleotides, and ADCs (Antibody Drug Conjugates).

On the biologics front, we will have a manufacturing facility that will come online at the end of 2024 and will allow our customers to go all the way to Phase 2 and beyond. We won the EcoVadis Silver Award for the second consecutive year and were recognized as the Best Workplaces in the Pharma, Biotech, and Healthcare sectors in India in 2023. We also received the Great Place to Work (GPTW) certification for the fifth consecutive year, making us possibly the only firm in the Indian Life Sciences sector to achieve this recognition.

**What will the investment in the Bangalore facility mean for Aragen's capability to conduct tech transfers?**
SD: Aragen has a 30-year track record of developing cell lines that have powered hundreds of INDs. We can do discovery, protein sciences, bioproduction, and cell line development at our California facility. Adding the manufacturing facility in Bangalore will allow us to expand our biologics service offering. The facility will initially have a bioreactor capacity starting at 2,500 liters and will be expanded to 21,000 liters. Earlier, we were doing tech transfers to other CDMOs, losing out on the value chain beyond generating the cell line. Now, we can do tech transfer in-house to our own facility, using the latest technology, and a plug-and-play platform.

**In which areas do you forecast growth?**
RS: In our Discovery business we are seeing renewed interest with new customers approaching us for new programs. Our Integrated Drug Discovery business has grown about 6-fold, in the past 18 months, which is terrific. We are also seeing strong tailwinds from the China+1 strategy.

SD: We have broadened our range of offerings in biologics, and can now go from Gene to GMP, allowing customers to take their projects to the clinic. The US is a key geography for us. We have deep roots in California with two facilities and a lot of R&D activity there. We are picking up hot pockets in other areas where there are emerging biotech activities, such as Colorado, Texas, or Florida, and we want to be represented there.

**How important is the ability to automate for CROs/CDMOs going forward?**
SD: Automation is critical from two perspectives - to improve our operational efficiency and to accelerate innovation. Our new facilities are completely embedded with state-of-the-art automation capabilities to support customers with AI-based assistance from discovery to manufacturing. We recently added significant API and intermediates manufacturing capacity at Vizag with online data control and data mining technology. This helps us analyze the data generated during each manufacturing batch and achieve batch improvements and cost savings. We also partnered with Getinge, a leading bioreactor manufacturer, and helped them launch their latest model of single-use bioreactors (SUBs). Using their digital twin technology and Aragen's platform process, we were able to demonstrate that new products can be brought to market seamlessly and faster.

**What will be the main catalysts ahead for the CRO/CDMO segment?**
RS: With the US elections and other ongoing geopolitical issues, increasing focus on geo-diversification will also be a key factor to look at. In recent times, there have been several strategic exits by investors and VCs that release capital to invest back in new ventures.

SD: We have seen unprecedented interest in our facilities with an increasing number of customers wanting to explore Aragen's capabilities. We have now added significant commercial scale capacity. We were already doing commercial projects but are now looking at significantly increasing the volumes in the coming times. ■

> We are extremely excited about the growth our hydrogen peroxide and packaging segments can bring.

# Daniel Prince

CEO
**PRINCE STERILIZATION SERVICES**

**What have been the main milestones for Prince Sterilization Services (Prince) over the past 12 months?**
Over the past year, there has been an increase in demand for Prince's services and business has been extremely strong. The company continues to expand and we are excited about the future. Our latest state-of-the-art 30,000 square foot GMP manufacturing facility in New Jersey allowed us to increase our capacity and throughput dramatically, and we can also offer new services such as assembled vials, nest and tub services, and vapor hydrogen peroxide sterilization to further expand our reach in the pharma and biotech industries. In the past three years, Prince has invested over US$18 million in equipment and facility leasehold improvements. In the 2nd half of 2024, capacity will be boosted significantly as new equipment comes online coupled with more automated processes and available facility space.

**What does Prince hope to achieve with the launch of its new packaging segment?**
The 2024 and 2025 years are extremely exciting for Prince as investments that were made several years ago are beginning to materialize and generate revenue. Vertically integrating packaging is a goldmine for Prince. All the products we sell require aseptic packaging. This opportunity is also for services to companies that do not have terminal sterilization but would like it done in an aseptic manufacturing facility under extremely clean conditions. The decision to launch a packaging segment was made by listening to our customer's needs and the demand in the market. We forecast tremendous growth in this area.

**What is Prince's growth strategy ahead?**
To bring a company beyond what a family can do organically, you have to consider acquisition and partnership options where we might, for example, become a platform and become a larger enterprise. This is the possibility we see for ourselves in the future. Prince is on a significant growth trajectory, and we must manage our growth as we expand and scale our offerings.

**The FDA recently recategorized vaporized hydrogen peroxide (VHP) as an established medical device sterilization method. How does this reinforce Prince's competitive advantage?**
This tremendously reinforces our competitive advantage and validates our decision to offer these services, as we believe that there must be alternatives to ethylene oxide due to its recent challenges. Prince decided to invest in vaporized hydrogen peroxide sterilization several years ago, and we are now ahead of the curve as the FDA has deemed VHP as an official terminal sterilization modality. We are set to become one of the first providers of contract VHP sterilization services and gain a sizable market share in medical device sterilization as companies turn away from EtO seeking an eco-friendly alternative sterilization modality.

**What is your outlook for the life sciences industry in 2024?**
I hope to see that the pharmaceutical industry, as is the case in the biotech industry, will shift its focus from treatment to prevention so that the human race will not suffer certain maladies, diseases, illnesses, and cancers and then recover from them, but rather, we will stay healthy and can expect a longer lifespan because we have learned from the past. There needs to be a mindset shift that focuses on what we can do to prevent sickness and disease, and the industry should understand that it will still be profitable by taking a proactive stance rather than a reactive stance. Overall, Prince is well-positioned to capitalize on high-growth sectors from emerging trends including an increasingly complex regulatory landscape, a rise in biologics and combo products, and a higher proportion of new drug approvals received by emerging and mid-tier pharma.

