THE NEW ERA OF LIFE SCIENCES 2024

INVESTMENT REPORTS

published in

Newsweek

The New Era of Life Sciences 2024

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This report captures a historical moment for life sciences. What were dreams or vague projections until recently are now solidifying realities. Highly personalized oncology therapies, the possibility of early cancer detection via a simple blood draw, AI's optimization of drug discovery, unseen breakthroughs in the formerly stagnating fields of neurology or dermatology—inspiring illustrations of each of these, and more, can be found in this piece, the result of more than 100 conversations with industry leaders.

But when dreams come true, new dreams replace them. That is what drives science. As the legendary biotechnologist and biotech founder Robert Langer told us: 'What is truly thrilling is the potential for discoveries that are currently beyond our imagination. Just as CRISPR emerged from basic research to revolutionize genetics, future breakthroughs will likely come from areas we are not even focused on today. It underscores the importance of supporting fundamental, curiosity-driven research.'

ROBERT CALIFF | COMMISSIONER OF THE **FOOD AND DRUG ADMINISTRATION (FDA)**

Should the FDA have a more flexible approach when it comes to new life-saving therapies?

Building on some of the lessons learned during the pandemic such as the benefits of enhanced communication and global regulatory collaboration, the FDA is committed to helping facilitate the development and approval of safe and effective treatments for patients with serious and rare diseases, especially when the product is the first available treatment.

READ THE FULL INTERVIEW

IN THIS REPORT...

STÉPHANE BANCEL | CEO, **MODERNA**
Our research is continuously evolving to include a broader range of diseases, including autoimmune disorders and cardiovascular diseases, highlighting mRNA's versatility.

PASCAL SORIOT | CEO, **ASTRAZENECA**
The personalized approach is already being applied across 90 percent of our portfolio.

DOUG LANGA | VP NORTH AMERICA, **NOVO NORDISK**
Insulin icodec would represent the first and only once-weekly basal insulin option for adults with diabetes in the U.S.

MARK VINEIS | COUNTRY PRESIDENT, **NOVARTIS CANADA**
There is a noticeable tension between the nurturing of biotech innovation and the bureaucratic barriers to health care innovation.

READ THE FULL INTERVIEWS

A Turn of Tide

When work on this project started, in November 2023, it was palpable that the industry had been through tough times. The sector was still undergoing its post-pandemic slump—the depression in investment and economic activity which followed the exuberance (some call it irrational) of the COVID-19 years. Yes, we were assured that it was a matter of time for it to be over, for funds, stationed behind the corner, to be unbound again. But the slump had been ongoing for longer than expected, and optimistic projections had to be taken with a grain of salt. Well, by the time our team attended the annual Biocom California Conference in San Diego in late February 2024, the tides had turned. By then, publicly traded biotechs were finally seeing an upward trend in their stocks and representatives from major VCs and financial institutions, like Goldman Sachs, were reporting marked increase in economic activity. 'Since January we have already seen strong and meaningful deals being made,' confirmed Joseph Panetta, the president & CEO of Biocom California. And indeed, M&As and IPOs, being solid barometers for the health of the biotech sector, have gone up recently. An example is the announced acquisition of MorphoSys by Novartis for $2.9 billion. And unlike the furies from the pandemic times, speakers at the Conference insisted, optimism is now based on hard science, like cell therapies, which are one of the centerpieces of this report.

WILLIAM HUMPHRIES | CEO, **ALCAMI CORPORATION**

We focus on trust and quality, we understand that every role we play is critical. Trust differentiates us and will likely become even more crucial as the legislation perpetuates, and if it evolves.

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While in San Diego, we spoke with Avidity Biosciences, who had just received an oversubscribed $400 million financing, which, we were told, came as a strong signal for the sector's recovery. The biotech is developing a new class of RNA therapeutics called Antibody Oligonucleotide Conjugates (AOCs) to treat muscle-related rare diseases, like myotonic dystrophy. 'The biotech sector is on the cusp of a recovery, fueled by continuous innovation and positive developments across the industry,' Avidity's president & CEO, Sarah Boyce shared. Importantly, she noted that investors are now much more judicious: 'The challenges of the past few years, accentuated by the COVID-19 pandemic, have led to a more discerning investment landscape, yet the advances in targeting previously untreatable diseases signal an exciting era for biotech.' Avidity is not alone to rejoice in the market renaissance—eight U.S. biotechs went public in just the first few weeks of 2024.

The Many Faces of Oncology

This is more than timely as new cancer diagnoses in the U.S. are expected to hit a record number—over 2 million—in 2024, according to the American Cancer Society. Personalized immunotherapies are where expectations are highest. As an illustration, Moderna, which became famous for its COVID-19 vaccine, is now working hard on advancing its mRNA technology in oncology. 'Our personalized approach, particularly our progress in treating melanoma, has shown promising results, with significant improvements in survival rates. These therapies, developed in collaboration with Merck, leverage the immune system's capabilities to better recognize and combat cancer cells, illustrating the potential of mRNA technology in oncology,' Moderna's CEO, Stéphane Bancel shared.

But what transpired from our numerous interviews is that the new superstars in oncology are cell and gene therapies. More than 1,000 such programs are currently in development and a good deal of them are meant to address hard-to-treat cancers. As Thermo Fisher Scientific's president of Biosciences, Amy Butler, put it: 'Cell and gene therapies hold tremendous potential to be curative for diseases that were previously deemed untreatable, such as childhood leukemia and breast cancer. These therapies offer a revolutionary approach by potentially eliminating the disease rather than merely managing symptoms.' Smaller biotechs tend to be the main drivers of innovation in this area, but pharmaceutical giants have a pivotal role to play too, especially due to their ability to channel considerable resources. Sebastian Guth, the COO of Bayer Pharmaceuticals and president of Bayer US, corroborated: 'Bayer has actively participated in this evolution by investing €3.5 billion in building our cell and gene therapy platform. We have made strategic acquisitions and partnerships, such as Ask Bio for gene therapies and Blue Rock Therapeutics for cell therapies, to strengthen our position.'

One can consider chimeric antigen receptor (CAR) T-cell therapies as the vanguard in oncology, particularly since the FDA has approved only six of them to date (the first approval was granted in 2017). They are a type of immunotherapy that involves the administration of genetically modified T-cells (the most powerful component of the immune system), which allow for greater precision in targeting cancer cells. Recent breakthroughs in this space indicate that these therapies may be a game-changer in oncology.

CAR Ts have demonstrated considerable success in treating deadly blood cancers, often leading to long-term remissions. All six FDA-approved CAR T-cell therapies, developed by Novartis, Kite Pharma, BMS and Janssen, target liquid tumors (blood and plasma). The efficacy of these treatments can vary and certain issues, such as cancer resistance and toxicity, persist. We spoke with a clinical-stage biotech, CARGO Therapeutics, that tries to overcome cancer resistance and increase the efficiency of developed CAR T-cell programs. 'Current CD 19-targeted CAR T-cell therapies have set a transformative precedent in large B-cell lymphoma treatment, with about

71  **in 2023**

new medicines approved by the FDA

Source: Nature

DR. ZACHARY ROBERTS | EVP OF R&D AND CHIEF MEDICAL OFFICER, **ALLOGENE THERAPEUTICS**

ALPHA3 will evaluate cema-cel as part of a 1L consolidation regimen in LBCL patients who are most likely to relapse. This is an incredibly innovative trial and one that just wasn't clinically possible until now.

READ THE FULL INTERVIEW

DANIEL J. HICKLIN, PH.D. | PRESIDENT & CEO, **WEREWOLF THERAPEUTICS**

Werewolf Therapeutics is developing a new generation of conditionally-activated immunotherapies, INDUKINE molecules, that hold the promise of providing more treatment options for patients with cancer.

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Get a fresh perspective at
cytiva.com/about-us

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CHRIS COZIC |
EXECUTIVE VP &
CHIEF PEOPLE OFFICER,
GENMAB

Genmab is a scientific leader in antibody research, inspired by the power of the human immune system to fight diseases.

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40 percent of patients achieving long-term complete response,' the company's CEO, Gina Chapman told us. Their goal at CARGO, however, is to address the 60 percent of patients for whom these therapies are not effective. 'Preliminary results are promising, showing a 53 percent complete response rate in this subgroup, which is remarkable considering these are patients with very limited options and a median survival of less than six months prior to treatment,' Chapman added. CARGO's lead candidate, firi-cel (CRG-022), is currently in Phase 2 trials.

