The GLP-1 Gold Rush

In this series of articles and interviews, we look at the trends shaping the GLP-1 market, including research avenues, the use of AI, and the challenges of characterization

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Welcome to the GLP-1 Gold Rush!

The trends and challenges shaping the market for GLP-1 therapeutics.

By Stephanie Vine

Once known mainly for treating type 2 diabetes, GLP-1 receptor agonists like semaglutide have become the face of a booming weight loss revolution. Novo Nordisk's semaglutide first gained FDA approval in 2017 as Ozempic, a once-weekly injection for diabetes. One of the drug's notable side effects – weight loss – quickly gained attention. By June 2021, the FDA approved a higher-dose version under the brand name Wegovy for chronic weight management.

Demand soared. In March 2022, Wegovy was officially in short supply in the US due to overwhelming interest. By the summer of 2024, Novo Nordisk reported that approximately 25,000 new US patients were starting Wegovy each week; roughly four times the number from December 2023. The company stated it was operating its manufacturing lines "24 hours a day, seven days a week." Off-label use of Ozempic for weight loss also led to supply shortages.

While most supply issues have now been resolved, demand for GLP-1s remains extraordinarily high. Market dynamics are still in flux, making it difficult to predict how this space will evolve, but it's clear that the potential market is enormous.

Arguably, this demand should have been expected. In many Western countries, weight and the desire to lose it has long been a cultural obsession. Fad diets come and go, and the appeal of a pharmaceutical "quick fix" is hard to ignore. Celebrity endorsements of Wegovy and Ozempic have only fueled public interest, with tabloids eagerly reporting dramatic transformations.

Although recent years have seen a focus on niche drugs for smaller patient populations, the anti-obesity market offers scale. And there's more than enough room for multiple players. Eli Lilly, for instance, has joined the race with tirzepatide, branded as Mounjaro for diabetes and Zepbound for obesity, both of which have shown compelling clinical results and are expected to compete head-to-head with Novo Nordisk's offerings.

With the market still in its early stages, there is enormous potential for optimization and differentiation. Long-acting formulations could become a key focus because of their potential for enhanced convenience and patient adherence. As weight loss drugs continue to blur the lines between patient and consumer, success may hinge not only on efficacy, but also on tolerability, accessibility, and lifestyle compatibility. In this context, the design and usability of the drug delivery device will be critical factors in patient experience and brand differentiation.

Manufacturing GLP-1 receptor agonists also presents significant challenges. These drugs are typically produced via solid-phase chemical synthesis, which is a labor- and resource-intensive process that involves sequentially building peptide chains one amino acid at a time. This method is technically demanding and has traditionally resulted in low yields per batch, making large-scale production complex and expensive. As a result, companies seeking to compete in this fast-growing market must be prepared to invest heavily in specialized infrastructure, equipment, and skilled personnel.

Moreover, success in this space requires tight coordination between drug production and the delivery device supply chain. The fill-finish process for injectables must align with the availability of pens, syringes, and other components, each of which may come from different suppliers. Any disruption in device manufacturing or logistics can create bottlenecks.

In short, while the GLP-1 market represents a huge commercial opportunity, it is one that demands technical excellence, operational agility, and strategic foresight across both pharmaceutical and engineering domains.

Drugs to Watch in 2025

Earlier this year, Clarivate published its annual Drugs to Watch Report. Eleven drugs were selected based on expected approval, clinical trial results, competitive landscape, market dynamics, and expected sales. We spoke with Mike Ward, Global Head of Life Sciences & Healthcare Thought Leadership at Clarivate, to find out if the GLP-1 explosion was as big as expected.

How challenging was it to whittle the list down to 11 drugs? Were there any disagreements about what should be included?
You might expect there to be some disagreements, but the process is quite structured and we can't include everything. Even with just 11 drugs, the report runs over 100 pages, and we also translate it into Korean, Japanese, Chinese, and Latin American languages.