**What are Prince's main priorities and goals for 2024?**
Prince will continue to focus on executing our plan and finalizing the performance qualifications of our new lines. Our growth initiatives and expansion plans are dependent on good management and execution. The company will also continue to focus on fostering healthy customer relationships. We are extremely excited about the growth our hydrogen peroxide and packaging segments can bring to the company in 2024 and beyond. We look forward to being a bigger company with larger resources to help us robustly execute our plan. ■





> Rather than merely facilitating tech transfers, we aspire to lead the innovation charge for our clients.

# Victor Swint

CEO
**FORMULATED SOLUTIONS**

**Can you introduce Formulated Solutions and share your latest updates?**
This year has been highlighted by several key achievements, most notably the acquisition of our 440,000-square-foot GMP Pharma production site in Cleveland, Tennessee. This facility has significantly enhanced our production capacity and capabilities across regulated topicals, nasal sprays, aerosols, and more. We consider it a sister plant to Largo.

Additionally, we have implemented a robust C-level structure, bringing in great leaders who can manage the scale of the growth we are experiencing. Overall, 2023 was characterized by the onboarding of new customers and achieving over 25% growth.

**Are there any trends in demand you are witnessing for Formulated Solutions' services?**
At Formulated Solutions, we cater to an extensive and diverse clientele within the Consumer Healthcare sector, including partnerships with eight of the world's top twelve consumer healthcare companies. This broad client base relies on us to manufacture a wide range of products, from OTC medications to those requiring New Drug Applications, as well as medical devices and cosmetic products. Our expertise spans across various product categories, including topicals, nasal sprays, oral dose liquids, and more, allowing us to meet the needs of both retail and physician-dispensed markets.

As for current trends, in 2024, we are observing a significant inventory overhang. Additionally, there is a heightened emphasis from key customers on quality standards.

**As an "onshoring trendsetter", what is your take on the onshoring manufacturing conversation in the US?**
The COVID-19 pandemic has exposed the fragility of global supply chains. Amidst ongoing trade wars, uncertainty surrounding the security of supply persists. Fortunately, our company possesses the necessary scale and expertise to manage intricate and complex technology transfers from various regions worldwide. As part of our strategic response, we have successfully repatriated most of our supply chain operations back into the country, with up to 99.9% of it now domestically managed.

Looking ahead, the cost implications of domestic production pose a significant challenge for the industry as a whole.

**Could you discuss any innovation-related investments?**
With a dedicated team of 40 professionals focused on development, we have made a significant commitment to research and innovation within the cost-conscious CDMO landscape. Recognizing the demand for a discreet, no-touch, no-drip, on-the-go hemorrhoidal treatment, our Innovation and Development team embarked on a mission to create a novel approach to hemorrhoid care. Our goal was to enhance ease of use and expand the range of situations in which individuals could comfortably manage this condition, which can arise unexpectedly.

In today's pharmaceutical landscape, large pharma and biotech companies are increasingly outsourcing their needs, highlighting the growing importance of innovative CDMO partners. Rather than merely facilitating tech transfers, we aspire to lead the innovation charge for our clients. Pharmaceutical firms are seeking agile partners capable of swiftly responding to market demands.

**How do you assess the health of the CDMO segment in 2024?**
I've noticed two significant trends recently. Firstly, there is an inventory overhang in the market, leading me to be more optimistic about the second half of the year compared to the first. I anticipate that innovation will be a key driver of growth opportunities for CDMOs during this period. Secondly, supply chain resilience has become increasingly important, reflecting our unwavering commitment to quality. The recent fluctuations in global supply networks have underscored the necessity for robust strategies to mitigate disruptions. We are dedicated to carefully managing our supplier relationships and have made investments in flexible GMP warehousing spaces to ensure the resilience of our operations.

**What makes Formulated Solutions unique in the CDMO space, and what will be the key priorities in 2024?**
We are anticipating aggressive growth this year. Our investments have opened numerous opportunities and expanded the company's capacity significantly, giving us confidence in sustaining double-digit growth for years to come. When assessing the capabilities of our two plants, we see ample room for expansion in various areas.
We are dedicated to ensuring that our values remain at the forefront of the company. Quality is our top priority, and we are committed to doing things the right way. Our focus is on bringing innovation to our customers to enhance their success, highlighting our dedication to customer-focused innovation. Our mission is to contribute to making the world a better place, and our vision is to become a world-class CDMO. ■

> We can now initiate projects in Budapest and conclude them at our larger-scale GMP facility in Spain and/or Mexico, offering to our customers an option for integrated project management for their programs.

# Saurabh Gurnurkar

Managing Director
**UQUIFA GROUP**

**Can you provide an overview of the Uquifa enterprise and the firm's highlights in 2023?**
Our enterprise primarily operates as a developer and manufacturer of small-molecule APIs and regulatory starting materials. Our manufacturing facilities, which are integrated campuses with R&D Labs, Pilot Manufacturing & Large-Scale Manufacturing are situated in Spain, Mexico, and Hungary. We are a team of 760 people across these locations with Business Development colleagues in North America, EU and Asia. The Uquifa brand brings with it a history spanning over 87 years, serving its customers across the global pharmaceutical and specialty chemical industries.

In the wake of the pandemic, the industry landscape has undergone considerable transformation. Since 2022, we have embarked on a new strategic direction, focusing on investing in what we refer to as our three Ps: our people, products, and plants. Central to this strategy are core values such as customer centricity, compliance, and science first. We have also been increasingly incorporating digitization tailored to our industry needs. For instance, we have implemented enterprise software across two of our three locations, automated certain aspects of our manufacturing processes, and are rolling out a digital quality management system. These efforts reflect a phase of internal evolution and a balanced investment strategy across our sites, including expanding the capacity of our process equipment, and laboratory infrastructure and enhancing warehouse capabilities.

**Could you elaborate on the expansion strategy for Uquifa in the US?**
Our enterprise has undergone significant evolution over the years. A pivotal moment in our journey towards becoming a CDMO from Europe materialized with the acquisition of SONEAS in 2018. SONEAS, based in Budapest, provided us with R&D laboratories y, a GMP pilot plant, and a relatively under-utilized large-scale pre-GMP manufacturing facility, which we saw as an opportunity. More crucially, it empowered us with development expertise, marking a significant shift from our previous role primarily as a contract manufacturer. Essentially, the D in CDMO, for us. Post-integration, we aimed to establish ourselves as a comprehensive solution provider from Europe for development and manufacturing requirements spanning Regulatory Starting Materials (RSMS), and Active Pharmaceutical Ingredients (APIs). This strategic direction has been well-received by our customer base. We can now initiate projects in Budapest and conclude them at our large-scale GMP facility in Spain and/or Mexico, offering to our customers an option for integrated project management or a One-Stop Shop as we call it, for their programs. Our primary markets, including the USA, Europe, and Japan, constitute approximately 85-90% of our sales. In the US, we serve two primary customer segments: established pharmaceutical companies that prioritize outsourcing manufacturing and development, and the growing biotech sector, which is driving innovation too.