CAR T-cell therapies can be autologous and allogeneic. In the case of autologous (from Ancient Greek *autós*, 'self'), T-cells are taken from the patient being treated, they are genetically modified and reinserted into their body. The aim is for the boosted T-cells to then destroy the cancer. The other type, allogeneic (from *állos*, meaning 'other'), involves a similar process, but cells are in that case provided by a healthy donor for multiple patients. Autologous treatments are the only ones currently available on the U.S. market. 'Allogeneic CAR T products are developed using T-cells from healthy donors. These cells are isolated in a manufacturing facility, engineered to express CARs to recognize and destroy disease, and modified via gene editing to limit autoimmune response when given to a patient,' explained Dr. Zachary Roberts, EVP of R&D and chief Medical Officer of Allogene Therapeutics. The company, whose lead program targeting B-cell malignancies is currently in Phase 2, claims to have overcome the issue of autoimmune reactions by additional gene editing. 'Our products are produced in advance, stored, and ready for rapid administration, drastically reducing the time from patient eligibility to treatment commencement,' Roberts added.

While we are still to see the first FDA green light in this space, the European Commission granted the first approval globally for an allogeneic T-cell immunotherapy back in 2022. The therapy, called Tabelecleucel and targeting relapsed/refractory post-transplant lymphoproliferative disorder (PTLD), was developed by California-based Atara Biotherapeutics. 'Our T-cell therapy has shown around 50 percent response rate in treating relapsed/refractory PTLD, leading to long-term survival in responders. This represents significant progress in a deadly disease with no approved therapies,' Atara's president & CEO, Pascal Touchon, added.

But while CAR T-cell treatments have made considerable strides in treating certain blood and plasma malignancies, the FDA has never approved them for treating solid tumors.' This has meant that more traditional approaches like chemotherapies and surgeries continue to be the primary options for solid tumors, which are also 90 percent of all cancers. The great news is that another type of T-cell therapy may be able to cut this Gordian knot. It was this January that the FDA approved the first cellular therapy for a solid tumor—the drug, called Amtagvi (lifileucel), is for metastatic melanoma and was developed by California-based Iovance Biotherapeutics. 'This

ADRIAN RAWCLIFFE |
CEO,
ADAPTIMMUNE

Adaptimmune aspires to be a leading, integrated commercial cell therapy company, transforming technology into valuable therapies for patients, developing and delivering innovative treatments for solid tumors and potentially changing the landscape of cancer treatment.

READ THE FULL INTERVIEW

achievement opens a new frontier in oncology,′ said Fred Vogt, Iovance′s interim CEO. In addition to melanoma, Iovance′s treatment has already shown promising results for non-small cell lung cancer.

But cell therapy and CAR Ts hold promises that go beyond oncology. ′One remarkable instance involves a patient who suffered from Myasthenia gravis for years and became immobilized in a wheelchair. She received a single dose. Within months, she regained the ability to walk—and she even surpassed her own husband′s stamina on a hike recently,′ shared Peter Maag, the CEO of Kyverna Therapeutics. Maag is confident that his company is on the verge of revolutionizing the treatment of autoimmune diseases. ′At a high level, autoimmune diseases involve the immune system attacking itself. We extract T cells from the patient, genetically re-engineer them, and re-inject them. It reminds me of resetting a computer to get everything back to normal,′ Maag said. Kyverna′s lead candidate, KYV-101, is already in Phase 2 for certain indications. Maag told us that part of its therapeutic allure stems from its prospective to offer a long-term remission for patients. Kyverna is not alone, as other biotechs, like Atara, also perceive the potential of cell therapies to fight autoimmunity.

Innovations in immunotherapy are not restricted to cell and gene therapies. Xilio Therapeutics, for example, is developing tumor-activated immunotherapies that allow for greater precision and, thereby, far less toxicity for healthy tissues. Systemic toxicity has been a principal problem of modern immunotherapies. Oftentimes patients′ tumors are successfully shrinking, but the therapy has to be discontinued due to overwhelming side effects. Xilio′s president & CEO, Dr. René Russo, shared: ′We have discovered that we can activate our first molecule, an anti-CTLA-4 monoclonal antibody, predominantly within the tumor—showing 70 to 90 percent activity in the tumor environment, while maintaining less than 15 percent activity in the circulating blood.

DR. RENÉ RUSSO | PRESIDENT & CEO, **XILIO THERAPEUTICS**

Our geographic precision medicines are tumor-selective immunotherapies designed to focus the immune system's tumor-destroying effect locally in tumor tissue but not in healthy tissues. By localizing activity to the tumor, we hope to overcome the toxicities of prior generations of immunotherapies.

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E. ANDERS KOLB | PRESIDENT & CEO, **THE LEUKEMIA & LYMPHOMA SOCIETY (LLS)**

An unintended consequence of innovation in health care is the widening gap between those who can access complex and costly therapies, and those who cannot. True innovation must prioritize broad access to care and this is a major focus for LLS.

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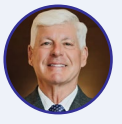
THE BIOTECH HUBS

DEBBIE HART | PRESIDENT & CEO, **BIONJ**
New Jersey continues to lead the way in biopharma innovation, harnessing its rich pharmaceutical legacy and ongoing support from both the private and public sectors. With a diverse and talented workforce and an unparalleled density of FDA-registered manufacturing facilities, the state encapsulates the entire drug development continuum – underscoring New Jersey's pivotal and leading role in advancing health care breakthroughs.



JOSEPH PANETTA | PRESIDENT & CEO, **BIOCOM CALIFORNIA**
California's life science sector is a colossal $450 billion industry, employing 400,000 people.

KENDALLE BURLIN O'CONNELL | PRESIDENT & CEO, **MASSBIO**
Massachusetts' distinction in the life sciences industry is primarily due to its unmatched density and richness of resources within a small area. Home to over 1,000 biotechs, 18 of the top 20 biopharma companies, investors, and academic institutions, Massachusetts offers an unparalleled ecosystem.

JANE DUNIGAN-SMITH | SVP & CSO, **BIOCROSSROADS**
Indiana is home to 2,700 establishments, including giants like Eli Lilly and Company, and leaders in ag biosciences such as Corteva. Indiana also boasts significant achievements in medical device manufacturing, with Warsaw recognized as the orthopedic capital of the world.

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'This targeted activity allows us to minimize side effects significantly, thereby enabling higher dosages and longer treatment durations.' Xilio is also developing two cytokine programs with the same objective, as cytokines have been known for their side effects. 'We have been able to administer significantly higher doses than previously possible, thanks to the tumor-selective activation of these molecules,' Russo told us, adding that these can now work in conjunction with cell therapies too.

Another company bent on solving the challenge of cytokine-based therapies is Werewolf Therapeutics. 'Werewolf' is a metaphor for the company's objective: 'They are designed to be delivered systemically and remain inactive throughout the patient's body, akin to a werewolf in daylight. However, upon entering the tumor microenvironment—comparable to the moonlight for a werewolf—our drugs are designed to transform into aggressive agents to stimulate a powerful immune response and unleash an attack on cancer cells,' Dan Hicklin, Founder & CEO of the biotech explained. 'Our solution involves creating cytokine prodrugs, called INDUKINE molecules, that remain inactive in circulation but activate upon reaching tumor tissue', Hicklin added. Werewolf is focused on treatments for melanoma, lung and kidney cancers.

After the many interviews we had in the oncology space, we concluded that thinking of cancer as a single disease is outdated and erroneous. Cancer has many forms and each of these may present differently in different patients. This is the great attraction of personalized medicine in oncology. That also means that, if we are to be successful in solving cancer(s), many different solutions will be needed—cell and gene therapies, radiopharmaceuticals, mRNA, cytokines... The list, most certainly, is yet to grow. And that is good news.

ALEC FORD |
CEO, **KARIUS**

Every year in the U.S., over 2 million patients with cancer are admitted to hospitals due to infections. Current diagnostics for infections often fall short resulting in poor outcomes. Our mission is to improve diagnostics and reduce the nearly 1000 deaths a day due to infection among immunocompromised patients.

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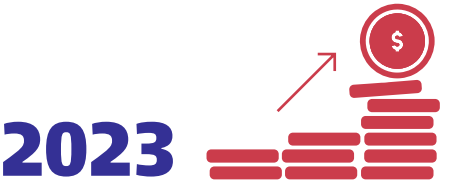

Biotech IPOs reached pre-pandemic levels during Q1 of 2024. That is more than three times what was raised from biotech IPOs in Q1 2023.

