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Industry trends and predictions for 2025

Megan Thomas speaks with industry experts about their predictions for drug discovery opportunities in 2025.

Technology, machine learning and AI

It is estimated that 15% of disease targets are druggable using conventional drug discovery techniques, according to Simon Kerry, CEO of Curve Therapeutics. He says: "As more novel tools and techniques emerge, I think we will see a rise in non-conventional drug modalities to address challenging disease targets. We have already seen these developments in areas such as cell and gene therapies (CGTs), antibody drug conjugates (ADCs), targeted degradation and molecular glues, and we are beginning to see "beyond the rule of five" molecules, including cyclic peptide and peptide-like compounds, as drugs."

As we move into 2025, the integration of artificial intelligence (AI) and machine learning (ML) in drug discovery will continue to accelerate, says Claudia Zylberberg, Board Chair and Co-Founder of Kosten Digital. She says: "AI integration in drug discovery is set to revolutionise the field. One compelling example of AI's impact on drug discovery is developing treatments for rare diseases. Using AI, researchers can analyse genetic, proteomic, metabolomics and phenotypic data to identify novel therapeutic targets more efficiently than traditional methods allow."

Moreover, cloud computing enables secure, large-scale data sharing and collaboration among researchers globally, facilitating AI-driven analytics, says Zylberberg. "There is a need for agreements and comprehensive approaches among groups to guide this data sharing more securely and compliantly. Combined with advances in computational chemistry, AI has the potential to make drug discovery faster, more accurate, and personalised, paving the way for a new era of therapeutic development and bringing treatments to patients at unprecedented speeds."

Additionally, Dan Goldstaub, Scientific Co-Founder of PhaseV, believes that AI will continue gaining prominence in 2025. He says: "Following advances made this year, including two Nobel Prizes for advancements in AI, its use will play an increasingly integral role, evolving from primarily preclinical applications to becoming central in clinical trials and drug development."

As efficiencies increase, Goldstaub predicts that AI will address long-standing ethical concerns in drug development, enabling researchers to more quickly detect, react and adjust. "This includes reducing exposure of patients to ineffective treatments and lowering attrition rates."

Meanwhile, Michael Chen, Co-Founder and CEO of Nuclera, comments: "We are starting to see advancements in protein synthesis technologies that mean gene-to-protein and gene-to-structure timelines take days rather than months or years. Most of these technologies integrate novel microfluidic automation and characterisation together with AI/ML data analytics so that protein work is less hands on and more meaningful for downstream drug discovery workflows."

> "AI integration in drug discovery is set to revolutionise the field"

In 2025, Chen believes it will become possible to optimise all stages of protein production from gene design to expression and purification in integrated platforms with less human variability. He concludes: "Automated expression, purification, and characterisation platforms will evolve and be capable of handling any protein class to power next-generation modalities such as PROTACs and molecular glues. Combined these will streamline protein synthesis, accelerating drug discovery, paving the way for the development of innovative treatments for a range of diseases."

Yvette Lu, Life Science Research Analyst at Ironstone Asset Management, Life Science REIT's Investment Advisor, thinks that being part of a strong ecosystem, with access to an unparalleled level of academic research and technology, will remain a priority for occupiers in 2025. She says: "A multi-faceted ecosystem that can draw on expertise from a range of historically disparate fields, such as life sciences and tech, has real merit, with enhanced cross-sector collaboration promoting greater innovation and speed efficiencies within fields such as drug development."

Professor Julie Frearson, Corporate Senior Vice President & Chief Scientific Officer at Charles River, thinks that the development of alternative methods in drug discovery remains critically important. She says: "With the significant advances in technology—including stem cell and organoid biology as well generative AI and large language models—the focus now is on appropriately implementing these tools to ensure they have a sustained, meaningful impact on drug discovery and development."

Drug policy and regulation

Frearson also comments on regulatory acceptance for therapeutic development. She says: "There is significant momentum among US government agencies—including the FDA and NIH. By growing that momentum, the industry can help build confidence in complex in vitro and in silico methods to drive further adoption and regulatory acceptance, ultimately accelerating therapeutic development."