**How do you view the growing use of AI and machine learning tools in the CDMO/CRO sector's digital transition in 2024?**
The discourse around AI is pervasive. From our standpoint as a fine chemical and pharmaceutical manufacturer, we foresee AI making significant contributions, particularly in supply chain management. There is a growing recognition of AI's capacity to streamline and optimize these processes. Additionally, AI holds promise in accelerating drug development timelines, especially in the initial phases of candidate identification and optimization for specific disease indications. In essence, we anticipate AI to enhance efficiency, particularly in supply chain management, and play a pivotal role in advancing research and development within the entirety of our value chain.

**With a notable portion of recent FDA-approved drugs being small molecules, do you expect this trend to strengthen?**
Small molecules have consistently dominated the landscape of new drug approvals, comprising over 50% of the total in the past decade. This trend underscores the enduring relevance and importance of small molecules in the pharmaceutical industry. While biologics represent a rapidly expanding platform, small molecules maintain their significance. Ultimately, two key factors drive this: the efficacy of the drug and its economic implications from both patient and payer perspectives.

**Could you outline the top priorities for you and your team this year?**
Our primary focus remains on our core values: Compliance, customer centricity, and placing science first. We are committed to focusing on our 3Ps and the variables we can control as an enterprise. Ensuring "right-first-time" (RFT) execution and optimizing our performance will be center-stage for our enterprise. The consolidation of our services into a one-stop-shop model aligns well with our strategic goals and we believe, enhances our value proposition in the market. ■





# Insights on Growth Areas for CDMOs

**Thierry Van Nieuwenhove**, CEO, **QUOTIENT SCIENCES**
"Small and emerging biopharma companies continue to be responsible for more of the molecules making their way to market, as demonstrated by record FDA approvals in 2023. We remain positive for 2024 as we begin to see early signs of a return to increasing biotech industry funding to support the growing number of new molecules in the development pipelines."

**Nick Shackley**, SVP and CCO, **VERANOVA**
"The development of ADCs as a therapeutic category faced challenges initially, dating back to the 2000s. However, with advancements in targeting and aligning on a molecular level, it has evolved into a prominent modality across therapeutic categories. We anticipate this trend to persist, contingent on ongoing clinical proof points. The entire value chain, encompassing ADC linker warheads, conjugation, and fill-finish, is poised for growth."

**Jueon Kang**, Chief Planning and Information Security Officer,
**LOTTE BIOLOGICS**
"The biologics market continues its upward trajectory, representing a significant and ever-expanding segment of the pharmaceutical industry. However, amidst this growth, challenges such as drug shortages underscore the widening gap between manufacturing capacities and market demands. Nonetheless, innovation thrives, with new biologics approvals and Phase 3 trials underway, signaling a promising outlook for the industry."

**Axel Schleyer**, CCO, **CYTOVANCE BIOLOGICS**
"The demand for large molecule manufacturing, whether mammalian or microbial, continues to increase and grow faster than small molecule manufacturing. This is an unsurprising trend as large molecules are disease-alternating, not just symptom-treating."

**Michael Quirmbach**, CEO and President, **CORDENPHARMA**
"Bringing manufacturing to the US is key. However, China is never far from the conversation. There are exciting manufacturing capabilities that can be leveraged. On the CDMO side, the US does not have many large manufacturing firms that could absorb all this demand. Bringing manufacturing capabilities back to the US represents an opportunity, but one that will come at a price for all involved."

# Chemical Firms Helping Pharmaceuticals Go Green

## Sustainability, but not at the price of efficiency

In 2015, following the COP21 in Paris, over a thousand companies joined the Science-Based Target Initiative (SBTi), aimed at bolstering corporate action for limiting climate change. In life sciences, pharmaceutical products alone account for a significant portion of emissions, ranging from 20-30%, and, as over 90% of all manufactured products rely on chemicals, the sector has a crucial role to play in helping the pharmaceutical industry lower its carbon footprint. While most industries aim to be carbon neutral by 2050 according to SBTi goals, life sciences set the target for 2030. But while big pharma with deep pockets seems increasingly willing to make multi-million capex investments in sustainable solutions, they have made it clear that going green will not occur at the price of efficiency.

**Technological and regulatory changes**

Having been paid "lip service" for many years, sustainability and ESG goals are today fundamental for pharmaceutical firms. In the EU, which has had a head start in ESG practices compared with the US, ESG reporting is no longer a voluntary practice. This has repercussions for the many US-based pharma firms doing business in there: As of January 2023, the EU adopted the Corporate Sustainability Reporting Directive (CSRD), which requires EU and non-EU companies with activities in the EU to file annual sustainability reports. For specialty chemical firms, such regulatory shifts are not necessarily seen as hindrances. According to Lubrizol's Chief Sustainability Officer, Elizabeth Grove: "There is a presumption that as the pharmaceutical space is extremely regulated, there is very little you can do from a sustainability and ESG standpoint, but this could not be further from the truth."

For specialty chemical firms, the future will be a balancing act between sustainability and efficiency. The development of more efficient catalysts that can be recovered, and the implementation of purification techniques that can further reduce waste and improve the efficiency of the manufacturing process are great advances in sustainability. Another example is the use of biocatalysts (enzymes that can catalyze reactions with high selectivity and efficiency) that reduce the need for harsh chemicals and solvents. ■





Image by Sandralise at Depositphotos



## Marion Kuhn

Director of Sales Management
**BASF PHARMA SOLUTIONS**

**What solutions have been most in demand from BASF Pharma's US customers and what are the trends driving demand?**

Over the last number of years, we have seen that our customers are now searching for collaboration and joint innovation with a strategic partner, rather than just simply searching for a supplier. In the biopharma field, for example, we are actively collaborating with customers and the industry to address the challenge of reducing variability in raw materials. By utilizing high-quality processing aids and excipients, troubleshooting can be simplified, thereby accelerating product development.

