

INVEST MENT REPORTS

published in

Newsweek



figures in the industry. Debbie Hart, president of BioNJ, the life sciences trade association for New Jersey, shared how the state is now at the forefront of cell and gene therapy. One example she cites is Cellares, which, with its state-of-the-art smart factory already established in New Jersey, recently secured a crucial FDA Advanced Manufacturing Technology designation for its cell therapy manufacturing platform, which can greatly improve access to these treatments. On the West Coast, Joe Panetta, who stepped down in December 2024 after 25 years at the helm of Biocom California, looks back with fulfillment as his organization was key for the transformation of California into a global biotech hub. Simply considering Amgen's breakthrough last year in the treatment of

lung cancer, or Gilead's strides in HIV, should suffice to convince the reader of California's significance for global health.

Taken together, the examples of New Jersey and California convey an important message. Much of the discourse around life sciences may appear to have a futuristic streak: We will cure this or that terrible disease. We will live to a hundred. We will come up with a cheap, miraculous medicine. The future tense can be tiring—for we journalists, but most of all for patients, whose distress is very much contemporary. Yet, stories like the ones we tell in this edition must serve to highlight the enormous progress that the industry is making—not years from now, but today.

IN THIS REPORT...



MATT SAUSE | CEO, ROCHE DIAGNOSTICS

We can perform comprehensive genomic profiling to uncover the molecular basis of a tumor. This allows doctors to provide tailored treatments. Over time, this will enable us to move to a future where we understand the molecular drivers for cancer and can deliver truly personalized health care.



DEBBIE HART | PRESIDENT & CEO, **BIONJ**

A hallmark of New Jersey's success is its continued leadership in FDA drug approvals. In 2023, more than 50 percent of all new drug approvals came from companies with a footprint in the state, underscoring its leadership in advancing medical innovation.



BRENT RAGANS | PRESIDENT, FERRING PHARMACEUTICALS U.S.

Ferring aims to more than double the size of its U.S. operation in terms of revenue within the next three to five years. After a period of strong growth, the company's innovations in areas like bladder cancer, the microbiome and reproductive medicine have set the stage for further expansion.



JACOB THAYSEN | CEO, ILLUMINA

Whether it is providing clarity for families dealing with rare genetic disorders or enabling rapid and precise cancer diagnoses, our goal is to ensure patients receive the answers they need when they need them.

READ THE FULL INTERVIEWS



GE HealthCare

Using AI, data and advanced technologies to realize the promise of precision care.

© 2025 GE HealthCare. GE is a trademark of General Electric Company used under trademark license. All rights reserved



In cell and gene therapy, crucial for treating tough conditions like cancer, cell quality and consistency are vital. PHCbi's precision technology aids researchers by visualizing cell metabolism in real time, advancing and safeguarding scientific research.

KYOKO (KAY) DEGUCHI | PRESIDENT & CEO, PHC GROUP



READ THE FULL INTERVIEW

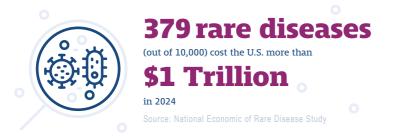
Hope resides in the fringes

When we published our 2024 report, children suffering from Leber congenital amaurosis 4 (LCA4)—a severe inherited retinal dystrophy—had only hope that one day they might see the world. Today, thanks to an investigational gene therapy, we know that the 11 kids who participated in the trials can, for the first time in their lives, discern a toy, recognize a human face and even spot a grain of sand. The biotech behind this achievement is MeiraGTx, which has now filed its therapy for approval under exceptional circumstances in the U.K., which would expedite the process.

Stories like that of MeiraGTx illustrate the transformative power of gene therapies on patients. More broadly, they highlight the potential for rare diseases R&D to emerge as the principal driver of therapeutic innovation. "Rare diseases have become a critical area for exploring new treatment modalities because, in many cases, there is no existing therapy, or even a model. For patients who have no options, innovative approaches are important," shares Marc Dunoyer, the CEO of Alexion, the rare diseases subsidiary of AstraZeneca. Ironically, the very severity and uncommonness of these illnesses can also be a blessing, as it allows for bolder approaches by both researchers and regulators. Moreover, rare disease drugs have historically had higher approval success rates compared to other drugs. The Tufts Center for the Study of Drug Development found that orphan-designated drugs had a Phase 1-to-approval success rate of 17 percent, compared to 7.9 percent for non-orphan drugs. Benefiting from faster approval pathways and enhanced regulatory incentives, entrepreneurs in the field face better odds of innovating successfully.