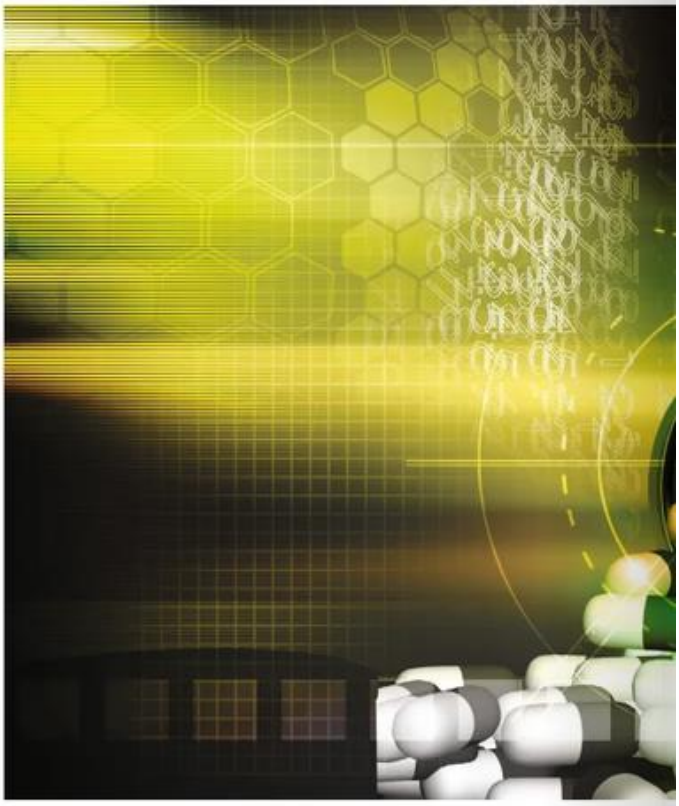
In 2025, the biopharma industry will increasingly embrace advanced automation and digital traceability to strengthen manufacturing safety and regulatory compliance, according to Joel Eichmann, Co-Founder and MD, Green Elephant Biotech. He says: "Driven by emerging standards such as the Biosecure Act, companies will adopt technologies that increase operational resilience and ensure supply chain transparency - critical for advanced therapies. Cybersecurity will also take centre stage, as the shift to digital manufacturing requires the protection of sensitive data and process integrity. For biotech startups, meeting these demands will mean prioritising partnerships and outsourcing for secure manufacturing. The companies that thrive will be those that combine innovation with robust compliance."

In addition, Dan Goldstaub predicts that regulatory bodies will increasingly recognise the role of AI tools in enhancing efficiencies and managing the complexities of trial design and drug development in 2025. "As a result, they will adapt their processes and collaborate more closely with innovators, allocating additional funds and resources to evaluate and approve AI-driven solutions."

Goldstaub adds that 2025 will see a significant increase in adaptive trials, with AI playing a leading role, as more companies integrate AI into their processes, allowing real-time adjustments based on ongoing trial data. He concludes: "Despite the promise of AI, the pharma and biotech industry remains highly conservative. As regulatory agencies like the FDA and EMA become more proactive and acknowledge that AI-driven trials can lead to more ethical and efficient practices, the wider industry will embrace these innovations responsibly."

Neuroscience

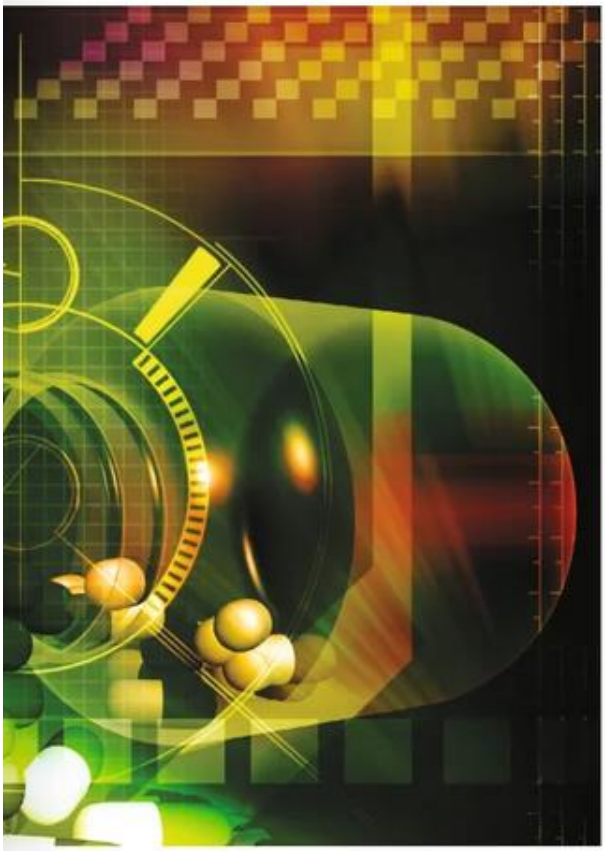
Interest in central nervous system therapies has increased hugely in 2024, according to Lovisa Sunesson, Director of Business Development of Vesper Bio. She notes that the FDA's accelerated approvals of Leqembi (lecanemab) and Qalsody (tofersen) for Alzheimer's disease and ALS, respectively, have helped pave the way for others and adds: "Here in the Nordics, things have really taken off. There are now more than 50 companies across the region active in neurological diseases, which are doing some excellent work. It feels like we've achieved critical mass."