Additionally, we actively work with customers to develop new processing aids and excipients for biopharma processes.

**Can you detail a couple of trends likely to drive the pharma ingredients segment of the pharma industry in 2024?**

In 2024 and even into the foreseeable future, we see digitalization and especially AI playing a key role not only in the manufacturing of pharmaceutical products, but also in many other areas like formulation development and regulatory compliance.

Increasing the speed of pharmaceutical development at every stage is becoming a key trend for our customers. To meet this need, BASF has developed several best-in-class digital tools, called Virtual Pharma Assistants (VPAs).

**What will be the main priorities for BASF Pharma Solutions in 2024?**

In 2024, BASF Pharma's priorities are to continue to listen to the customer, research investments that drive our competitiveness, and expand our product, digital, and service offerings.

For the biopharma industry, we are already continuing to build on our strong expertise in surfactant chemistry, chemical manufacturing, and biopharma application in order to broaden our portfolio of fit-for-use ingredients for Cell Culture, Downstream Processing, and Formulation. We are collaborating even more closely with industry leaders on tailor-made solutions for this emergent market. ■

## Elizabeth Grove

CSO
**LUBRIZOL**

**Can you discuss the importance of sustainability and ESG for both customers and investors and how Lubrizol balances sustainability with performance and efficacy?**

Sustainability in the pharma space primarily means efficiency in delivery, and that is what our products can bring to customers. Lubrizol introduced two new pharma excipient products in 2023 with great sustainability profiles: Apinovex, a polyacrylic acid excipient that enhances solubility and allows for the development of more efficient oral dosage forms with high, stable drug loading; and Apisolex, an amino-acid-based, solubility-enhancing excipient for injectable drug formulations. Apisolex can increase the solubility of hydrophobic APIs by up to 50,000 fold to effectively increase its bioavailability for better absorption. We are focused on supercharging the delivery of APIs so that we can increase the drug's efficacy, reducing the amount of excipient material needed, and ultimately enhancing sustainability for our customers.

In the manufacturing process, Lubrizol's carbomers and polycarbophils enable our customers to use less energy and water during processing. That's because they can be processed using dry compression, dry granulation, and wet granulation which still requires less water. Because the tablets can be smaller, our customers get a higher yield for the energy that is used. Lubrizol is also focused on sustainability in our manufacturing and we have set the target to reduce our combined Scope 1 and Scope 2 emissions by 20% by 2030.

**What will be the main challenges and opportunities for specialty chemicals companies operating in the life sciences space in 2024?**

Adding more regulation around sustainability to the existing regulatory requirements for life sciences applications will be one challenge. More governments are requiring companies to report their Scope 1 and Scope 2 GHG numbers and holding each party in the value chain accountable. So ensuring that we are ready for that level of transparency – up and down the value chain - will become more important. ■


NH


SV

## Neil Houston and Sibu Varghese

NH: Director Pharmaceuticals Americas
SV: VP Pharmaceuticals
**IMCD**

**What have been the main highlights for the company over the past 12 months?**
NH: In terms of developments in the Americas in 2023, IMCD established activities in Argentina; acquired Maprin in Chile; acquired Allianz in Columbia, a distributor focused on APIs; and acquired Sachs Chemical in Puerto Rico, which complemented our business in dry powder excipients with their specialty solvents portfolio.

SV: IMCD will focus on expanding our presence in the API, agrochemical synthesis, nutraceutical, and biopharma areas. We do not yet have a synthesis business line in the US and would want to bring that capability to the country. We have a base for nutraceuticals, but we would like to expand more into the ANI space.

**What is IMCD's growth strategy in the Americas moving forward?**
SV: IMCD will focus on expanding our presence in the API, agrochemical synthesis, nutraceutical, and biopharma areas, as we believe these are the segments where there will be great growth potential. We do not yet have a synthesis business line in the US and we want to bring that capability to the country. We have a base for nutraceuticals, but we would like to expand more into the ANI space.

**What will be the main catalyst for the life sciences industry in 2024?**
NH: Although Novo Nordisk recently announced its deal with Catalent, I believe most of the M&A activity we will see in 2024 will be in the biopharma arena. Recently there has also been less flight of manufacturing capacity from the US compared to a few years ago, and we hope to see the reshoring of central pharmaceutical ingredients gain momentum.

SV: Innovators are under price pressures, which might impact the viability of products and then the number of products coming to market. These price controls could be counterproductive to the reshoring of pharmaceuticals. ■

## Mike Radomsky

CEO
**CMC PHARMACEUTICALS**

**How did 2023 unfold for CMC Pharmaceuticals?**
2023 was a great year for us. We continued to build on the momentum from 2022 and made significant progress in various areas. Early in the year, a lab expansion project was completed and we continued to add new customers and technologies to our portfolio. As a result, we are confident that 2024 will be our best year yet.

One of the key highlights in 2023 was our continued collaboration with the Department of Defense, particularly on Nerve Agent Defense programs. We successfully expanded our portfolio of pharmaceutical countermeasures for the US government, which was a significant accomplishment for us.

**What will the DEA approval to handle Class II to V controlled substances mean for CMC going forward?**
In Mid-2023, CMC Pharma hit another milestone when we received DEA approval to handle Class II through V controlled substances. It allows us to legally handle a broader range of pharmaceutical ingredients, including opioid pain medications and sleep aids.

**Are there any specific chemistry trends or areas of demand that CMC is noticing in the industry?**
We have observed two notable trends in the industry: The repurposing of drugs for new indications, and the development of combination products. We have been actively involved in both areas.

**What are the key priorities for capitalizing on potential growth in 2024?**
The collective sentiment within the company is one of unwavering confidence that 2024 will surpass all previous years in terms of success and achievements. Looking ahead, we are strategizing to expand our service portfolio beyond laboratory services. ■





# Lab Services Ramping Up

## No slowdown in sight for labs

In the wake of the COVID-19 pandemic, the significance of laboratory services has been brought to the forefront like never before. These facilities have served as the backbone of public health infrastructure, facilitating diagnostics, monitoring, and research critical for managing and combating the spread of infectious diseases. With funding and innovation programs almost back to pre-pandemic levels, US pharma firms will be looking for the best lab partners to fully leverage their healthy R&D pipelines, as poor laboratory practice yields compliance issues, increased downtime, and delayed product introductions.