And when they do, the implications of their therapies go far beyond their original target. "Many of the advances seen today, such as gene editing and RNA-based therapies, originated in rare disease research before moving into larger indications," says Dunoyer. Arcturus Therapeutics, for instance, is addressing cystic fibrosis via a new delivery mechanism. "Our cystic fibrosis program is a prime example, where the ability to inhale mRNA safely could have a huge impact on the pharmaceutical industry. The rare disease field offers a shorter regulatory pathway to approval and a higher likelihood of success. This makes it an attractive space for evaluating next-generation technologies like mRNA therapeutics,' shares Arcturus' CEO, Joseph Payne, as the company is expecting results from its Phase 2 trials in 2025.

Similarly, the CEO of MeiraGTx, Alexandria Forbes, believes the biotech's delivery approach will have broad effects: "Our strategy involves local delivery with small doses, which has shown effectiveness in diseases beyond retinal disorders, including conditions like Parkinson's." We find the same pattern in the story of Ultragenyx, which, with its four approved therapies to date, is a reference in the field. "Rare diseases serve as unique biological models, providing a deeper understanding of the biological processes that underlie a wide range of conditions. For instance, our work with galactosialidosis led to an interesting finding: the protease









We've made a major discovery and named a novel stem cell targeting COPD, the third leading cause of death. Animal studies show full lung regeneration in 10 days. Phase I trials are now underway to advance this off-the-shelf allogeneic cell therapy platform.



ABDULKADER RAHMO | CO-FOUNDER, PRESIDENT & CSO, **SMSBIOTECH**

READ THE FULL INTERVIEW

• involved in this condition also affects amyloid buildup, which is central to Alzheimer's disease. This discovery has the potential to lead to a gene therapy approach for Alzheimer's, providing a new avenue for treatment," Emil Kakkis, Ultragenyx's CEO and founder, says. This year, his company is anticipating its first gene therapy approval. Those who anticipate it even more, no doubt, are all the kids who suffer from Sanfilippo syndrome—an inherited metabolic disorder that causes progressive neurological degeneration and developmental delays, due to the body's inability to break down certain sugars. "It is typically diagnosed in children between 2 and 6 years old, and by the age of 10 or 12, they often become bedridden and may pass away as early as the second decade of life," Kakkis says. Ultragenyx's gene therapy is potentially life-changing.

Incyte, with a market cap of over \$11 billion at the time of writing, can easily be considered a biotech that "made it." We asked its CEO, Hervé Hoppenot, what is behind the company's achievements: "Our primary focus has always been on innovative science. Not all science is innovative;



BRIAN GOFF | CEO, AGIOS PHARMACEUTICALS

The insights we have gained in understanding the glycolytic pathway and its role in red blood cell metabolism have directly contributed to the development of therapies for rare blood disorders, like PKD, thalassemia and sickle cell disease.



MARK VINEIS | COUNTRY PRESIDENT, NOVARTIS CANADA

While we respect the procedural steps, we believe that for products treating acute diseases, especially those with no clinical alternatives, the process should prioritize the patient rather than the procedure. Unfortunately, we have not seen significant improvements in this regard in Canada.

READ THE FULL INTERVIEWS

the true challenge lies in exploring uncharted territories to uncover the unknown," he tells us. Hoppenot is genuine about the company's culture of venturing into "the unknown." Incyte has consistently pioneered new treatments, such as the first FDA-approved products for myelofibrosis and polycythemia vera. Presently, Incyte is working on addressing unmet needs in oncology and inflammation and autoimmunity (IAI).

Another European company, argenx, with its stock up by more than 20 times since its IPO in 2017, has equally been walking on untrodden paths. The biotech's name comes from the Greek myth of the Argonauts—an ambitious team on a bold journey. "In biotech, many companies push new technologies onto existing disease targets, but we believe in discovering new biology," argenx's CEO Tim Van Hauwermeiren tells us. The company's work is centered on finding novel ways to modulate the immune system to address autoimmunity. The success of argenx has so far been driven by Vyvgart, a medication approved in 2021 for generalized



myasthenia gravis (gMG). "About 40 percent of gMG patients in our trials became completely symptom-free, while 80 percent experienced a clinically meaningful improvement in muscle strength. Importantly, there were no significant safety concerns. In real-world use, more than 5 percent of patients report living symptom-free, essentially regaining the life they had before diagnosis." Vyvgart has since been approved for two other diseases (in the U.S. and in Japan). But the potential for broader effects is enormous: "This opens the door to treating over 100 autoimmune diseases, with three indications already approved and many more in development," concludes Van Hauwermeiren. When asked what message he has for other European biotech leaders, argenx's CEO is clear: "Ambition is key. Too often, European biotech companies sell their assets or exit early instead of going all the way. In the U.S., we have seen more companies push through to build long-term value."