Olivia Cavlan, Chief Corporate Development and Strategy Officer at Alchemab, agrees that neuroscience in general is becoming an increasingly exciting field. She says: "The wave really started with the amyloid-beta data trickling through from 2022 with lecanemab and early donanemab data releases suggesting disease modifying potential. In parallel, Karuna's KarXT Phase III data represented a long sought-after breakthrough for disease modifying therapies in neuro-psych, and culminated in BMS' acquisition of the company for $14bn in 2023. Building on this momentum, the FDA's 2023 approval of Qalsody (Tofersen) for ALS based on a blood biomarker reduction, neurofilament light chain (NfL), has made neuro, and ALS specifically much more tractable from a clinical trial perspective."

Managing disease and the clinic

AstraZeneca's Regina Fritsche-Danielson, Senior Vice President and Head of Research and Early Development, Cardiovascular, Renal and Metabolism (CVRM), BioPharmaceuticals R&D, says that CVRM diseases represent one of the biggest



health challenges globally, affecting millions of people and increasing as populations age. She says: "There is growing evidence that shows how interconnected CVRM diseases are and the need to manage them holistically, leading to better outcomes for patients. The interconnectedness of disease is why we are pioneering novel combinations that address multiple mechanisms to help patients manage their comorbidities and slow disease progression. For example, in obesity – if we can address durable weight management and improve long-term health by tackling interrelated diseases and organ protection, we can make a real difference."

While scientists continue to explore exciting new paths, it has become obvious to HaYoung Lee, Chief Strategy Officer at MEPSGEN, that drug development needs to reinvent its model. "Bringing a new drug to market costs about $2.6 billion, and 95% of candidates fail in clinical trials, often due to inadequate human physiological testing. To address this, organ-on-chip technologies and automated organ modelling devices are becoming essential tools."

He continues: "As science progresses, microphysiological systems (MPS) are able to integrate cell complexity and interconnectivity, which makes them the perfect tool for high-throughput screening and disease modelling."

Despite 75 years of steroids being used in the first line of treatment in many inflammatory diseases, Martha Stone, CEO of Steritas, says they are still not a cure.

She believes researchers and clinicians are equipped to quantify steroid-toxicity, permitting a shift in steroid-prescribing behaviour. "Measuring and monitoring side-effects will alleviate patient suffering and healthcare burden, creating an evidence-based opportunity to taper steroids to the lowest therapeutic dose both in research and clinical practice."

On the other hand, David McErlane, Group President at Catalent Biologics, sees the industry standing on the verge of transformative change. He says: "Personalised therapies are becoming more of a reality, driven by breakthroughs in genetic profiling. These advancements help us understand individual genetic variations in a way that allows for more precise, patient-centred healthcare, targeting specific illnesses or diseases effectively."

Cancer burden and research

In February 2024, the World Health Organization (WHO)'s cancer agency, the International Agency for Research on Cancer (IARC), released the latest estimates of the global burden of cancer covering 185 countries and 36 cancers[1]. Over 35 million new cancer cases are predicted by 2050, a 77% increase from the estimated 20 million cases in 2022. There is hope, however, according to experts.

Andreas Pahl, CEO of Heidelberg Pharma, says: "There's been huge progress in cancer over the last two decades with a host of new drugs and technologies extending lifespans for many common types of the disease. But it's a sad statistic that 90% of cancer-related deaths are due to cancer's ability to become resistant to today's drugs. Research will shift toward finding therapies for resistant diseases, that also have the potential to be safer and more effective in the early stages. For this, we will need drugs with different mode of action than those that came before them."

Olivia Cavlan also weighed in, noting that J&J's roll out of their FcRn therapy, nipocalimab, continues to show impressive Phase III outcomes across a range of immunological conditions. She says: "Next wave therapies such as CAR-T approaches for systemic lupus erythematosus is an area I'm watching closely."

According to Statista, the market for cancer drugs is expected to reach $300 billion by 2032[2]. Simon Kerry believes this will be driven by a range of factors, including "the need to find safer and more effective drugs, and an increasing focus on therapies that are personalised to the patient." From an industry perspective, he says that several key drugs are going to encounter competition from cheaper generics or biosimilars. "These factors are going to drive investment in cancer drug research in the coming years and decades."