Source: BioPharma Dive

THE ONCOLOGY VANGUARD

SEBASTIAN GUTH | PRESIDENT, **BAYER US**
The advancement in cell and gene therapies is pivotal. We have seen a significant increase in FDA approvals in this area. Bayer has actively participated in this evolution by investing $3.75 billion in building our cell and gene therapy platform.

MARKUS WARMUTH|
CEO, **MONTE ROSA THERAPEUTICS**
Monte Rosa's therapeutic candidates, designed as orally bioavailable drugs, offer a novel approach to cancer treatment by targeting specific genomic aberrations or oncogene over-expressions. This method stands out for its convenience and potential for higher market penetration compared to injectable therapies.

EMMANUEL ABATE | PRESIDENT, GENOME MEDICINE, AND HEAD OF SUSTAINABILITY, **CYTIVA**
The history of biologics is mostly about moderating disease, but cell and gene therapies can be curative and that's why they generate so much excitement.

MATTHEW B. KLEIN, M.D. | CEO, **PTC THERAPEUTICS**
Our gene therapy for the rare disease AADC deficiency has allowed children who were previously unable to spontaneously move to begin to lift their heads, crawl, and walk, transforming their lives.

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Uncovering Cancer

Tackling deadly diseases like cancer via advanced therapeutics is only one side of the coin; the other is early detection. Luckily, breakthroughs in diagnostics are also proliferating.

Every health system and, naturally, every individual would be greatly relieved if a universal early detection cancer test were discovered. We spoke with a company that claims to have made significant progress in that direction. GRAIL has developed a multi-cancer, early detection blood test called Galleri that 'can identify over 50 types of cancers, focusing particularly on highly lethal cancers that lack existing screening modalities in population health, such as pancreatic, esophageal, and liver cancers,' GRAIL's CMO, Jeffrey Venstrom told us, emphasizing that nearly 70 percent of cancer deaths are caused by cancers without recommended screening. The Galleri test identifies genomic features and abnormal DNA fragments in one's blood, employing advanced techniques to also provide information about a tumor's location. But, with about 40 percent of positive predictive value for the moment, the test is still not to be used in isolation and at the expense of traditional screening. 'Over the next few years, our primary goal is to secure broad adoption and FDA approval through our ongoing clinical trials and our breakthrough designation status,' Venstrom added. GRAIL has also initiated a collaboration with CMS (Centers for Medicare and Medicaid Services) to conduct a real-world implementation study, called the REACH, targeting the Medicare population.

Others, like Personalis, are targeting patients who have already had cancer. 'Our focus is on individuals with a high risk of recurrence, where the value and impact of early detection justify the cost. As technology costs decrease, expanding to broader early detection becomes more feasible,' reasoned Christopher Hall, the CEO of Personalis. The Bay Area biotech's technology is centered on the identification of Minimal Residual Disease (MRD) and utilizes whole-genome analysis to create a unique tumor profile for each patient.

As we find out, however, treating patients with cancer is not just about cancer. 'Over half of all cancer deaths are due to infections, not the cancer itself,' said Alec Ford, the CEO of Karius—a company that provides rapid and accurate diagnosis of infections, notably focusing on oncology patients. Cancer patients are exceptionally vulnerable to infections, Ford explains, adding that traditional approaches to infectious diagnosis are slow and cumbersome, threatening many of these patients' lives. 'By analyzing a small blood sample, within just 24 hours we can identify microbial DNA from over 1,000 pathogens, including bacteria, fungi, parasites, and viruses,' Ford highlighted the benefits of the Karius test. At any rate, the examples of GRAIL, Personalis and Karius demonstrate that, in oncology-related diagnosis too, multiple lines of action are required.

STEVE SCHAEFER |
PRESIDENT,
KYOWA KIRIN NORTH AMERICA

Focusing on the rare disease space enables us to target investments into meeting patients' needs with precision and empathy, often touching lives in profound ways. Our work to bring these innovations to patients extends beyond scientific achievement; it is about the real-world impact we hope to have on individuals and their families.

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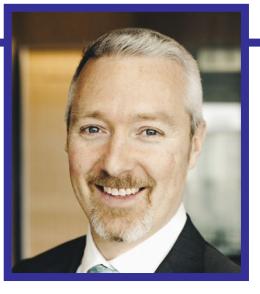

DR. DAVID O'NEILL |
PRESIDENT, **FACIT**

FACIT is changing the research economics dynamic – by using seed capital to not only support IP discoveries and entrepreneurs, but also to encourage startups to grow roots in Ontario and promote a self-sustaining innovation ecosystem.

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The Hidden Catalysts in Medical Innovation

The driving force behind my three-decade-long commitment to life sciences is the profound impact we make on patients' lives and public health.

PAUL MCKENZIE | CEO, **CSL**

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Beyond scientific conundra, a major concern associated with most of these novel therapies is their accessibility. This is an issue inherent to personalized medicine. While much more precise, potent and sparing for the patient, it involves significantly more resources. As in the case of autologous cell therapies, an entire team of scientists may be engaged to work on the modification of the cells of a single patient. In fact, a record was recently broken with the price of Orchard Therapeutics' (a subsidiary of Kyowa Kirin) Lenmeldy gene therapy drug set at $4.25 million. 'The pricing really reflects the profound impact hematopoietic stem cell gene therapies can have—helping transform a fatal, devastating disease into something that may be addressed with a one-time treatment. It also recognizes the significant investment required to bring such innovative, personalized treatments to market for an ultra-rare disease,' Kyowa Kirin North America's president, Steve Schaefer explained. Whereas these are certainly valid points, the question of accessibility remains to be solved.

As mentioned, specifically in the CAR T-cells space, costs can be tempered via the allogeneic card, which allows for the production of multiple doses from a single manufacturing run. Yet, solutions do exist for autologous therapies, which can have important advantages in certain cases. Service providers, like Contract Development and Manufacturing Organizations (CDMOs), can have a key role to play here. Cellares' CEO & Co-Founder, Fabian Gerlinghaus, emphasized the degree of the scalability problem: 'About 20 percent of patients are dying on the waitlist even though they are eligible for approved cell therapies because the industry is unable to meet patient demand.' Cellares has developed a manufacturing platform, called Cell Shuttle, which, Gerlinghaus claims, successfully integrates and automates the entire cell therapy manufacturing process into one place. 'It encapsulates the functionality of approximately 100 benchtop instruments in a single, compact machine,' Gerlinghaus said, adding that this 'reduces labor and space requirements by 90 percent. The other key difference is that the Cell Shuttle can process 16 cell therapy processes simultaneously.' Gerlinghaus anticipates that the Cell Shuttle will be able to meet worldwide demand for cell therapies in the future.

We have significantly expanded our R&D capabilities, including doubling the footprint of our flagship Innovation Center in Bridgewater, NJ. In this highly collaborative environment, we work closely with customers to develop customized solutions.

MICHAEL STUBBLEFIELD | CEO, **AVANTOR**

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Cellares is an example of how contract service providers can play a critical role in supporting the work of biopharma companies. Another such illustration comes from Nucleus RadioPharma, a CDMO operating in the space of radiopharmaceuticals. Highly promising, such therapies rely on low-energy isotopes that integrate cancer-targeting molecules. Radiopharmaceuticals can allow for precise tumor treatment while minimizing damage to surrounding tissues. 'The potential in this field is significant, especially for conditions like neuroendocrine tumors and prostate cancer, where targeted radiotherapy could have a transformative impact,' Théodore Leondaridis, the Global Oncology Head of Pierre Fabre Group shared with us. The company is considering its entry into this space, as the sector is attracting more and more attention, as exemplified by recent news about AstraZeneca's pending $2.4 billion acquisition of Fusion Pharmaceuticals, known for developing next generation radioconjugates. But for all their prospects, radiopharmaceuticals have an Achilles' heel—manufacturing and logistics. Nucleus RadioPharma's CEO, Charles Conroy, told us that the industry is particularly challenging 'due to the short half-life of isotopes, which complicates logistics similar to shipping ice without refrigeration.' To address this, the CDMO is establishing multiple production sites across the U.S. 'We are strategically situating our facilities near major medical centers

to expedite the transfer of isotopes and drugs into patient studies and eventual commercial use,′ Conroy said. But while infrastructural issues persist, Conroy is optimistic that the large investments that the sector is attracting will solve these. ′Contract service providers have become increasingly relevant as innovators, as well.′ ′The shift from small molecules to large molecules and biologics marks a significant evolution in health care. This transition necessitates specialized expertise in areas like cell and gene therapy, where CDMOs excel,′ observed William Humphries, the CEO of Alcami Corporation. To respond to this new reality, global service providers are expanding and/or profiling their activities. ′We have broadened our service scope by acquiring CELLforCURE from Novartis, a state-of-the-art cell and gene therapy manufacturing unit. This acquisition allows us to offer a more comprehensive range of CDMO activities, extending our expertise from small molecules to cell and gene therapy,′ the CEO of the French-based SEQENS, Pierre Luzeau, told us.