Often, the best way for insights from rare diseases to be passed on to a broader range of therapeutics is via mergers and acquisitions or other forms of collaboration with bigger pharmaceutical companies. Novo Nordisk, which recently acquired Dicerna Therapeutics, a rare diseases biotech that developed RNAi therapies, demonstrates the value of a healthy biotech-pharma ecosystem. "Since integrating Dicerna, we have expanded our focus beyond rare diseases to include more prevalent conditions, such as diabetes, obesity and cardiovascular diseases. These are major global health challenges where RNAi has the potential to provide transformative treatments," says Novo Nordisk's SVP, Jacob Petersen. To our question about his definition of success, Petersen replies: "Success, to me, means that we can bring these groundbreaking therapies to patients at scale, making their lives easier and improving disease management. With RNA technologies, some treatments could even become one-time therapies with lifelong effects."

Last year at the Biocom California Global Life Science Partnering & Investor Conference in San Diego, it was not clear whether SMSbiotech's new type of stem cell therapy would ever see human clinical trials. As we reached back to Abdulkader Rahmo, the cofounder and president, we were pleased to find out that, after more than a decade of work, the company's therapy for chronic obstructive pulmonary disease (COPD) is commencing Phase 1 clinical trials in Australia. "The approval [to begin clinical trials] itself is a significant achievement because the cells we



Al is revolutionizing medical imaging. The possibilities are transformative, and we are excited about what lies ahead. By combining data from multiple modalities—imaging, lab results and genetic information—into integrated applications for clinicians, we're pushing the boundaries of precision care.



READ THE FULL INTERVIEW



Historically, our emphasis has been on diagnosing cancers, whether they are blood-based or solid tumors. However, we are strategically shifting our focus toward therapy selection, particularly within precision medicine, where we identify unique biomarkers and gene expressions to match patients with the most effective treatments.



WARREN STONE | PRESIDENT & CHIEF OPERATING OFFICER, NEOGENOMICS

READ THE FULL INTERVIEW

are working with are largely unknown to the scientific community and regulators," Rahmo tells us. Small Mobile Stem (SMS) cells, the backbone of this therapy, stimulate the body's own stem cells instead of building foreign tissue. One of the expected benefits is an increased safety profile compared to traditional stem cell therapies. The first safety data is to be announced about four months into the trial.

Where oncology finds its compass

It is common knowledge by now that cancer cannot be deemed a single disease. Yet even within a cancer variant, medicine is increasingly differentiating, to the point of being personalized. Last year we explored predominantly one aspect of personalized medicine—cell therapies. This year we turn to other approaches, notably, the growing convergence of diagnostics and treatment.

To treat in a personalized manner, one must diagnose in the same vein. "Today, when a patient is diagnosed with cancer, it is no longer just about chemotherapy. There is a wide range of biomarkers and targeted therapies that can be used independently or in combination with traditional treatments. Matching a patient's specific cancer profile with the right treatment options is essential for achieving the best outcomes," shares the president and COO of NeoGenomics, Warren Stone. It is clear that the future of cancer care will rely heavily on innovations in diagnostics. The trend is of convergence between diagnostics and treatment into a single discipline. "This approach not only ensures the treatment is more effective but also minimizes invasiveness and toxicity. As a result, both diagnostics and precision medicine are becoming integral to modern cancer therapy," Stone adds.

What you see is what you treat

Perhaps the forerunner in this confluence is the field of theranostics—whereby radioisotopes are used to first image a patient's tumor for diagnostics and then therapeutically treat it. GE HealthCare, traditionally known for its medical imaging, is actively expanding into this area. "While the theranostics market is still developing, its potential is immense. With over 20 new drugs expected in the next five to 10 years, we are optimistic about its growth and impact on patient care worldwide,"



When it matters, it matters who you ask.

2025 NeoGenomics Laboratories, Inc. neogenomics.com

At Veracyte, we prioritize the generation of clinical data. The more data we have, the more insights and evidence we can generate, which drives adoption, reimbursement, inclusion in clinical guidelines and continued innovation.

MARC STAPLEY | CEO, VERACYTE



READ THE FULL INTERVIEW

shares GE HealthCare's president and CEO of imaging, Roland Rott. The company has introduced new devices and updated traditional ones to become an integral part of that trend: "For example, in cancer care, our PET imaging system, Omni Legend, is optimized for diagnostic radioisotopes that visualize certain tumors, so specialists can confirm this cancer is treatable using targeted radionuclide therapies, which are known for precisely attacking the cancer while sparing healthy tissues," Rott illustrates.