We ranked the 26 shortlisted drugs, providing a rationale for each selection and its position. The ranked list then went back to the analysts, and we ask for their feedback.

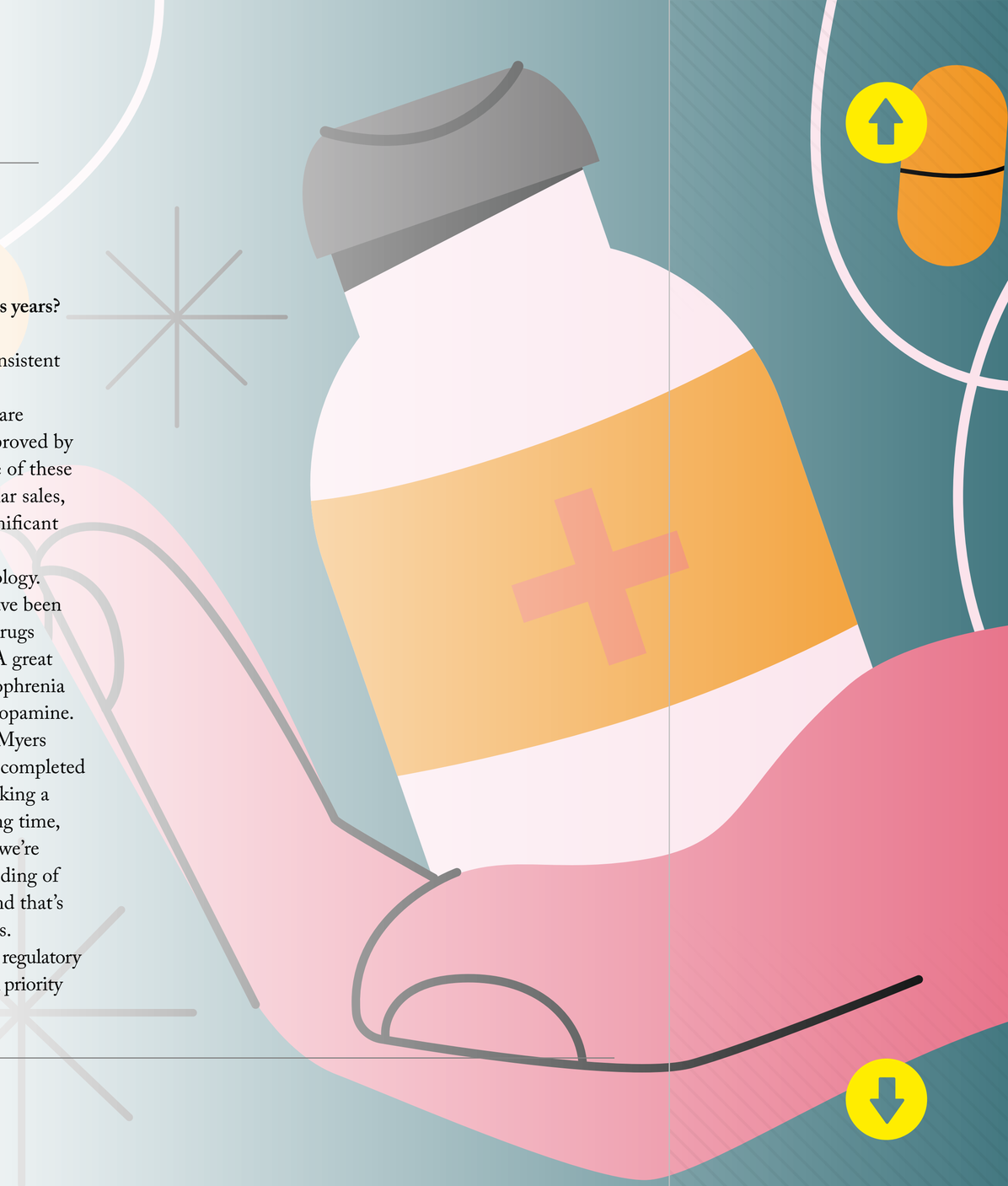
Originally, we had 12 drugs on the 2025 list, but in October, our number 12 pick was dropped because the company announced that its pivotal readout had been pushed to 2026, delaying its potential market impact. Given that, we decided to set it aside as a possible drug to watch for the 2026 report instead.