Crucially, more than meeting new demands, service providers are also proactive innovators. A telling illustration comes from Codexis, which offers engineered enzymes to its various clients. One of its platforms, ECO Synthesis, is designed to address the scalability and sustainability challenges that have characterized the RNA synthesis space. Particularly the latter is a topic that has received little media attention but, as we are told, conventional RNA synthesis is heavily reliant on environmentally detrimental solvents. ′ECO Synthesis operates in water, dramatically reducing the carbon footprint and eliminating the need for large-scale, expensive containment facilities. This innovation not only promises a more sustainable approach but also significantly reduces capital investment requirements, enabling the production of siRNA at scales previously deemed unfeasible,′ the CEO of Codexis, Stephen Dilly noted.

TREVOR P. CASTOR | PRESIDENT & CEO, **APHIOS CORPORATION**

Zindol highlights our platform's capacity to offer natural, effective treatments with fewer side effects, addressing significant needs in areas like hyperemesis in pregnancy and post-operative care and versatility for improving quality of life.

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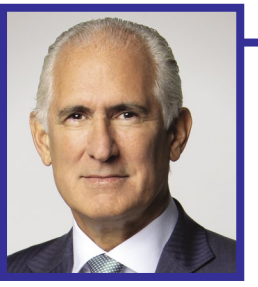

KEVIN ALI | CEO, **ORGANON**

Achieving a women's health moonshot is within our collective reach. I'm energized by the positive trends I see across scientific discovery, focused government attention and private sector that are turning this future into our present.

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THE ADVENT OF SERVICE PROVIDERS

JAMES FOSTER | PRESIDENT & CEO, **CHARLES RIVER LABORATORIES**

Cell and gene therapy represents the most dynamic growth area within our portfolio, signaling a significant shift in our business focus.

MICHAEL MCMULLEN | PRESIDENT & CEO, **AGILENT TECHNOLOGIES**

Our technology allows for live cell analysis, enabling researchers to observe the metabolic health of cells in real time. This capability is crucial for evaluating potential therapeutic treatments' effects.

CARL HANSEN, PH.D. | FOUNDER AND CEO, **ABCELLERA**

In May 2023, AbCellera announced a $512 million co-investment with the governments of Canada and British Columbia to build new capabilities and infrastructure to develop innovative antibody-based medicines.

AUDREY GREENBERG | CHIEF BUSINESS OFFICER, **SK PHARMTECO**

Platform technology, distributed manufacturing, automation, and AI will revolutionize therapy production and distribution.

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The Forefront of Tech

You probably remember how until recently, medical data management was a manual chore, with each patient's details recorded on paper. But the digital revolution has transformed this process. However, now medical data is not just digitized; it is also centralized in the cloud—something resembling an immense, invisible filing cabinet.

The magic unfolds when AI intervenes in this vast pool of centralized data. With lightning speed, AI identifies patterns and connections that would take humans much longer to uncover. As Mandar Paralkar, Global VP and Head of Life Sciences, SAP, told us, this makes AI 'increasingly used in drug discovery, quality control, and regulatory submissions, enhancing outcomes by managing both structured and unstructured data'. According to McKinsey & Company, AI application boosts the efficiency of initial manual assessments of drug targets by over 30%. Furthermore, AI-enhanced compound screening in silico has not only tripled the performance of chemical compound activity models but also slashed the time needed to pinpoint new leads by more than fourfold—which means no less than drugs being discovered at four times the pace. Insmed, an innovator in the field of rare disease therapies, is one of the examples of a biotech starting to leverage these tools.

As CEO Will Lewis told us: 'The company's collaboration with Google Cloud aims to integrate AI in drug discovery, development, commercialization, and internal operations to enhance efficiency and innovation.' In his view, 'AI's potential to accelerate understanding and optimize processes without replacing the human element signifies a pivotal moment in the industry.' Similarly, the CEO of Labcorp, one of the largest CROs in the world, told us that AI plays a transformative role in both customer-facing and operational aspects of the company's work. 'For example, we employ neural networking to enhance patient check-in processes at our service centers, improving accuracy and efficiency in patient identification and insurance verification. This not only speeds up the process but also allows our staff to focus more on patient care,' Adam Schechter highlights. However, AI's power comes with a corresponding responsibility; Dr. Diem Nguyen, CEO of global health company SIGA, warned us that 'The dual nature of AI and biotechnology present significant benefits and risks. While these technologies have led to many advancements in virus sequencing and treatment development, they can also pose a threat if used malevolently.'

TOM LANGAN | PRESIDENT AND CHIEF COMMERCIAL OFFICER, **VERADIGM**

Unique to Veradigm is our ability to engage providers directly via the Veradigm Network. Our experience and knowledge in catering to providers, life science, and health plan customers also contribute to our competitive edge.

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THE NEXT FRONTIER

MARK HERBERT | VP OF BIOPHARMA BUSINESS DEVELOPMENT, **VARDA SPACE INDUSTRIES**

The unique conditions of low Earth orbit offer a compelling value proposition for the pharmaceutical industry. Varda's operational costs for space-based manufacturing are justified by the significant benefits that can be achieved, such as the development of novel drug formulations and the potential to unlock discoveries that are not possible on Earth.

JOHN VELLINGER | PRESIDENT, **REDWIRE IN-SPACE INDUSTRIES**

We specialize in developing research equipment and facilities for space to discover new opportunities that can improve human health on Earth. Microgravity, which cannot be simulated on Earth, offers a unique environment for life science and physical science processes.

SEEMA VERMA | EVP AND GM, **ORACLE HEALTH AND LIFE SCIENCES**

Oracle is innovating by integrating vast amounts of data from our electronic health records, which are one of the largest in the world, and clinical trial management systems.

JOHN CROWLEY | PRESIDENT & CEO, **BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO)**

Advancing biotechnology is crucial for many reasons. My leadership at BIO emphasizes biotechnology's significance in ensuring preparedness against pandemics, enhancing public health, and bolstering the strength of our nation and allies.

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AI & Drug Discovery

A biotech specialized in the treatment of cancer, Genmab, has begun to utilize AI across several of their operations, as revealed by their creation of an AI incubator to foster innovation, generating over 140 concepts in various areas. While currently focused on simpler tasks, Chris Cozic, Executive Vice president & chief People Officer, told us that the future application of AI in their operations is poised for grander challenges. Specifically, Genmab believes that AI will play a 'significant role in predictive analysis and protein design,' which involves using AI to firstly understand and secondly manipulate protein structures. Proteins play a central role in drugs as they often serve as targets that the drugs bind to, modifying biological processes to treat diseases. Consequently, this means that with AI we can predict how proteins interact with other molecules—which enables researchers to virtually design proteins with specific therapeutic properties. This capability has the potential to be a game-changing advance compared to previous drug discovery methods, which relied heavily on trial and error and extensive laboratory experiments, making the process slower and less efficient.

AstraZeneca's CEO, Pascal Soriot, further illustrated the rapid application of AI into their drug discovery efforts: 'Our AI-enabled platforms are using generative models to identify potential drug molecules twice as fast as traditional processes and help us prioritize those that will be most effective. We are also using generative AI and machine learning in antibody discovery, cutting the time to identify target antibody leads from three months to just three days.' Service providers, like PerkinElmer, have also been quick to integrate AI in their offerings. 'Our OneSource services offering exemplifies how AI can optimize operations within biopharma R&D labs. By relieving scientists from the burdens of instrument complexity and maintenance, we enable them to focus on their primary objective: drug development. AI aids in predicting lab utilization rates, maintenance requirements, energy consumption, and other operational aspects,

DEBASHIS GHOSH | PRESIDENT, BUSINESS GROUP, **TATA CONSULTANCY SERVICES**

GenAI is paving the way for a health care system that is responsive, affordable, and personalized. This aligns perfectly with emerging trends in precision medicine, promising a future where complex diseases are treated effectively and economically.

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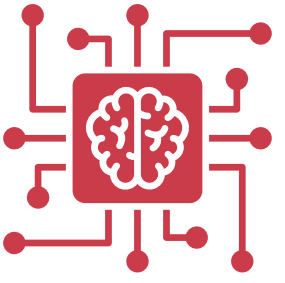
3.5B 2023



8B 2030

Over recent years, total investment in AI-mediated drug discovery is $3.5 billion by 2023 – expected to reach $8 billion by 2030.