In addition to limited toxicity, theranostics address overtreatment, which is a far too common problem. Many treatments are administered to patients who lack the molecular target needed for the therapy to work. "The fundamental principle of theranostics is: What you see is what you treat.' If the imaging scan does not detect a target on a patient's tumor, then the therapy is not administered, thereby avoiding unnecessary treatment," stresses Manfred Rüdiger, the CEO of Ariceum Therapeutics, a German biotech company. This has the added benefit of considerably cutting health care costs: "Imaging is relatively inexpensive compared to treatment—approximately \$1,000 for imaging versus \$100,000 for therapy. If only 10 percent of scanned patients are eligible for treatment,

Powering
Next-Gen
Molecular Assays with
Raw Materials & Services
that Drive
Workflow
Innovation

Reduce complexity.
Enhance Stability.
Improve assay sensitivity.

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services
Innovation

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services
Innovation

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services
Innovation

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services
Innovation

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services
Innovation

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services
Innovation

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services
Innovation

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services
Innovation

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services
Innovation

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services
Innovation

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services
Innovation

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services
Innovation

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services
Innovation

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services
Innovation

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services
Innovation

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services
Innovation

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services
Innovation

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services
Innovation

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services
Innovation

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services
Innovation

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services

Powering

Next-Gen
Molecular Assays with
Raw Materials & Services

Powering

Next-Gen
Molecular Assays with
Raw Molecular

the financial savings from avoiding ineffective treatments are substantial," Rüdiger points out.

Guided by intelligence

To learn more about the future of precision medicine, we reached out to one of the foundational companies in genomic diagnostics—Illumina. Next generation sequencing (NGS), a high-throughput technology that rapidly deciphers large sections of DNA or RNA with unprecedented accuracy, is at the heart of precision diagnostics today. In its scaling and commercialization, Illumina played a pivotal role. The company's CEO, Jacob Thaysen, shares his excitement about moving beyond pure genomics analysis—into multiomics: "Multiomics represents the integration of various biological data types, such as genomics, transcriptomics, epigenomics and proteomics, to provide a deeper understanding of biology. While genomics remains the foundation, we have learned that genomic data alone is often insufficient to fully understand biological systems." Thaysen explains that the advent of artificial intelligence (AI) has enabled the industry to venture into much more complex analysis. "With the ability to analyze genomic, RNA, epigenetic and proteomic data on a single platform, we are entering a transformative era," he says, adding: "Over the next decade, this integration will redefine how health care systems, researchers and the pharmaceutical industry approach biology and medicine."

Sorting out access

According to Illumina's CEO, only about 40 perecent of U.S. cancer patients receive genomic profiling. This brings to the fore a problem that is very much inherent to the industry—innovation is costly. As a result, it can take years until advanced therapeutic and diagnostic solutions reach most people. The task to attenuate inequalities of this kind must involve all actors, from government to insurers and providers. Innovators, especially the larger ones, have an important role to play too. We spoke with Matt Sause, the CEO of Roche Diagnostics, which itself has been at the forefront of genomic diagnostics. "NGS is a critical technology for the future of health care and especially so



CLAUS ZIELER | CHIEF COMMERCIAL & MEDICAL AFFAIRS OFFICER, ASTELLAS PHARMA

We have seen remarkable advancements in areas like genomics and antibody therapies, transforming how we treat diseases and improving patient outcomes. However, innovation does not come for free, and the challenge lies in how to pay for it.



UMANG VOHRA | MANAGING DIRECTOR & GLOBAL CEO, CIPLA

Post-independence, India prioritized access to highquality medicines, and Cipla fulfilled that need. While we are largely known for generics, today we also lead in innovation



ALEC FORD | CEO, KARIUS

Procedures like bronchoscopies for pneumonia alone can cost thousands of dollars, and these figures exclude hospital stays, additional procedures and empiric antibiotics. The Karius Test can provide equivalent or superior diagnostic insights at a fraction of these costs.

READ THE FULL INTERVIEWS

in oncology," Sause tells us. The company has recently unveiled a new class of NGS, which could markedly speed up genome analysis. Such advancements can address the continuous challenge of access to advanced diagnostic and to corresponding therapeutic solutions. Sause illustrates Roche Diagnostics' broader efforts to improve access: "One example of improving access is our self-collection HPV test, which received FDA approval last year. Cervical cancer is one of the most preventable cancers, yet it still causes many deaths globally, partly due to sample collection. Allowing women to collect their own samples can significantly improve access, as we are testing now in a pilot in Peru's rural areas."

Veracyte is leveraging genomic insights to advance cancer treatment. It has developed a test, the Decipher Prostate Genomic Classifier, that informs treatment decisions for prostate cancer patients—for example, determining whether chemotherapy, radiation therapy or active surveillance is most appropriate. "Despite the proven value and inclusion in key guidelines, however, only a third of prostate cancer patients receive such tests," Veracyte's CEO, Marc Stapley, tells us. Costs for such novel tests are certainly an issue, as reimbursement can be inconsistent. Ultimately, however, spending more on diagnostics and less on treatment will lead to cost reductions for health systems. Stapley believes that the main setback is health care's inherent status quo bias. "It takes time to change clinical practice, which underscores the importance of evidence, so that physicians, patients and payers can trust a test's results and impact," he notes.