Throughout this process, the analysts can challenge the rankings. If someone feels strongly that a drug should be included or prioritized differently, they can lobby for it. For 2025, however, everyone was happy with the final selection. I think that's largely because we involve people early on, so they feel like they've had their say.

How does the 2025 list compare with the lists from previous years? What trends and shifts are you seeing?
Cancer treatments remain a major focus. This has been a consistent trend in recent years, and it's likely to continue.
One notable shift we've seen is the growing emphasis on rare disease treatments. For example, over half of the drugs approved by the FDA during 2024 had orphan drug designation. Some of these rare disease therapies won't necessarily achieve billion-dollar sales, but they're still hugely important because they address significant unmet medical needs.

Another area where we've seen a lot of movement is neurology. Whether in neuropsychiatry or neurodegeneration, there have been some major approvals in this space, including Alzheimer's drugs that we've highlighted as drugs to watch in previous years. A great example from this year's list is COBENFY – the first schizophrenia drug to target muscarinic pathways (M1/M4) rather than dopamine. Originally developed by Karuna, it was acquired by Bristol Myers Squibb in a $14 billion deal announced in 2023, which was completed in 2024. The drug secured FDA approval in November, marking a significant change in how schizophrenia is treated. For a long time, big pharma has been stepping away from neuroscience, but we're now seeing renewed investment. Advances in our understanding of neurological diseases are breathing new life into the field, and that's reflected in both drug development and regulatory approvals.

Another big industry trend is the increasing use of expedited regulatory pathways, such as fast track, breakthrough therapy designation, priority



Drugs to Watch in 2025 (cont...)

"The emerging potential of GLP-1s beyond diabetes and obesity is also catching attention, such as cardiovascular benefits. Semaglutide has been shown to reduce cardiovascular events by about 20 percent in patients with existing cardiovascular disease."

review, and accelerated approval. Nearly two-thirds of new therapies are now getting approved via one of these mechanisms.

GLP-1s are a hot topic. Did people see this explosion of interest coming?

If you go back six years or so, GLP-1s weren't a major focus. In fact, some companies, like Pfizer, deprioritized their GLP-1 programs. Right now, neither Eli Lilly nor Novo Nordisk are in the top 10 pharma companies by revenue, but this will change by 2030. You can see how the market is already anticipating this; Eli Lilly is now the most valuable pharmaceutical company in the world by market capitalization, and Novo Nordisk is the largest European pharma company by the same measure. These two companies are expected to dominate in the coming years.

GLP-1s were originally developed for type 2 diabetes, but their success in obesity treatment has been a game-changer. Semaglutide (Wegovy) was approved for obesity as early as 2021 and has shown strong weight-loss results in clinical trials. Tirzepatide (Mounjaro/Zepbound) has been even more impressive in obesity trials. That said, these drugs aren't perfect. There are still challenges; side effects, including gastrointestinal issues, can be unpleasant, and patient dropout rates are high. There are also concerns about muscle mass loss alongside weight reduction. The fact that they are all injectables can also be a barrier for some patients.

That's why companies are working on next-generation GLP-1s, such as combination therapies or oral versions that could reduce side effects, preserve muscle mass, and improve tolerability. There's huge scope for improvement, which is where a lot of the focus is shifting.

The emerging potential of GLP-1s beyond diabetes and obesity is also catching attention, such as cardiovascular benefits. Semaglutide has been shown to reduce cardiovascular events by about 20 percent in patients with existing cardiovascular disease. There's also early research suggesting potential applications in neurodegenerative conditions, such as Alzheimer's and Parkinson's. There is a lot of room for further exploration.

Biotech companies developing next-generation GLP-1s are also seeing a surge in interest. Companies that had previously struggled to book meetings with pharma companies are now being chased.