Source: Fortune Business Insight

thereby enhancing efficiency and productivity,' Dirk Bontridder, PerkinElmer's CEO said.

The Solution to Equity in Clinical Trials?

To address the limitations inherent in the traditional management of clinical trials, decentralized trials and AI promise an opportunity for transformation, as exhibited by our conversations with innovators in the field. Seema Verma, EVP and GM at Oracle Health and Life Sciences, told us that the current state of trial management is 'remarkably manual,' characterized by 'extensive paper documentation and labor-intensive data entry processes.' This approach heightens the risk of errors and hinders efficiency of trials, with a considerable amount of time spent on data handling. Julie Ross, president and CEO at Advanced Clinical, asserts that 'the next significant challenges in clinical trials revolve around leveraging AI and business process automation. As we move towards decentralized trials, the focus is on making trials more accessible to patients in diverse locations.' Decentralization in clinical trials not only enhances the efficiency and scalability of data management but also fosters greater diversity among participants, as it breaks down geographical and logistical barriers, enabling a more representative cross-section of the population to contribute to and benefit from research. This is not a minor point. Looking at the diversity statistics of clinical trials: 'in all the medications approved by the FDA in 2020, the clinical trial participants were: 75 percent White, 11 percent Hispanic, 8 percent Black African American, 6 percent Asian. Only 30 percent of the participants were over 65 years of age and more than half of the patients were located in the US' (Teva Pharma). Consequently, if clinical trials with integrated AI could reduce the number of participants needed in placebo arms (referring to a group of participants who receive a placebo instead of the active treatment) and utilize data-driven approaches to streamline trials, these percentages could become increasingly balanced.

ANTHONY COSTELLO | CEO, **MEDIDATA**

No amount of technology can replace trust in the clinical trials process. We need to bridge the gap between the vast amount of data patients create in a lifetime and the tiny fraction of those data used in clinical trials today. This can only be done with the right combination of technology and trust.

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AI APPLICATIONS

DR. DIEM NGUYEN | CEO, **SIGA TECHNOLOGIES**
The dual nature of AI and biotechnology present significant benefits and risks. While these technologies have led to many advancements in virus sequencing and treatment development, they can also pose a threat if used malevolently.

PRIYA ABANI | PRESIDENT & CEO, **ALIVECOR**
AliveCor has incorporated a network of forward-looking cardiologists into our platform to facilitate tele-appointments between these specialists and our users. This service began modestly with only a handful of appointments each month but has seen significant growth into the triple digits.

JOSEPH DEVIVO | PRESIDENT & CEO, **BUTTERFLY NETWORK**
Telemedicine is integral to our vision of health care's future, where patients can perform scans at home with professional oversight from afar. Our clinical studies have shown promising results in self-scanning by patients under telemedical guidance, moving us closer to a world where health care is more accessible and immediate.

JASON GOREVIC | FORMER CEO, **TELADOC HEALTH**
The growth in our mental health business reflects the pent-up demand in this sector. Our platform addresses challenges like navigating the health care system and the stigma associated with seeking mental health care.

MICHAEL STOMBERG | CEO, **PROPHARMA**
It is crucial to underscore that while AI opens up unprecedented possibilities, it does not replace the need for human expertise. The real value lies in combining AI's capabilities with the deep domain knowledge of our professionals to ensure the highest quality outcomes.

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YOUR PARTNER IN THE NEW AGE OF ALZHEIMER'S DISEASE

A new age for Alzheimer's disease (AD) stands before us, with unprecedented possibilities for patients, families, and health care professionals. Eisai's four decades of AD research helped pave the way for scientific breakthroughs and advances that are shaping the future of neurology.

To learn more visit **US.EISAI.COM**

Eisai

hhc
human health care

This new format of decentralized clinical trials is being implemented by Medidata, a Dassault Systèmes brand and leading provider of clinical trial solutions to the life sciences industry. CEO, Anthony Costello, told us that 'patients now participate actively from their locations, contributing data through mobile phones and wearables, significantly changing the landscape of data collection and increasing the authenticity and applicability of clinical trial data in real-world settings.' Additionally, Costello explained that 'recently we have focused on harnessing AI to leverage data from the 33,000 trials we have conducted, which aids in optimizing trial designs and operational efficiency.'

Verily, Alphabet's health technology branch, is also dedicated to making clinical research easier for its biopharma clients. Verily Viewpoint, part of the company's suite for enhancing clinical research, includes services aimed at optimizing clinical trials through technology. 'This encompasses patient recruitment, consent processes, and clinical trial management. Viewpoint, also includes Workbench, which connects data providers and researchers on a collaborative health care data platform for analysis and insights and, exemplifies Verily's innovative approach to clinical research, enabling more efficient, data-driven studies,' Verily's Chairman and CEO Stephen Gillett told us.

The Bones of Innovation

As we witness the exponential advances made through software, hardware advancement seen in robotics, glucose monitoring and other medical devices craft the bones of the life sciences. Globus Medical, originally focused on spine health, has expanded its influence into orthopedics and trauma care. With the advent of robotic technology, surgical procedures have undergone a transformation, 'revolutionizing the field by providing surgeons with high precision tools for tasks like pedicle screw placement, allowing them to focus more on patient care rather than the technical aspects of surgery.'

QUENTIN BLACKFORD | PRESIDENT & CEO, **IRHYTHM TECHNOLOGIES**

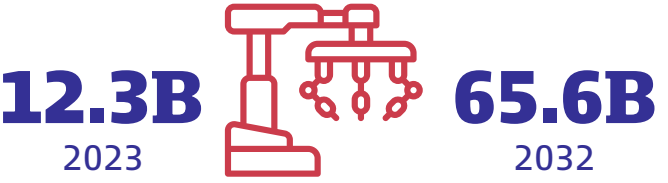
In the next five years, I envision iRhythm playing a pivotal role in detecting, predicting, and preventing disease on a global scale. While our initial focus was on cardiac health, our future includes expanding into adjacent markets like sleep disorders, hypertension, and heart failure.

READ THE FULL INTERVIEW

Dan Scavilla, CEO of Globus Medical, told us. Similarly, Zimmer Biomet is making strides in the integration of robotics to the field of extremities care. The company's ROSA Shoulder system is the world's first robotic-assisted surgery system for shoulder replacement, according to the company's CEO. Their hardware devices are not only advancing per se, but also by connecting to the cloud and leveraging the power of interconnectivity. As president & CEO, Ivan Tornos, told us, 'Virtually all products in our portfolio either collect data or feed data to the rest of the interconnected ecosystem of care. With partnerships with Apple and Microsoft.'

A company that was founded with the very idea of applying AI to medical devices, and as early as 2006, is iRhythm Technologies. Its objective is to provide a more effective alternative to the traditional Holter monitor, which is a wired portable electrocardiogram (ECG) that records the electrical activity of the heart for up to 48 hours. IRhythm's device, called Zio, is a patch ECG monitoring device designed to be worn continuously for up to 14 days. 'We know that many cardiac arrhythmias are missed with the Holter monitor due to the limited time in which they are worn by patients. Our device outperforms the conventional Holter monitor in effectiveness and convenience, backed by substantial clinical data—helping physicians reach a definitive diagnosis and decrease time to treatment,' iRhythm's president & CEO, Quentin Blackford, told us. The data Blackford refers to is analyzed by iRhythm's FDA-cleared AI algorithm, compared against a database of various arrhythmia readings, validated by trained cardiac technicians and presented to physicians as an actionable report.

Another illustration of the integration of hardware and software comes from one of the leaders in thrombectomy devices, Penumbra. The company has developed tools which, with computer assistance, can remove blood clots much more seamlessly. As Penumbra's Co-Founder & CEO, Adam Elsesser, explained, the traditional, manual approach often involved significant blood loss as well as the risks coming from the intervention of a human hand. 'Lightning Flash and Lightning Bolt 7 represent significant innovations in thrombectomy by improving the efficiency and safety of blood clot removal. These



Health care Robots Market Size:
estimated growth at a CAGR of 18.4 percent
Source: Acumen Research and Consulting

computer-assisted vacuum thrombectomy technologies are built on the concept of mechanical clot removal, which is becoming preferable to drug-based methods due to the latter's risk of bleeding and the necessity for careful monitoring. Our approach, focusing on aspiration, aims to maximize safety, speed, and simplicity and avoid damage to the delicate structure of the blood vessels,' Elsesser said. Both Lightning Flash and Lightning Bolt 7 employ sophisticated algorithms to recognize the difference between blood clot and blood flow, making lives of both surgeons and patients easier.