As the drug pipeline broadens with the post-pandemic recovery, pharma firms need more early-stage partners to formulate drugs and have their products meet FDA requirements, before thinking about large-scale manufacturing. Beyond diagnosis, laboratory services are crucial for monitoring disease trends and epidemiological patterns. By analyzing data collected through testing and surveillance programs, laboratories provide valuable insights into the prevalence, transmission dynamics, and geographical distribution of diseases. This information is indispensable for public health authorities in devising targeted interventions, allocating resources effectively, and implementing preventive measures to curb disease spread.

Regulators tend to keep pharma executives on their toes. As technologies change, regulations change. Not only is the pharmaceutical industry amongst the most regulated sector, but it is one where regulatory changes are frequent and numerous. Maintaining regulatory compliance is key to patient safety, and this starts in the lab. Trends in FDA-drug approval suggest a recent shift in the way drugs are formulated, particularly when it comes to the development of combination products. For both cost and efficiency purposes, pharma firms have favored reformulating existing drugs rather than restarting the chemistry process completely to create entirely novel ones. Mike Radomsky, CEO of lab contractor CMC Pharmaceuticals, expanded on the development of innovative dosage forms in the API space: "There is growing interest in combination products that incorporate multiple active ingredients into a single formulation."

The emergence of novel pathogens – caused by endemic factors such as population aging or exogenous ones like climate change – pose a constant challenge to global health security. Laboratory services serve as early warning systems, capable of rapidly detecting and characterizing emerging infectious threats. By leveraging advanced molecular techniques, such as whole-genome sequencing, laboratories can identify new pathogens, track their evolution, and assess their potential for causing widespread harm. India-based ZIM Pharmaceuticals is currently developing "New Innovative Products (NIP)" using its proprietary technology platforms, including molecules that may be crucial to respond the emergence of new pathogens. Anwar Daud, managing director, said: "Topics to monitor will be changing disease profiles and the emergence of 'cures' for chronic conditions like diabetes."

As biotechs secure funding and advance their drug development programs, the demand for lab services is only expected to increase. Laboratories will remain key to providing formulation development, stability studies, and process scale-up services to ensure that the drugs arriving on the market are safe for public health. ■

**Chad Rohrer**
Global President
**ASP**

> "[ESG] is a topic at the forefront of discussions. There is a delicate balance between implementing necessary changes without disrupting critical operations, but also a recognition that action is needed."

Image by alexraths at Depositphotos

# New Technologies

> I would describe 2023 as the year of GenAI, with widespread adoption and discussion surrounding its potential across all levels of organizations.

**Rohit Vashisht**
Co-Founder and CEO
**WHIZAI**

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Image courtesy of Cold Chain Technologies (CCT)

# Genome Editing Technologies: Beyond Science Fiction

## Conciliating science and ethics

Two decades after the completion of the Human Genome Project, a 13-year international effort to discover the complete set of human genes and make them accessible for further biological study, biomedicine is now entering a new uncharted territory. Today, genetic mutations can be reversed thanks to genome editing technologies. Today, CRISPR technology is employed in over 20 clinical trials that span diabetes, cardiovascular diseases, blood, immune, and other rare disorders.

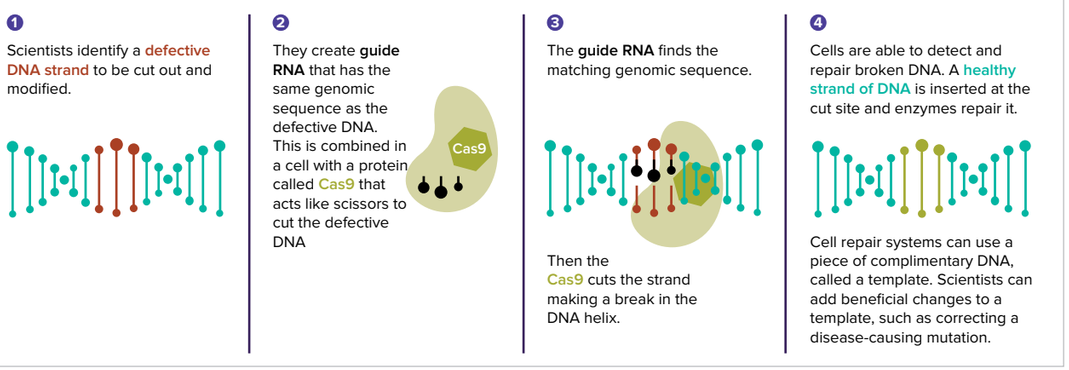
**2023, a milestone year for gene editing**

For genome editing, 2023 will be remembered as the year during that the FDA approved the first-ever CRISPR treatment in the US. Only 11 years after Jennifer Doudna and Emmanuelle Charpentier first described the game-changing technology in a scientific paper, the FDA gave its green light to Vertex and CRISPR Therapeutics' Casvergy to treat sickle cell disease. This approval sparked a wave of innovation in the first half of 2024, with scientists now working on improving the delivery to make the technology more accessible. Keeping sickle cell disease as an example, Vertex highlighted the complexities of transferring the treatment to Africa, as the regimen involves a hospital stay, with doctors removing the bone marrow, editing the cells, and then transplanting them back.