A number of providers are actively addressing accessibility issues. "As cancer diagnostics becomes more complex, more customized and more costly, we plan to build on our core technologies and existing infrastructure to offer more specialized solutions," shares Kyoko Deguchi, the CEO of PHC Group. Lourdes Weltzien, Life Sciences president of Meridian Bioscience, stresses the potential of



Over the past decade, about 95 percent of ThermoSafe's products have transitioned to bespoke designs, reflecting the industry's shift towards personalized medicine. Customers now require solutions that address not just temperature and time but also specific payload and delivery needs, signaling how rapidly medicine and science are advancing.



JIM LASSITER | VICE-PRESIDENT/GM, THERMOSAFE

READ THE FULL INTERVIEW

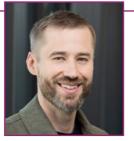
innovative liquid biopsies, being noninvasive, to drive down costs, while bringing a high level of diagnostic accuracy. "We launched our Liquid Biopsy Master Mixes at the end of 2023 into early 2024 to help developers create more effective cancer screening tests. This marks an important new chapter for us, as we leverage our deep expertise in assay development to support the future of cancer diagnostics," Weltzien notes.

It transpired in a number of our interviews that AI may have an essential role to play at improving access. Much of this has to do with streamlining otherwise burdensome (and costly) processes, whether in research labs or hospitals. The CEO of Tempus AI, Eric Lefkofsky, shares: "We will touch nearly a million lives through genomic efforts, generating vast datasets to drive efficiency and innovation in biopharma and academic research. Currently, we are connected to 2,700 hospitals—nearly half of all U.S. hospitals—and aim to reach 80 percent to 100 percent connectivity. This network is critical for deploying AI solutions at scale, ensuring doctors and patients



To date, no one else has used AI to successfully de novo design antibodies for hard targets like HIV caldera or ion channels. We see the real value not in selling AI as a service but using it to create novel drug assets—that's our differentiation.

SEAN MCCLAIN FOUNDER & CEO, ABSCI



READ THE FULL INTERVIEW



biomolecules to improve health. On top of being a global leader in heparin and active ingredients, we've pursued sustainability through circular economy, supporting human, animal and plant health.

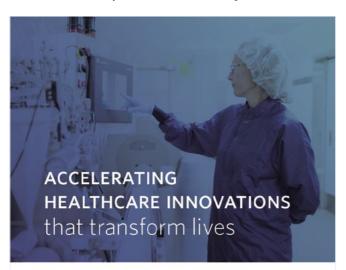
LUIS SOLERA CEO, BIOIBERICA



READ THE FULL INTERVIEW

access these predictive insights." Furthermore, AI is increasingly transforming clinical trials, enhancing efficiency, safety and patient engagement. Medidata offers digital solutions that integrate remote monitoring, telemedicine and home health services to reduce travel requirements and enable participation through, among others, mobile apps. The objective is to engage more patients with trials. "Greater patient engagement in clinical trials is essential to improving health care outcomes and ensuring treatments reflect the needs of diverse populations," Medidata's COO, Joe Schmidt shares. Additionally, AI solutions like Medidata's can eventually reduce the long timelines of clinical trials, bringing costs further down.

Looking into the future, AI may improve access to treatments by designing drugs de novo, i.e., entirely on its own. Absci is a company that has developed an AI antibody design platform. One of its antibodies is entering clinical trials this year, with the second expected for 2026. "ABS-101 is our anti-TL1A antibody for inflammatory bowel disease, entering the clinic shortly, with a Phase 1 interim readout expected in the second half of the year. We believe it has the potential to be a best-



From breakthrough treatments to products that enhance everyday life, Catalent accelerates the journey of your transformative solutions from development to market.

No matter where your innovation starts, we are here to propel it forward.

SMALL MOLECULES | BIOLOGICS | CELL & GENE THERAPY | CONSUMER HEALTH



GLOBAL + 1 888 SOLUTION (765-8846) catalent.com © 2025 Catalent, Inc. All rights reserved. in-class antibody in the TL1A space, and this will be a key milestone, marking our transition to a clinical-stage AI drug discovery company," Sean McClain, Absci's founder and CEO tells us. Should de novo AI drugs become a reality, they are likely to be produced at a fraction of the cost and time required for traditional therapies.