Prytime Medical Devices is also bringing innovative tools to the aid of surgeons with the aim of minimizing blood loss. Its focus is severe internal bleeding that is often the result of car crashes or war-related traumas. The Texas-based company's CEO, David Spencer, shared: 'The challenge with internal bleeding, especially in the case of severe trauma, is that traditional exploratory surgery to locate and address the source of bleeding has a high mortality rate.' To address that, Prytime has developed a tool called REBOA which involves inserting a balloon catheter into the aorta through a small incision in the leg, effectively blocking blood flow to control hemorrhage and maintain vital blood supply to the heart, lungs, and brain. 'This approach significantly reduces the invasiveness of the procedure and increases the chances of survival by preventing further blood loss,' Spencer told us. The REBOA technology is notably used in Ukraine. 'The inability of the Ukrainian military to evacuate casualties quickly due to drone threats has made our technology crucial for providing soldiers with a chance to survive by 'turning down the faucet' on hemorrhage, thus buying time for medical intervention,' Spencer shared, noting the similar urgent necessity in civilian car crash cases.

Genes and Proteins

Next Generation Sequencing (NGS), having revolutionized the study of the human genome, may be a familiar term by this point. We spoke with a Japanese start-up, Mitate Zepto Technica, which, through the use of semiconductor technology, claims to be able to make DNA analysis up to a hundred times cheaper. 'Traditionally, analyzing DNA sequencing data necessitated outsourcing or the use of supercomputers, a process that could take weeks and was prohibitively expensive,' Keisuke Harashima, Mitate Zepto Technica's CEO shared. Still in prototype phase, the company aims to launch its technology in early 2025. Simultaneously, proteomics, the study of proteins, has not received the same amount of attention as genomes. Proteins are coded by genes. There are 20,000 genes in the human genome, and these create over 1 million proteins that comprise the human proteome. Our understanding of the proteome is pivotal, since this could allow for a deeper understanding of biological processes, leading to insights into the mechanisms of diseases, such as Alzheimer's, whose progression can be traced via proteomic signatures. Omid Farokhzad, a pioneer in the field and a Founder of Seer, told us: 'Seer was founded to address the key challenges faced in the field of proteomics, with the aim to elevate our understanding and technological capabilities up to par with those of genomics.' He is certain that advancements in proteomics like the Proteograph are yet to reveal many previously unknown biological insights. Referring to the company's analytical device, the Seer Proteograph, Farokhzad added: 'Since the introduction of our product, the tools at the ready for scientists to analyze the proteome have significantly advanced. We have moved from being able to analyze a few hundred proteins in a handful of complex samples, such as plasma, to detecting up to 10,000 proteins in plasma and conducting studies with thousands of samples.' Seer has already announced important partnerships with companies like Thermo Fisher and SpaceX.

ADAM ELSESSER |
CO-FOUNDER & CEO,
PENUMBRA

Our goal is to significantly expand access to CAVT so patients [with blood clots] are able to get more advanced treatment quickly, potentially resulting in better care.

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DAVID SPENCER |
PRESIDENT & CEO,
PRYTIME MEDICAL DEVICES

Prolonged REBOA buys physicians time, meeting a large unmet military and civilian need in advanced hemorrhage control. Physicians in Ukraine are using pREBOA-PRO to transport their soldiers to safety, while U.S. physicians are documenting 4X more time to treat their hypotensive patients.

READ THE FULL INTERVIEW

KEISUKE HARASHIMA | FOUNDER & CEO, **MITATE ZEPTO TECHNICA**

Our innovative device completes genome analysis in just five minutes at a fraction of traditional costs. This technology not only speeds up DNA calculations but is also set to significantly lower operational expenses, making genomic medicine more accessible and cost-effective globally.

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Enhancing Diabetes Management

According to the World Health Organization, approximately 422 million people suffer from diabetes, of which Americans represent 37.3 million. The prevalence of diabetes is rising steadily, disrupting the lives of those diagnosed by demanding both management and monitoring, according to the Centers for Disease Control. Yet, this task has become much simpler through innovation in monitoring systems. A glucose monitor features a sensor that goes easily inserted beneath the skin, where it can measure glucose levels in the fluid around cells. The sensor then generates an electrical current based on the glucose concentration, and the monitor then translates this current into a readable glucose value.

Before the development of glucose monitors, people with diabetes primarily relied on urine glucose tests to manage their condition. As Timothy T. Goodnow, president & CEO at Senseonics, explains, 'CGM (Continuos Glucose Monitoring) represents a leap forward in diabetes management, providing continuous glucose readings that offers the user a dynamic view of their glucose levels in real time. This technology moves beyond traditional finger-stick tests, offering glucose data every five minutes'. Goodnow further highlighted the future direction, stating that 'innovations will aim to further reduce the management burden on people with diabetes by eliminating external components and integrating directly with personal devices for seamless glucose monitoring.' Similarly, the president of Ascensia, Rob Schumm, emphasized the role of software integration, 'The company's cloud-based solutions and partnerships aim to provide a more cohesive and user-friendly experience, allowing for real-time data sharing with health care providers and caregivers, thus improving disease management.' Once again we stumble upon the recurring trope interconnectivity, enabling predictive analytics and real-time data sharing, and rendering diabetes management far simpler for millions.

This pace of innovation keeps on increasing; AI is speeding up drug discovery, and cloud-based systems provide an interconnectivity of elements that were previously impossible to connect. And then there is the hardware—robots that bring precision to surgeries that were once fraught with greater risks. These advancements represent big leaps—maybe too big for us to fully understand just yet—towards a future where health care is radically faster and more integrated than ever before.

Alzheimer's: Approaching a Cure

Prevalence and Economic Impact

Alzheimer's slow impairment of memory and cognitive functions continues to divide the wider scientific community, given the disease's complex nature, involving a mix of lifestyle, genetic, and environmental factors. Seven million Americans grapple with Alzheimer's, according to the Alzheimer's Association. In view of an aging population and extended life spans, the figure is projected to double by 2050. The financial toll is equally impactful, as Alzheimer's care is expected to cost $360 billion in 2024 according to the Alzheimer's Association, rising to nearly $1 trillion by 2050.

However, investors are also up to the challenge. There has been a notable shift in investment focus towards neurological disorders in recent years. Previously, the sector was known for the hesitancy it caused in investors, who had spent billions in research on diseases like Alzheimer's that brought little progress. But recent breakthroughs have changed this, transforming the sector into one of the most promising and attractive investment areas.

REGENERATIVE MEDICINE

ROBERT LANGER | INSTITUTE PROFESSOR, **MIT**

Tissue engineering and regenerative medicine, which I have worked on extensively, offer ways to create human-compatible tissues and organs. While the prospect of using animal organs, such as pig hearts, presents an intriguing solution to the organ shortage crisis, I do not believe it will replace other approaches. Instead, these technologies will likely coexist.

ABDULKADER RAHMO | PRESIDENT & CSO, **SMSBIOTECH**

Unlike conventional stem cell therapies, which typically involve the differentiation of stem cells into specific cell types, SMS cells stimulate the body's endogenous cells to regenerate tissue. This approach ensures the regenerated tissue is fully compatible with the host, avoiding potential immunological issues associated with foreign cells

LAURA NIKLASON | PRESIDENT & CEO, **HUMACYTE GLOBAL**

Our therapeutic product, the Human Acellular Vessel (HAV), uses human cells to create replacement tissues. This technology leverages a bioreactor process that mimics the human body's environment, enabling us to grow engineered arteries that can treat various vascular diseases.