Recent months also saw a collaborative impetus amongst big pharma and technology companies to democratize gene editing. In 2022, technology leader Illumina and Nashville Biosciences launched a ground-breaking "Alliance for Genomic Discovery" aiming to accelerate the development of therapeutics through large-scale genomics and the establishment of a preeminent clinical genomic resource. As of 2024, eight of the pharma heavyweights – AbbVie, Amgen, AstraZeneca, Bayer Bristol Myers Squibb (BMS), GSK, Merck, and Novo Nordisk – have agreed to collaborate in the generation of 250,000 whole-genomes for discovery purposes. Ashley Van Zeeland, VP corporate and business development at Illumina, explained: "We are increasingly seeing companies deeply incorporating genomics throughout multiple, different, aspects of their business – from research and discovery applications through diagnostic and therapeutic development. Genomics is integral to delivering on the promise of precision medicine." ■

### How DNA defects can be edited out

**The Crispr-Cas9 technique can fight sickness at its source**




Source: Financial Times Research



Image by vitstudio at Depositphotos



## Ashley Van Zeeland

VP Corporate and Business Development
**ILLUMINA**

**How crucial are partnerships to building the genomics ecosystem?**
We collaborate to expand access to next-generation sequencing (NGS), to pioneer new applications and technologies, and more. This includes the creation of large datasets for discovery purposes to jointly develop the next, most meaningful clinical applications that can benefit from our technology. In 2022, Illumina and NashBio launched the Alliance for Genomic Discovery aiming to accelerate the development of therapeutics through large-scale genomics and the establishment of a preeminent clinical genomic resource. Member companies aim to identify disease associations and targets for intervention by analyzing whole-genome sequence data derived from Vanderbilt University Medical Center's BioVU, a biobank of more than 250,000 de-identified human DNA samples and associated longitudinal, structured, and de-identified clinical data. This is an innovative new model for the ecosystem and benefits both the industry and the biobank by unlocking the value of the rich information through a consortium approach. The significant scale of this project reflects the value of genomics for various applications going forward. We are increasingly seeing companies deeply incorporating genomics throughout multiple, different, aspects of their business. Genomics is integral to delivering on the promise of precision medicine, and we continue to improve our technologies to enable our customers to get the most out of their genomic applications. ■

## Lauren Linton

Executive Director
**UC SANTA CRUZ GENOMICS INSTITUTE**

**Can you introduce the Genomics Institute?**
As we generate amounts of genomic data, the Genomics Institute is working to apply this data to real-world problems. The Institute has human health applications, community health applications, and environment and conservation applications. We also have strong DEI initiatives in genomics research and education, with six separate mentorship and training programs that cater to students from underrepresented backgrounds. It is a great turning point; we have gotten so good at sequencing genomes that it is a common language now, and we must start focusing on function.

**What is the latest in genomics, and how can genomics have an impact on human society today?**
We are now driving the "pangenome project," or pangenomics, where the goal is to build the true diversity of human representation in a family of complete reference sequences. By doing that, we increase the value, power, and relevance of human reference genomics, make it easier to look at genetic conditions that vary based on ancestry, and ultimately derive a more complete human health representation. New technologies are enabling the idea of a pangenome, which a few years back would have been beyond our capacity. You need more diversity in the samples themselves used for sequencing and to depict that computationally to see where the differences are located. ■

## Karen Lackey

CEO
**X-CHEM**

**Can you provide an overview of X-Chem?**
X-Chem is a platform company dedicated to pioneering innovative technologies, primarily in the realm of small molecule drug discovery acceleration.

**Can you discuss X-Chem's DNA-encoded library technology?**
What sets X-Chem apart is our focus on top-notch library designs and the ability to conduct complex chemistry in the presence of DNA, resulting in billions of compounds per target for screening. The quality, cost and cleanliness of our data also make them highly compatible with AI technologies, offering more than just hit identification. To simplify, the process involves screening compounds tagged with DNA against a protein target, allowing for various selection strategies to identify desired ligands. This can range from discovering novel binding modes to achieving selectivity over mutants or other related proteins. The fact that X-chem has the expertise to translate this mass of DEL screening data into actionable chemistry design and test iterations means that our clients get more data, faster, and accelerate their own drug discovery pipelines. The assessment of AI-powered drug discovery platforms within the life sciences industry in the US is multifaceted. At X-Chem, we have practically incorporated AI into our drug discovery pipeline, focusing extensively on optimizing the properties of molecules. ■

# Assessing the Role of AI in Drug Discovery

## From hype to reality?

AI (Artificial Intelligence) has long been used by the life sciences industry, but it appears to have reached an inflection point in 2023. More than a sudden attraction to future-facing innovations (in an industry that has historically been slow to adopt novelties), drugmakers are facing mounting pressures to discover drugs and bring them to market faster and cheaper. AI therefore appears as a lifeline to help overcome long-standing challenges like high failure rates and lengthy development timelines. The previous year saw a stampede of startups coming into the life sciences industry with AI and ML (Machine Learning) tools that are (finally) fit for purpose, leading the AI market in healthcare and life sciences to double in size to become valued at US$20 billion in 2023 compared with US$11 billion in 2021. In their quest for efficiency, accuracy and speed, 2023 saw major drugmakers betting on AI to accelerate drug development. And this trend is here to stay.

**From the drawing board to the Boardroom**

From recognizing the potential to realizing it, Big Pharma and other large biotechs shifted AI from the drawing board to experimenting with it for their lead candidates. Many of the executives interviewed have identified the acquisition and implementation of innovative products (such as AI platforms) as key strategic objectives going forward. Sanofi launched its own AI app in 2023, to become what CEO Paul Hudson called, "the first pharma company powered by artificial intelligence at scale". Roche plans to build its own AI tool, dubbed RocheGPT. Pfizer, AstraZeneca and Boehringer Ingelheim all made hundred-million-dollar investments in target and lead identification. AI-powered discovery tools have matured to the point that leading biotechs are confident leveraging them for their lead assets. CAR-T-focused Arcellx is increasingly using AI at the higher levels of drug discovery in its mission to revolutionize cell therapy. Its CBO, Aileen Fernandes, explained the potential: "We are actively considering how it can augment our efforts in drug development and bolster our pipeline. We are particularly seeing its potential in target identification, especially concerning synthetic domains and optimized targets."

Perhaps the most harrowing example of AI's growing importance in the life sciences industry is its transition from the drawing board to the Boardroom. Nearly every executive mentioned AI during their JP Morgan Conference speech in January 2024, and over a dozen interviews with pharma and biotech executives suggest that AI is now CEO territory, compared with a few years back. Rohit Vashisht, co-founder and CEO of WhizAI, recalled the growing involvement of C-level executives: "Previously, AI was often perceived as complex and esoteric, hindering widespread adoption across organizations. C-level executives now recognize AI's potential to drive innovation, enhance operational efficiency, and gain a competitive edge in the market."