Reshaping an ecosystem

Most of the therapies discussed in this article belong to the rapidly growing class of biologics—drugs derived from living organisms rather than chemically synthesized like traditional small molecules. Their rise has fundamentally reshaped the life sciences services ecosystem, from manufacturing to logistics. In a conversation with Jim Lassiter, general manager of ThermoSafe, we learned how the company's temperaturecontrolled packaging solutions became critical during the mRNA vaccine rollout. "The pandemic underscored the need for robust solutions to maintain extreme temperature requirements and stability in biologics," he notes. Lassiter emphasizes how deeply the industry's needs have evolved: "Over the past decade, about 95 percent of ThermoSafe's products have transitioned to bespoke designs, reflecting the industry's shift towards personalized medicine. Customers now require solutions that address not just temperature and time but also specific payload and delivery needs, signaling how rapidly medicine and science are advancing."

The growing intricacy of advanced therapies is driving consolidation among service providers. Siegfried, a global CDMO (contract development and manufacturing organization), exemplifies this trend through recent acquisitions. Siegfried's new CEO, Marcel Imwinkelried, speaks of his company's expansion across multiple fronts: "A key milestone on this journey was the acquisition of a biotechnology company focused on the development and manufacturing of AAV and lentiviruses for cell and gene therapies, which positioned us to enter the personalized medicine space." Siegfried is also building a new R&D facility and growing its presence in the U.S. to meet rising demand.

In recognition of the greater weight of small and midsized companies in the advanced therapies space, companies like Siegfried are investing in early phase development capabilities. As biotechs are particularly



It starts with our mindset. Catalent has always embraced change, and that takes courage, ambition and a tolerance for occasional failure. You need internal honesty to admit what is not working, correct it quickly and keep innovating. That attitude has been central to our success.

ALESSANDRO MASELLI PRESIDENT & CEO, CATALENT



READ THE FULL INTERVIEW

We are leveraging our expertise to advance RNA therapeutics, specifically through the ECO platform, which enables enzymatic synthesis of RNA-based medicines. Our approach involves innovative solutions like our ligation strategy, which stitches together RNA strands to create complete molecules.



STEPHEN DILLY | CEO, CODEXIS

READ THE FULL INTERVIEW

Medidata is revolutionizing clinical trials with advanced technologies and patient-centric designs, creating rigorous, inclusive and impactful experiences for patients, sites and sponsors, while accelerating timelines and improving accuracy.

JOE SCHMIDT | CHIEF OPERATING OFFICER, MEDIDATA

READ THE FULL INTERVIEW

short in capital in the earlier stages of their pipeline development, they tend to rely on CDMOs with flexible, early phase expertise to de-risk manufacturing, accelerate timelines and conserve resources for core R&D.

Pharmaceutics International, Inc. (Pii), a midsized CDMO that takes pride in its early phase to commercialization capabilities, is another illustration of the aforementioned consolidation trend. The company was acquired in 2025 by Jabil. The now-famous new subset of biologics, GLP-1 inhibitors, are driving much of the M&As in the service providers' industry. "We are already a major player in the auto-injector space, with our devices used for insulin, GLP-1 drugs and other biologics. Our entry into the CDMO market strengthens our position further. The industry saw a significant shift when Novo



JOHN FOWLER | PRESIDENT & CEO, PHARMACEUTICS INTERNATIONAL, INC. (PII)

What truly sets us apart is our focus on complex formulations. For instance, in aseptic manufacturing, we have expertise in handling high-viscosity, oil-based injectables and sustained-release drug products, which require unique sterile filtration techniques.



JULIE ROSS | PRESIDENT & CEO, ADVANCED CLINICAL

The future of clinical trials will increasingly integrate decentralized tools, enhancing access for more diverse patient populations. These tools will not be one-size-fits-all; instead, their implementation will vary based on location, patient demographics and trial requirements.



WILLIAM HUMPHRIES | CEO, ALCAMI CORPORATION

Around 50 percent of biologics, cell and gene therapies and other large molecules are outsourced to CDMOs. This shows a growing comfort level within the industry.



LARS PETERSEN | PRESIDENT & CEO, FUJIFILM DIOSYNTH BIOTECHNOLOGIES

While large molecules and biologics are a growing market, our focus is broader. We are committed to building trust-based partnerships rather than specializing in specific modalities.



DR. MICHAEL QUIRMBACH | CEO, CORDENPHARMA

CDMOs like us play a critical role in helping pharmaceutical companies bring these new peptidebased medicines to market.

READ THE FULL INTERVIEWS

Nordisk acquired three Catalent fill-finish sites after Novo Holdings completed its acquisition of Catalent in December 2024. This has created opportunities for manufacturing partners like Jabil and Pii to fill the gap,' Jabil's SVP, Michael Mahaz, tells us.