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Innovative Treatment Approaches

Japanese giant Eisai, has recently been in the spotlight thanks to the launch of LEQEMBI, designed to target and clear the infamous amyloid beta plaques, known for their strong association with Alzheimer's disease and contribution to neurodegeneration and cognitive decline. Paul Hawthorne, Executive VP and chief Business Officer, told us about the significant benefits of their new treatment, stating that 'we estimate that over 10 years cumulatively, the gradual adoption of LEQEMBI treatment at this pricing approach could give back about 60 percent of the potential positive social impact of several tens of billion dollars to the U.S. society.' These savings would come from the treatment's positive effects, such as improving health outcomes and reducing health care costs. Martin Tolar, president & CEO at Alzheon also highlighted advancements in treatment options with their drug ALZ-801, noting, 'We have completed enrollment for the pivotal APOLLOE4 Phase 3 clinical trial of our novel oral medication, ALZ-801/valiltramiprosate, which as our data have shown, avoids certain adverse effects, such as brain edema and microhemorrhage, that have been seen with other treatments'. This promising drug candidate might be out in the market very soon, as Tolar told us that they 'expect to complete the pivotal Phase 3 trial this year and aim for regulatory approval shortly thereafter. If all goes according to plan, ALZ-801 could be available in the U.S. by 2025.' Another notable example in the field is that of Sinaptica Therapeutics, which specializes in personalized neuromodulation, a novel approach to Alzheimer's treatment. Ken Mariash, CEO, explained their therapy, which has completed a Phase 2 trial, to us: 'Our patented new Alzheimer's treatment is based on precision non-invasive brain stimulation, using high-powered magnetic fields to induce electrical currents in the brain. The study demonstrated an 82 percent slowing of Alzheimer's progression on the primary endpoint, using a painless treatment with virtually no side effects'. These new approaches considerably minimize adverse effects, slowing the progression of Alzheimer's and offering patients better coexistence with the disease. Though the ultimate cure for Alzheimer's remains hypothetical, these new developments offer hope for patients that so desperately need it.

An Answer to the Mental Health Crisis?

The mental health crisis seems to be an epidemic, with 'one in eight people worldwide suffering from a mental disorder,' according to the World Health Organization—a figure exacerbated by the COVID-19 pandemic. As CEO of atai, Florian Brand, told us, mental health issues 'include a range of conditions such as depression, addiction, and anxiety.'

Amidst this unprecedented epidemic, you might have noticed a resurgence of interest in psychedelic treatments, particularly psilocybin, for conditions such as treatment-resistant depression. A historic study by Johns Hopkins in 2006 has revitalized the field: It was the 'first research since the 1970s to administer a classic psychedelic (psilocybin) to drug-naïve participants.' The study revealed that 'psilocybin led to profound experiences that 67 percent of participants rated as among the top five most meaningful experiences of their lifetime.' Additionally, 'the single psilocybin session led to positive changes in moods, attitudes, and behavior for 14 months (and possibly longer), with 64 percent indicating the experience increased well-being or life-satisfaction.' The research also 'established the safety of high dose psilocybin administration,' showcasing its potential for profound therapeutic impact. (Hopkins). In response to these promising developments, companies

SINAPTICA™ THERAPEUTICS

KEN MARIASH | CEO, **SINAPTICA**

This Phase 2 trial showed 80 percent+ slowing of Alzheimer's progression on gold standard cognitive and functional endpoints using non-invasive neuromodulation, leading to Sinaptica's founding. I've never encountered placebo–controlled efficacy data as strong.

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LONG-AWAITED BREAKTHROUGHS

JESSICA BALLINGER | PRESIDENT & CEO, **LYNDRA THERAPEUTICS**

Lyndra's approach fundamentally changes the treatment paradigm for schizophrenia and bipolar disorder. Traditional treatments require frequent visits to health care facilities for injections. Lyndra's oral dosage form, deliverable at home, simplifies the treatment regimen to just once a week, enhancing patient adherence.

MARTIN TOLAR | FOUNDER, PRESIDENT & CEO, **ALZHEON**

The challenge in identification and development of new treatments has been immense, especially considering the long-standing reluctance of investors to fund research in this area. However, our team's relentless focus on understanding of the disease process has led to significant breakthroughs

OMID FAROKHZAD | CHAIR, CEO & FOUNDER, **SEER**

The Proteograph's applications extend into various areas of health research. Collaborations with institutions like Mass General Hospital have enabled studies that trace the progression of Alzheimer's disease through proteomic signatures, identifying proteins previously unrecognized in the context of the disease.

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such as atai Life Sciences and Otsuka are exploring the therapeutic potential of psilocybin, which, as Brand told us, 'works by inducing a neuroplasticity burst, which forms new neural connections in the brain and supports the growth and survival of neurons.' The latest studies are demonstrating 'a robust evidence base for the potential efficacy of psychedelics in treating mental health conditions, with promising response and remission rates for even the most stubborn cases such as treatment-resistant depression.'

Furthermore, in relation to psychedelics, Japanese big pharma company Otsuka has recently acquired psychedelic biotech Mindset Pharma for Mindset Pharma for $59.1 million dollars. This move is particularly meaningful as it depicts a radical attitude shift from the big players on the field, seeing potential in an area that was previously considered unfruitful and dangerous. Bearing in mind that no psychedelics—with the exception of esketamine—have seen FDA approval yet, a move from big pharma into the field, with its expertise and experience, might provide the final push needed for these new treatments to arrive in the market. Tarek Rabah, CEO at Otsuka NA, claims that Otsuka is 'dedicated to advancing science in mental health care, exploring new treatment mechanisms, including the potential of psychedelics to help treat psychiatric conditions and neurological disorders with high unmet needs.' Caution is still advised by the medical community, and drugs of the sort remain a taboo—exemplified by the fact that a person possessing at least 25 milligrams of psychedelic mushrooms or another hallucinogen can face a possible sentence of up to 15 years in prison.

Despite the challenges and societal taboos associated with these substances, the significant investments by leading pharmaceutical companies and the promising results from recent studies underscore a potentially transformative era in mental health therapy. This wave of innovation could well provide crucial breakthroughs for those suffering from some of the most challenging mental health conditions, potentially reshaping our approach to mental wellness in the decades to come.

Sabirnetug is at the forefront of next generation AD therapies, showing selectivity for toxic a-beta oligomers in our Ph 1 trial. With ALTITUDE-AD, our Ph 2 trial, we're one step closer to providing patients with a differentiated treatment option.

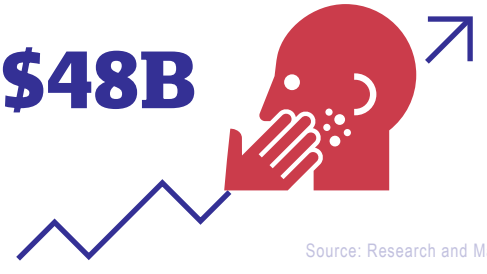
DANIEL O'CONNELL | CEO, **ACUMEN**

READ THE FULL INTERVIEW

Skin Deep: Advancements in Dermatology

The skin is the largest organ of the human body, serving as a protective barrier between us and the world. Yet, in this curious society of ours, the skin came to represent much more than its strict biological functions. As noted by Frank Watanabe, president & CEO at Arcutis Biotherapeutics, 'The skin, being a 'calling card' to the world, plays a crucial role in our social interactions and self-esteem.' The regulation and upkeep of important biological functions and the quest for aesthetics coexist in this area, rendering dermatology a very particular field. The market dynamics are equally compelling. According to Almirall's Chairman and CEO Carlos Gallardo, 'There is a wave of innovation in dermatology due to a deeper understanding of disease biology and the introduction of biologics'.

A notable example of innovation in the field is that of Dermavant's VTAMA cream, the first non-steroid cream on the market, which targets the underlying mechanisms of plaque psoriasis—a chronic autoimmune condition characterized by raised, red patches covered with a silvery white buildup of dead skin cells. This cream, acting as an aryl hydrocarbon receptor (AhR) agonist, fosters skin homeostasis by downregulating inflammatory mediators, without any of the negative side-effects that often come alongside classic steroidal creams. Todd Zavodnick, CEO of Dermavant Sciences, notes the significant adoption of VTAMA, with 'just under 14,000 unique prescribers and over 300,000 units sold within the first 20 months. Frank Watanabe, President at Arcutis Biotherapeutics also participates in the fight against psoriasis: 'Our lead product, ZORYVE (roflumilast) cream, is suitable for chronic use, and is specifically approved by the FDA for sensitive skin areas.' These newer treatments promise to address the severity of the symptoms that affect patients' quality of life.



The global dermatology market will reach a valuation of $48bn by 2027, and has been growing at double digit figures year on year

At Dermavant, we want to establish VTAMA cream as the foundational therapy for plaque psoriasis in adults and potentially, atopic dermatitis, if approved by the FDA. Our goal is to transition the field from conventional treatments to innovative, effective, and safe treatment options, essentially moving from the 'cassette to digital music' era in dermatological treatments.