An AI-designed FDA-approved drug remains unrealistic in the near future, however, AI will undoubtedly make more strides in optimizing the properties of molecules, leveraging predictive data, and helping drug candidates meet target product profiles. But integrating AI in drug discovery is a complex endeavor, not least given the stringent regulations. When asked about the timeline for the approval of an AI-generated drug, Karen Lackey, CEO of small molecule drug discovery acceleration platform and DNA-encoded library (DEL) technology pioneer X-Chem, forecasted: "I do not foresee it happening until we reach the era of quantum computing. Currently, human intervention is necessary to set up and interpret data, ask pertinent questions, and gather necessary information for an Investigational New Drug (IND) application."

**Reinventing with GenAI**

There is no doubt that GenAI (Generative Artificial Intelligence), notably deep learning models and networks, is revolutionizing how pharma firms can develop drugs and bring them faster to market. In recent years, the business case for GenAI has moved from one of interrogation to one of democratization in adoption; a McKinsey report of June 2023 highlighted that "the fastest adoption of generative AI is in high tech, banking, pharma, medicine and life sciences."

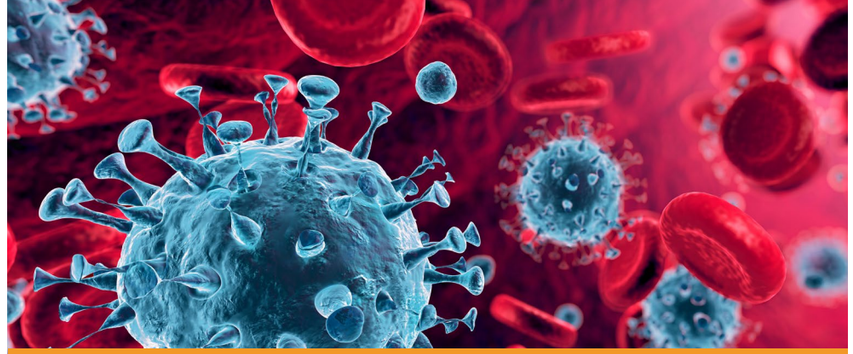
2023 was a pioneer year for GenAI across the life sciences spectrum: Biotech Adaptyv Bio leveraged GenAI to launch a protein engineering foundry to develop new medicines, and University of Central Florida researchers introduced an AI-assisted technology for drug-target affinity projections. Insilico Medicine developed a drug candidate using a tenth of the usual cost and a third of the time. To sum up the high-impact end, executives can leverage GenAI for faster drug molecular design (up to 25% reduction in production period, according to a BCG report), accelerated clinical development that could cut down writing time by a third, and enhanced quality management. In many ways, 2024 and 2025 will be about moving from hype to reality for GenAI's applications in life sciences, and building trust amongst regulators, innovators, and pharma executives.

We are not yet at the dawn of an AI-discovered drug. Pharma companies are more likely to leverage the tool to augment the human scientific experience, rather than to replace it. When asked if AI itself could discover drugs, ChatGPT, the most popular artificial intelligence app, humbly answered: "While AI offers promising opportunities in drug discovery, it is important to note that it is not a replacement for human expertise but rather a tool that can enhance human capabilities in the complex process of discovering and developing drugs. Collaboration between AI systems and scientists remains crucial for successful drug discovery." ■



Image by Siarhei at Adobe Stock





# Viruses Are Back: Humanity and the Life Sciences Industry

## Reaction to action

Some infectious diseases that were once sidelined are now resurfacing and posing an emerging threat. Indeed, one side argues that it is the improvements in illness detection that are causing a perceived rise in outbreaks. The other highlights the changes in societies, the environment, and climate as factors that are driving new viruses to emerge, and old ones to move to new places. The outcomes of this debate will be significant for the survival of the human species. Recent history and current events show that pandemics and climate change are the biggest threats to one of Earth's most fascinating mammals.

Why are ethical debates about humanity's relationship with viruses relevant in a business intelligence piece? Because the pandemic has caused the life sciences industry to realize it had to move from a reactionary stance to a proactive one to address present and upcoming challenges. The investment community – public players, venture capitalists, private equities for whom a short-term investment in the industry amounts to five years – has, perhaps, lost sight of the greater mission of an industry that is like no other. Keeping patients in sight is paramount, not least to Interbiome's CEO Roger Erickson, who stated: "There is a growing divide between the mission-oriented uses for inventions and the investment and policy communities. In the bio-pharma world, people are getting lost in molecular mechanisms, biomarkers, and platforms, and often are disconnected from the actual diseases targeted and the populations the methods are being developed for."

It is hard to deny that humans' relationship with the Earth is not to some extent the cause of some changes we are currently experiencing. Every year, we cut down 15 billion trees and over 20 million hectares of forest, bringing us closer to other animals. Their viruses spill over to us, ours to them, and infectious diseases can spread faster. The interconnectivity of our world also shows that we can bring disease from one capital to another in less than 24 hours. In 2023, for the first time in decades, malaria cases in Florida baffled experts, and dengue made its way to the Western hemisphere. And the outlook points towards a sustained spread of tropical viruses to temperate zones. Speaking to the impact of climate change, population increase, urbanization, and deforestation on human biology, Trevor P. Castor, president and CEO of the biotech Aphios, which means "virus-free"' in Greek, explained: "The industry will have to adapt by either creating better and quicker vaccines, or we will have to be able to rid those new viruses quickly from biologics and biotechnology products which can be a carrier of viruses."

In the long term, a proactive stance is a profitable option for the industry and society. While more studies about the COVID-19 pandemic crop up almost daily, it appears clear that preventing the spread of the virus would have been less costly on the industry and society than retroactively treating. For Daniel Prince, CEO of Prince Sterilization Services, there ought to be a mindset shift that focuses on what we can do to prevent sickness and disease: "I hope to see that the pharmaceutical industry will shift its focus from treatment to prevention so that as a human race we will not suffer certain maladies, diseases, illnesses, and cancers and then recover from them, but rather, we will stay healthy and can expect a longer lifespan because we have learned from the past."

Earlier in 2023, the WHO warned that dengue and chikungunya were spreading beyond their geographical zones of transmission. As of mid-2024, half of the population is at risk of the diseases, according to GAVI, the Vaccine Alliance. The rapid pace of climate change exceeds the ability of both humans and animals to adapt. This not only heightens vulnerability to health issues but also facilitates the easier spread of viruses, bacteria, and parasites to new territories previously unaffected. Indeed, a 2022 study published in Nature Climate Change revealed that out of 375 infectious diseases examined, 218 (58%) had been exacerbated by climate change.