Catalent, a global CDMO, was recently acquired by Novo Holdings. We spoke with its CEO, Alessandro Maselli, to learn more about the company's future plans. 'Now, as a private company with a refueled balance sheet, we can invest and grow in key areas like cell therapies, mRNA, and gene therapy—fields that are still young and volatile. This chapter will allow us to bring these assets to maturity,' Maselli shares. By being personalized and advanced, biologic therapies are also very costly (they can cost, on average, 22 times more than small molecules). As Maselli reminds us, CDMOs have an important role to play in driving down costs: "Biologics are targeted therapies for smaller populations, meaning smaller production volumes and lower asset utilization, which makes internal manufacturing uneconomical for innovators. CDMOs like us can combine volumes across clients to optimize asset use."





The unmet need in neurology is unparalleled, and while recent advancements, such as breakthroughs in Alzheimer's and multiple sclerosis, are encouraging, I believe the most significant breakthroughs are still ahead of us.

STEFAN KÖNIG | CEO, MERZ THERAPEUTICS



READ THE FULL INTERVIEW



G. V. PRASAD | CO-CHAIRMAN & MANAGING DIRECTOR, DR. REDDY'S LABORATORIES

Industry-wide growth cemented India's reputation as the "pharmacy of the world." However, while we lead in generics and APIs, true innovation remains a work in progress.



JOE PANETTA | PRESIDENT & CEO, **BIOCOM CALIFORNIA**

It has been a privilege to lead Biocom California, and I am excited about the future under Tim Scott, who brings invaluable experience from founding and growing his own biotech company. Tim understands firsthand the needs and challenges faced by biotech companies.



DOUG DRYSDALE | CEO, CYBIN INC.

We are not just treating symptoms anymore; we are seeing long-lasting changes, with some patients experiencing remission after just a couple of doses. Psychedelic-based therapeutics could fundamentally reshape psychiatry.



BETTINA HAMELIN | PRESIDENT, INNOVATIVE MEDICINES CANADA

From the moment a medicine is globally launched to its listing on a public formulary in Canada, the average timeline is three and a half years. By comparison, in the United States, once a medicine is approved, it is immediately available to patients. This delay in Canada creates a significant disadvantage.



MATTIAS PERJOS | PRESIDENT & CEO, **GETINGE**

We use AI and machine learning in hospital surgery planning, optimizing patient flow and sterile goods logistics. AI is now a component of nearly every R&D project we undertake.



KENDALLE BURLIN O'CONNELL | PRESIDENT & CEO, MASSBIO

MassBio now has 1,752 members, reflecting substantial growth from 1,600 members last year. This is a testament to the thriving life sciences community here in Massachusetts, which continues to be a global leader in innovation and collaboration.

READ THE FULL INTERVIEWS

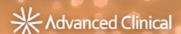
Codexis, a California-based company specializing in the manufacture of complex therapeutics, caters to the needs of its partners by proactively innovating enzyme-based manufacturing solutions. The company has recently developed solutions for RNA synthesis, offering an alternative to the traditional chemical RNA production. "By demonstrating multiple methods to produce the same molecule, we are showing partners that a transition from chemical to enzymatic synthesis is feasible. This versatility is attractive for companies looking to reduce costs and carbon footprint while retaining product quality," shares the company's CEO, Stephen Dilly. Speaking of carbon footprint, pharmaceutical companies increasingly turn to sustainable providers similar to Codexis. Luis Solera, CEO of Bioiberica, a Spanish-based company specializing in the production of active pharmaceutical ingredients (APIs), stresses his company's circular model. "When extracting biomolecules from animal sources, less than 1 percent of the raw material is used for APIs. The remaining 99 percent is repurposed, making efficiency and sustainability critical to our business model,"Solera shares.

The Age of Neurology

Building on recent advances, 2024 brought more good news for neurology patients—from the first FDA-approved disease-modifying therapy for early Alzheimer's to breakthrough oral BTK inhibitors for MS that reduce relapses by 50 percent. We spoke with some of the leaders in the space to share their stories of treating stubborn diseases like multiple sclerosis (MS), Alzheimer's and debilitating migraines.

Driven by the new optimism as well as the ongoing unmet needs in the field, Merz Therapeutics is concentrating on specialty neurology focused on more complex neurological diseases. The German pharma acquired in 2024 two therapies for multiple sclerosis and Parkinson's, with the ambition to expand its presence in specialty neurology and boost access to treatments. "We are focused on ensuring that both therapies reach a larger patient population, particularly in regions where they are not yet available," Merz Therapeutics' CEO, Stefan König, shares. Additionally, the company is advancing its internal pipeline, where König sees much potential. "We are particularly excited about expanding our neurotoxin's potential through clinical research in the treatment of migraines, with a large Phase 3 study set to begin soon. These studies will be the largest clinical trials Merz Therapeutics has ever undertaken, aiming to address both prevention of episodic and chronic migraine," König says. Severe migraines are also the target of Lundbeck, a Danish company. Charl van Zyl, the CEO, is proud of the first intravenous FDA-approved therapy for migraines. "VYEPTI provides sustained relief, allowing patients to regain control over their lives by reducing the unpredictability of migraine attacks. This is a game-changer for those suffering from severe migraines, as it enables them to plan their lives without constant fear of an impending episode," van Zyl tells us.