TODD ZAVODNICK | CEO, **DERMAVANT SCIENCES**

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Anti-aging solutions have also become a prominent trend across the lifesciences, spanning from supplements and nutrition to dermatology. Allergan Aesthetics is pushing the trend further, with 'products that contribute to this broader movement by focusing on local tissue aging, offering treatments that restore tissue function or create a more youthful appearance at the site of treatment.' Darin J. Messina, Ph.D., Senior Vice president, Aesthetics R&D, told us more about the science behind their approach: 'Focusing on stem cells, biomaterials, and growth factors, we aim to restore tissue function through regenerative cues, enabling our body's stem cells to rebuild damaged tissues. This approach is pivotal in both aesthetic and therapeutic applications, showcasing our commitment to innovation in regenerative medicine.' Through the use of these regenerative use of stem cells and biomaterials, Messina claims that their ultimate mission 'is to empower confidence by evolving consumer perceptions from vanity towards quality of life and youthful aging.

Balancing Nature and Science

A trend is emerging across the life sciences: that of 'returning to nature'. CEO Rob Fried of longevity supplement developer, ChromaDex, describes this period as 'marked by a contradiction where, alongside health advancements, lifestyle factors such as consumption of ultra-processed foods counteract potential gains in health.' In view of this challenge, the dietary supplement industry has become one of beacons of this trend, promising customers an enhanced well-being through the consumption of natural compounds. However, the supplements industry operates largely without the typical oversight of pharmaceuticals, as the FDA does not require these products to undergo pre-market approval. This means that the efficacy and safety of supplements do not have to be validated through objective and standardized scientific trials—even though some companies do engage in stringent analysis of their products—before they reach consumers. When bearing in mind that according to the Council for Responsible Nutrition, 74 percent of U.S adults take dietary supplements, 55 percent qualifying as regular users, the fact that quality varies significantly, and products often do not deliver the advertised benefits becomes very problematic. In this somewhat chaotic context, some companies stand out by committing to scientific rigor and natural ingredients. Several supplements companies are trying to use natural methods to tackle one of the biggest modern challenges—overconsumption and obesity. Some of the most alarming figures stem from this area. Worldwide, more than 1 billion people are

obese—650 million adults, 340 million adolescents and 39 million children, according to WHO. The U.S. adult obesity rate stands at 42.4 percent, according to the National Institutes of Health. Furthermore, worldwide adult obesity has more than doubled since 1990, and adolescent obesity has quadrupled, according to the World Health organization. Calocurb's Founder and CEO, Sarah Kennedy, told us that 'navigating the modern world, filled with endless temptations, especially unhealthy food choices contributing to rising obesity and mental distress levels, presents a considerable challenge.' The New Zealand-based company's research into evolutionary biology has led to the discovery of a specific hop extract that curbs appetite by targeting bitter taste receptors. As noted by Kennedy, 'Published clinical trials have shown a hunger reduction of 30 percent, craving reduction of 40 percent and average calorie intake reduction of 18 percent after one hour.'

Nature's Sunshine Products, with its reach across 40 countries and a product portfolio of over 600 items, is another example in the space of the nature-centric approach. As Terrence Moorehead, CEO, told us, 'recognizing the diminished nutritional value in modern diets and lifestyle factors contributing to poor health, we emphasize the importance of gut health as foundational to overall well-being.' Moorehead is mindful of the market it operates in, as he told us that 'the primary challenge for Nature's Sunshine is differentiating itself in a market saturated with companies that prioritize marketing over genuine nutritional value.'

Supplement company LifeVantage focuses on the activation of the body's natural processes: 'Modern lifestyles have diverged significantly from our bodies' original programming, creating a 'perfect storm' for not only increased oxidative stress, but a decline in function, leading to numerous health issues. Our activation approach seeks to counteract this by reactivating our body's natural processes, rather than merely supplementing or putting a bandaid on the real issue,' Steve Fife, president & CEO, told us. Fife emphasized the science underlying their products: 'Our original focus on the NRF2 pathway, a critical area for managing oxidative stress, set us apart from the very beginning by enhancing the body's response to stress beyond what traditional supplementation offers.'

Our success in addressing significant challenges in rare diseases not only showcases our commitment to making a difference in patients' lives but also sets the stage for future breakthroughs.

MATTHEW B. KLEIN M.D. | CEO,
PTC THERAPEUTICS

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The gut influences various bodily systems through the gut-brain axis, gut-skin axis, and its interaction with the liver and kidneys in drug metabolism. It is a nexus point for understanding and treating a multitude of health issues.

BEN SCRUGGS | CHAIRMAN AND CEO,
ALTIS BIOSYSTEMS

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A story exemplifying the passion this sector can arouse in individuals and entrepreneurs is that of Rob Fried, CEO of ChromaDex. Fried transitioned from successfully producing several Hollywood blockbusters to the supplements space thanks to a vision of metabolic health and anti-aging playing a central role in the society of the future; Fried did not see this as a trend, 'but as a reflection of a deeper, philosophical inquiry into the nature of life, death, and the human condition.'

The company's operations are heavily centered on the science of NAD, a coenzyme critical to cellular repair and metabolic functions, which 'declines as we age, contributing to the aging process.' Fried told us: 'My fascination with NAD and its potential in slowing aging is rooted in its foundational role in cellular health and energy metabolism. ChromaDex's focus on NAD, particularly through its product nicotinamide riboside, aims to combat age-related decline in NAD levels, thereby addressing aging at a cellular level.' In simpler terms, NAD tackles aging by addressing it 'at a cellular level.' According to Fried, the feedback of users of their product span 'from miraculous health recoveries in infants to improvements in cognitive functions in adults.' However, its widespread use faces some challenges, including 'the dietary supplement industry's history of mixed messages and unverified claims, which has led to a general skepticism among consumers.' ChromaDex intends to distinguish themselves from these companies through a 'commitment to rigorous scientific research, regulatory compliance, and safety, setting us apart in an industry rife with misinformation and questionable practices.'

Whereas the dietary supplement industry is criticized for its reliability, companies such as the ones we have featured show a productive commitment to merging nature with science providing solid benefits. Their work bridges the ever increasing gap between our ancient biological needs and modern lifestyle demands, setting a new standard for what consumers can and should expect from trustworthy supplements.

To be continued ...

This report, woven from discussions with over a hundred pioneers in the field, not only highlights the current innovations in personalized medicine, early detection technologies, and AI-enhanced drug development, but also invites us to dream anew. The commitment to fundamental, curiosity-driven research is not just a cornerstone, but a catapult into future discoveries that may yet again surpass our imaginations. At the end of our interview, Christopher Molloy, Chancellor Emeritus at Rutgers University, spoke to the importance of keeping true to this path, and we believe that in his message lies the kernel of the scientific spirit: 'It is crucial to adhere to rigorous scientific principles, communicate advancements clearly, and confront disinformation. As we explore new frontiers, like artificial intelligence, ensuring these technologies are developed responsibly and remain under control is vital. Ultimately, maintaining a commitment to truth and ethical conduct in science will help society understand and address its challenges effectively,'

Working on the second edition of The New Era of Life Sciences has brought us the additional gratification that a fine work's serial nature may entail—we have been delighted to have new and fascinating voices join in, while observing the very real progress that most of our past year's interviewees have made towards their respective objectives. With this in mind, and given the undisputable nobility of life sciences' overarching task—saving human lives—we are more than looking forward to next year's edition when, hopefully, more dreams will have become reality.

Despite common misconceptions, the aesthetic field is deeply rooted in science, not merely vanity. We prioritize technologies that address unmet needs within the aesthetic space, ensuring our offerings stand out for their safety and effectiveness.

DARIN J. MESSINA PH.D. |
SENIOR VP, AESTHETICS R&D,
ALLERGAN AESTHETICS / ABBVIE

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177.5B  **2023**

The global dietary supplements market size was estimated at approximately $177.50 billion in 2023

Source: Grand View Research

INVESTMENTS AND RESULTS

PHIL MURPHY | GOVERNOR OF **NEW JERSEY**
Last year, companies with a footprint in New Jersey accounted for more than 50 percent of all novel drug approvals.

PETE SALZMANN | CEO, **IMMUNOVANT**
Immunovant has attracted significant attention and investment from the market, highlighted by a $200 million investment from Roivant Sciences in August of 2021 and a $450 million capital raise in October of 2023.

ARND KALDOWSKI | CEO, **SONOVA GROUP**
We have been pioneers in introducing rechargeability and full connectivity with Android and Apple devices in hearing aids. We are exploring the integration of AI and deep neural networks for enhanced denoising capabilities directly in the hearing aids. This would significantly improve the user's ability to discern speech from background noise.

ROBERT BLUM | PRESIDENT & CEO, **CYTOKINETICS**
Aficamten demonstrated significant improvements in patients with obstructive hypertrophic cardiomyopathy across all endpoints in a Phase 3 clinical trial, including measures of exercise capacity, quality of life and safety. These results represent a pivotal moment for patients and our company.

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