Carlos Bañado, CEO of ARScience Biotherapeutics, thinks Interleukin-2 (IL-2)'s potential as an adjuvant and companion drug is driving innovations with delivery technologies to enhance efficacy and reduce side effects. He says: "Traditionally administered by injection, IL-2 delivery now explores slow-release formulations including nanoparticle carriers and hydrogel-based platforms which help maintain therapeutic levels over extended periods, reducing the need for frequent dosing. Additionally, oral delivery systems are under investigation to make administration less invasive and improve patient compliance. With continued advancements in delivery and formulation, IL-2 is poised to become an essential component in diverse therapeutic regimens, enhancing outcomes across a spectrum of challenging diseases."

Luke Oh, CEO of NeoImmuneTech, thinks that by 2025, there will be advancements in treating Acute Radiation Syndrome (ARS) with new approaches that enhance the body's immune response. He says: "Currently, treatment options for ARS are limited and mainly focus on managing symptoms. High doses of radiation severely weaken the immune system by reducing white blood cells, increasing infection risk. Emerging therapies such as the ones that target IL-7 receptors aim to stimulate the production and function of immune cells, particularly T cells, to help the body recover more effectively from radiation damage. By safely boosting the immune response, these innovative strategies offer a promising new avenue for ARS treatment. Ongoing research in this area holds great potential for transforming ARS care in the near future."

Molecular glue degraders (MGDs) are also playing a key role in biopharmaceuticals, overcoming limitations of bivalent degraders to expand the druggable space to previously undruggable targets, according to Neil Torbett, CEO of PhoreMost. He says: "Continued development of MGD discovery platforms is enabling systematic identification and optimisation of MGDs by designing and evaluating novel protein-protein interactions. MGDs offer a targeted approach for cancer-specific degradation, reducing damaging side effects associated with current treatments and improving patient outcomes – it is a revolutionary space, with many exciting developments already in the pipeline for 2025."

Helen Bright, CSO of Centauri Therapeutics, adds that whilst immune therapy has become the cornerstone of cancer treatment over the last decade, its potential in the fight against difficult-to-treat bacterial infections is yet to be realised. She says: "Traditional antibiotics focusing on bacterial inhibition are insufficient in meeting the needs of current patient populations and highlights the importance of a patient-focused immune approach. Novel immune therapy approaches will be crucial to overcome these limitations, particularly against multidrug-resistant bacteria. These novel approaches would of course also have application across other therapeutic indications, including adding to options for immune therapy in oncology."

> Drug development needs to reinvent its model

Cell and gene therapy

In August 2024, PartnerRe wrote that there are currently over 500 therapies in various stages of development, and it is anticipated that by 2025, the FDA will approve an additional 10 to 20 gene and cell therapies[4], and the sector continues to expand.

Erik Wiklund, CEO of Circio, says that current gold standard virus-based gene therapy faces substantial limitations in potency, repeat dosability and manufacturing cost. He says: "Advances in nucleic acid design, such as circular mRNA and stealth DNA vectors, will enable the field to move from viral vectors towards safer, cheaper, repeat-dosable formats. However, bringing the advantages of these novel nucleic acid systems to patients will require complementary delivery technology to efficiently reach specific target cells and organs."

According to Wiklund, 2025 will be the year when exciting nucleic acid and delivery technologies converge to create novel therapeutic candidates to tackle devastating genetic diseases and bring the curative prospects of gene therapy to a broader patient population.

Matthieu de Kalbermatten, CEO of CellProthera, expects to see an increasing number of CGTs focusing on non-oncological indications, such as cardiology and neurology. He says: "While the effectiveness of cell therapy has been now demonstrated in clinical trials, the technological progress made in recent years means that we will succeed in optimising production costs and thus be able to offer these regenerative treatments also to patients suffering from chronic diseases. Advances in gene editing, stem cell reprogramming, and tissue engineering may also enable targeted repair and regeneration, moving beyond symptom management to directly address root causes of non-cancer diseases. This shift could be transformative for millions affected by otherwise untreatable conditions."

Natalia Elizalde Urdiain, Chief Business Development Officer of VIVEbiotech, says: "This year has been a record year for new CGT approvals, with seven new therapies approved in 11 months. I expect this regulatory success will continue to drive the space to grow in new directions in 2025."