Another German biotech, Immunic Therapeutics, is investigating a new multiple sclerosis drug with improved therapeutic results as well as a promising safety profile. "While current treatments focus primarily on reducing relapses, they do little to halt the progression of disability that occurs independently of these relapses. Approximately 50 percent



Clinical Research Solutions Others Only Promise, But WF DFLIVER

Learn More at advancedclinical.com

We are striving to deliver the best outcomes where we operate, combining technology to support physician decision-making. That is the definition of being bold—solving those four meaningful problems—and I'm betting on this company to crack the code on all of them in the next three to five years.



IVAN TORNOS | PRESIDENT & CEO. ZIMMER BIOMET

READ THE FULL INTERVIEW

of MS progression stems from this neurodegeneration, leaving patients increasingly disabled despite treatment," Immunic's CEO, Daniel Vitt, tells. The company's new drug, Vidofludimus calcium, now in Phase 3 trials, aims to address this gap with an innovative mode of action that includes neuroprotection. Crucially for MS patients, the drug has shown great promise in terms of side-effects: "In clinical trials involving over 1,800 individuals so far, the safety and tolerability profile was nearly identical between the drug and placebo groups," Vitt highlights.

Not all developments have been positive, unfortunately. We are following the story of Alzheon's war with Alzheimer's for a third year now. The CEO, Martin Tolar, was excited about the company's Phase 3 trial of its oral Alzheimer's drug candidate ALZ-801, focusing on high-risk patients with two copies of a certain gene. Results published in April 2025, however, showed that ALZ-801 did not meet its primary endpoint in the full study population. The drug did show benefit in a subgroup of patients, so the fight no doubt continues. Akin to cancer, the complexity of neurological diseases often means that improvements are incremental and take many years.

Medtech—continuing evolution

Since our previous conversation with the CEO of Penumbra, Adam Elsesser, the company has launched its newest thrombectomy device, Lightning Flash 2.0. The key improvement to this device used to remove blood clots is in the optimized software controlling the process. "The software ensures that aspiration activates only when the catheter is in contact with a clot and deactivates immediately when not, minimizing blood loss," Elsesser notes. Advancements of this kind, while seemingly incremental, can in fact save many lives. As Elsesser illustrates: "This has reduced procedure times drastically, particularly for pulmonary embolism cases. Procedures which took 45 minutes to over an hour can now be completed in as little as four to six minutes, revolutionizing both patient outcomes and the physician experience."

That Penumbra's new product is essentially a software update is no coincidence. The entire medical devices industry is making strides in digitization. Known for its wearable Zio monitor, which records all heartbeats over a 14-day period, iRhythm Technologies is actively using AI to enhance arrhythmia detection. "Today, around 5.5 million ambulatory



Our focus is on maintaining our reputation for relentless innovation.

ADAM ELSESSER | PRESIDENT, CHAIRMAN & CEO, PENUMBRA, INC



READ THE FULL INTERVIEW



We are excited about the potential of our devices. Data shows a strong correlation between arrhythmias and chronic conditions like diabetes, COPD, OSA and CKD—and many patients with these conditions are asymptomatic for arrhythmias until a serious event, like a stroke, occurs.



QUENTIN BLACKFORD | PRESIDENT & CEO, IRHYTHM TECHNOLOGIES

READ THE FULL INTERVIEW

cardiac monitoring tests are prescribed annually, mostly by cardiologists and electrophysiologists. However, nearly 25 million patients annually are potential candidates for arrhythmia detection in primary care," iRhythm's CEO, Quentin Blackford, shares. The company is now working proactively with primary care providers to ensure early detection of arrhythmias, which emerging data show are often associated with chronic conditions such as diabetes. Moving away from the cardiovascular system into orthopedics, companies like Zimmer Biomet are reinventing themselves with new tech. "We collect data before, during and after surgery and use it to drive shorter hospital stays, reduced surgery times and better outcomes," shares the president and CEO of Zimmer Biomet, Ivan Tornos. Zimmer Biomet achieves this via its digital care platform, Mymobility, that the company offers in partnership with Apple. Tornos also highlights Zimmer Biomet's "smart implants": "We are the only company making a 'dumb' titanium knee smart by embedding sensors that capture patient gait and range-ofmotion metrics post-surgery. The implant, called Persona IQ, together with our Mymobility care management platform, allows surgeons to remotely monitor patient data based on recovery thresholds, providing an efficient way to analyze and review recovery trends."