A proactive stance in tackling climate change and the population's impact on the environment could also yield opportunities for seasoned life sciences VCs. In December 2023, RA Capital, one of the largest VC funds with investments in over 290 biotechs, created Planety Health, a fund dedicated to climate tech wave investments. According to a funding partner, the idea stemmed from the realization that, despite backing biotechs that would produce successful therapies across the spectrum, people would still be dying by the millions from the effects of pollution.

Biotechs have been using viruses for good for centuries. Domesticating cellular hijacker viruses to make them our allies is a way forward for the industry. Beyond that, investors, executives, and scientists alike ought to grasp the generational challenge posed by pandemics and climate change to make the interests of shareholders and that of patients collide. As the world finishes recovering from one of its most widespread pandemics in history, and braces for more viral-related challenges, the life sciences industry is on a mission to, as proactively as possible, keep humanity safe. ■

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| COMPANY | WEBSITE | COMPANY | WEBSITE |
|---|---|---|---|
| AGL | https://www.theaglgroup.com/ | Meteoric Biopharmaceuticals | https://www.meteoricbiopharma.com/ |
| Allucent | https://www.allucent.com/ | MPM Capital | https://mpmbioimpact.com/ |
| Aphios | https://aphios.com/ | Nasdaq | https://www.nasdaq.com/ |
| Aragen Life Sciences | https://www.aragen.com/ | Nivagen | https://www.nivagen.com/ |
| Arcellx | https://www.arcellx.com/ | Noramco | https://www.noramco.com/ |
| Ascendia Pharmaceuticals | https://ascendiapharma.com/ | OTC Markets Group | https://www.otcmarkets.com/ |
| Ascidian Therapeutics | https://ascidian-tx.com/ | Pennsylvania Biotechnology Center (PABC) | https://www.pabiotechbc.org/ |
| Advanced Sterilization Products (ASP) | https://www.asp.com/en-us | Panavance Therapeutics | https://panavance.com/ |
| AtkinsRéalis | https://www.atkinsrealis.com/ | Particle Sciences Inc. an Agno Pharma Company | https://particlesciences.com/ |
| Avara Pharmaceuticals | https://www.avara.com/ | PBOA | https://pharma-bio.org/ |
| Axplora | https://www.axplora.com/ | PCI Pharma Services | https://pci.com/ |
| BASF | https://www.basf.com/ | Pfizer CentreOne | https://www.pfizercentreone.com/ |
| Biocom California | https://www.biocom.org/ | Pharma.Aero | https://pharma.aero/ |
| BioNJ | https://bionj.org/ | Piramal Pharma | https://www.piramalpharmasolutions.com/ |
| ChemPacific Corp. | https://www.chempacific.com/ | Prince Sterilization Services | https://princesterilization.com/ |
| Citi Commercial Bank | https://www.citigroup.com/ | Procos SPA | https://www.procos.it/ |
| CMC Pharmaceuticals | https://www.cmcpharm.com/ | PwC | https://www.pwc.com/ca/en/industries/healthcare.html? |
| Cold Chain Technologies | https://www.coldchaintech.com/ | QB3 | https://qb3.org/ |
| Coral Drugs | https://coraldrugs.com/ | Quartic.AI | https://www.quartic.ai/ |
| CordenPharma | https://cordenpharma.com/ | Quotient Sciences | https://www.quotientsciences.com/ |
| CurTec | https://www.curtec.com/ | RLDatix Life Sciences | https://rldatix.com/en-nam/ |
| Cytovance Biologics | https://cytovance.com/ | SAI Life Sciences | https://www.sailife.com/ |
| Dipharma Francis | https://www.dipharma.com/ | Samsung Biologics | https://samsungbiologics.com/ |
| EisnerAmper | https://www.eisneramper.com/ | Sever Pharma Solutions | https://www.severpharmasolutions.com/ |
| Emirates SkyCargo | https://www.skycargo.com/ | Shackelford Pharma | https://www.shackelfordpharma.com/ |
| Enzene Biosciences | https://www.enzene.com/ | Signet Healthcare Partners | https://www.signethealthcarepartners.com/ |
| Etihad Cargo | https://www.etihadcargo.com/en | Simtra BioPharma Solutions | https://biopharmasolutions.baxter.com/ |
| EY USA | https://www.ey.com/en_us/industries/life-sciences | SK pharmteco | https://www.skpharmteco.com/ |
| Fisiopharma | https://www.fisiopharma.com/en/home-en/ | SkyCell | https://www.skycell.ch/ |
| Flamma Group | https://www.flammagroup.com/ | Stevanato Group | https://www.stevanatogroup.com/en/ |
| Formulated Solutions | https://www.formulatedsolutions.com/ | Symeres | https://symeres.com/ |
| Grand River Aseptic Manufacturing (GRAM) | https://www.grandriveraseptic mfg.com/ | Systech | https://www.systechone.com/ |
| Illumina | https://www.illumina.com/ | Thermo Fisher Scientific | https://www.thermofisher.com/ |
| IMCD | https://www.imcdgroup.com/ | Tosk | https://tosk.com/ |
| INCOG | https://www.incogbiopharma.com/ | Trifarma | https://www.trifarma.it/ |
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| Intermed | https://www.intermedindia.com/ | Uquifa Group | https://uquifa.com/ |
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| LaVoie Health Science | https://lavoiehealthscience.com/ | West Pharmaceutical Services | https://www.westpharma.com/ |
| Lead Candidate | https://www.leadcandidate.com/ | Whiz.AI | https://www.whiz.ai/ |
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| Lubrizol | https://www.lubrizol.com/ | Xontogeny | https://xontogeny.com/ |
| Marinomed | https://www.marinomed.com/en/ | Ymmunobio | https://www.ymmunobio.com/ |
| MassBio | https://www.massbio.org/ | Zim Laboratories | https://www.zimlab.in/ |
| MBrace Therapeutics | https://mbracetrx.com/ | | |



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We would like to thank all the executives and authorities that took the time to meet with us.

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