In particular, she says development of lentiviral vector-based technologies are likely to increase, including in vivo gene therapies delivered directly to patients as vaccines, as well as in vivo CAR-Ts and for rare disease treatment. She adds: "This would build on a rise in clinical trials utilising in vivo lentiviral vectors observed in 2024. Expansion of CAR-Ts to autoimmune disorders, lupus, type 1 diabetes, and additional conditions will bring hope to new patients. We also predict new cell therapies against solid tumours, exploring applications of sophisticated CAR-Ts and alternatives like TCR-T and TILs while using lentiviral vectors as gene transfer technologies, based on the ongoing discussions with our biotech and pharmaceutical company partners."

Josh Ludwig, Global Director Commercial Operations at ScaleReady, says that the CGT sector continues to navigate the challenging landscape of

reduced investor confidence and downsizing due to unsustainable business models, where 2024 has again seen many CGT companies cutting large numbers of staff or shuttering completely. He says: "The industry must adopt high-throughput solutions that enable efficient scale-up and scale-out to reach the many patients in need. In 2025, we expect acknowledgment that the adoption of such technologies is the only acceptable path forward to meet patient demand, delivering more efficient manufacturing processes that will expand patient access to life-saving therapies without compromising on quality or cost."

Stella Vnook, CEO of Likarda, weighed in, sharing her belief that from hormone replacement to CGTs, sustained and targeted delivery can be the key to transforming a drug candidate from one that struggles in clinical trials to a safe, effective treatment that reaches the market. She says: "As biotech and pharmaceutical companies look to improve therapies and extend IP protection, 2025 promises to be a pivotal year for hydrogel encapsulation technologies."

"CGTs are undeniably one of the most groundbreaking developments within our sector in recent times", says Brian Burke, Chief Commercial Officer at Tozaro. "With more treatments being developed every year, we're now at a stage where we can prescribe a wealth of CGTs to patients for different conditions - potentially even before full presentation of pathology. However, it is essential that the industry works to further improve accessibility and affordability moving forward. Optimising manufacturing processes to drive new therapies to market faster and at a reduced cost is a key element of these efforts, and we see this emerging as a major focal point through 2025."

Burke also notes that viral vector production and purification to facilitate delivery of genetic payloads is a significant technical and economic pain point. He says: "Current approaches are costly and give low yields due to over reliance on processes developed for antibody manufacturing. Emerging technologies, such as chemically-derived affinity ligands, represent an exciting prospect to transform this area – offering increased yields, reduced manufacturing costs and the ability to rationally design reagents. This helps to tailor them to each application, rather than having to design new processes or make large adaptions around the reagent. By investing in crucial research to address important manufacturing bottlenecks like this, we can help solve accessibility issues and bring life-saving treatments to all patients who need them."

CGTs have faced numerous challenges of late, according to Lee Markwick, Senior CMC Translation Consultant at eXmoor Pharma. These include limited investment and withdrawal of approved therapies, alongside concerns over T-cell malignancy. However, he says that 2025 offers a glimmer of hope. "Inflation is decreasing, investment streams are beginning to flow, and numerous CGT are anticipated to apply for market authorisation. Furthermore, new technologies are becoming available to solve the challenges associated with commercial scale manufacturing. Therapy developers should focus on three essential areas to stand out from the crowd in 2025; strong clinical data emphasising safety and efficacy, a sustainable, commercially-viable CMC strategy and demonstrable commercial benefits with a justifiable reimbursement strategy."

New approach methodologies

Tomasz Kostrzewski, Chief Scientific Officer of CN Bio, says that new approach methodologies (NAMs), particularly organ-on-a-chip (OOC), are gaining significant traction across the industry - driven, in part, by key legislative changes, alongside an impressive body of data demonstrating OOC models to be a viable, often more effective, and cost-saving alternative to traditional approaches. He says: "We're now at a stage, where mass adoption of these technologies is starting to happen, which will ultimately lead to faster and more accurate drug discovery with human relevant translational data generated more simply and more rapidly, early in the process."

Broadening the use of NAMs into exciting new applications is key to keeping up with the industry's rapid evolution, says Kostrzewski. "We're seeing this in the OOC market, tackling crucial challenges in disease modelling, safety toxicology, ADME profiling, and also across more specific applications, such as dose escalation studies in oncology. NAMs, including OOC, have the potential to revolutionise the drug discovery and development landscape, and we're anticipating transformative developments as the sector moves into 2025."

Mike Nicholds, CEO and Co-Founder of Newcells Biotech, agrees that 2024 has given us a lot to be excited about in the drug discovery and development sector, particularly as the integration of NAMs accelerates. He says: "With new, promising drug candidates emerging faster than ever before, and the development of innovative new research tools now beginning to keep pace, I think there is general anticipation that market growth will really ramp up throughout 2025."

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