While the potential of GLP-1s in diabetes was recognized early, few people anticipated just how quickly they would take off in obesity and what the broader applications would be.

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Test with the experts

A Healthcare Revolution?

In celebration of The Medicine Maker's 10-year anniversary, we reached out to over 100 experts in pharma and healthcare to ask for their views on key disruptors, and the big changes in the next 10 years. Here's what experts had to say about obesity and GLP-1s.

Torsten Wöhr, CCO, Bachem

When it comes to disruptors, all current indicators suggest GLP-1 and hormone-derived peptide drugs will make a big difference. People call it the healthcare revolution, and I tend to agree. These drugs represent the beginning of a blur between lifestyle, nutrition, healthy living, and medicine.

When you lose weight, you feel better about yourself – and naturally, everyone will want that choice for themselves (irrespective of doctors and healthcare systems). The industry must now get ready for that possibility. With lifestyle, it is more important than ever that you can scale manufacturing effectively, fast, and produce quality at low cost.

We also should not avoid the reality of sustainability in this conversation. If for every injection there is roughly two liters of DMF that goes down the drain, consumers won't feel good about the product. These are great molecules, and our part is to make them safe, affordable, and environmentally friendly.

Sarah Browne, Vice President, Clinical Development, Altimmune

Rather than a one-size fits all approach to drug design and development, personalized therapies and treatment regimens tailored to the unique needs of patients have become a cornerstone of modern healthcare. A great example of this is the industry's innovation in obesity. As a multifactorial disease, obesity has historically been a challenging condition to treat because of the complex interplay of genetic, behavioral, and environmental factors. However, the development of new therapies that mimic naturally occurring hormones in the body has revolutionized obesity management – improving patient outcomes and bringing a renewed focus on treating obesity as a chronic disease rather than a lifestyle issue.

In the next 10 years, the obesity drug development landscape will continue to evolve as we place even greater emphasis on patient-centric approaches to develop therapies with enhanced tolerability and enable more precise

A Healthcare Revolution? (cont...)

targeting of obesity-related pathways, leading to treatments that are more effective for specific patient subgroups – addressing cardiovascular health, liver health, metabolic health, and more.

I also expect we'll see the integration of emerging tools and technologies, such as AI and wearable technologies, into clinical trials to enable accessible and equitable approaches to research and innovation. Integrating AI into clinical trials can drive enhanced efficiency from the patient selection and enrollment process to more robust measurement of clinical endpoints. In preserving invaluable time and resources, while bolstering non-invasive measurement capabilities, these improvements stand to reduce the costs associated with traditional drug development.

Hayley Crowe, EVP and GM Global Life Sciences, Ecolab

GLP-1 drugs – like Ozempic, Wegovy, Mounjaro, and Zepbound – have taken the world by storm. They address a significant unmet medical need with proven, almost universal effectiveness, which has created a blockbuster scenario. However, many patients still cannot access these drugs or choose not to use them due to factors such as cost, availability, or a dislike of needles. There is growing interest in making these drugs more accessible, and one potential solution is developing them in pill form.

Novo Nordisk already offers a low-dose oral GLP-1, which has shown promising results in late-stage trials for a higher-dose oral version. While smaller than traditional biologics, they share similar bioavailability challenges. Ensuring a reliable supply chain will also be crucial to meet patient demand.

This must be managed to keep costs affordable for both payers and patients while allowing manufacturers to protect their margins and recoup their investments.

Early estimates suggest that oral GLP-1s could be priced 25 percent lower than injectables if they reach the market. Over the next decade, if the pharmaceutical industry succeeds in developing non-injectable biologics, it could lead to a significant transformation, providing broader access and lower costs for patients.

Tom Sellig, CEO, Adare Pharma Solutions

The next decade is shaping up to be a period of significant innovation and change, and I think we can look forward to more efficient processes, groundbreaking treatments, and ultimately, better outcomes for patients worldwide.

One area is oral solid dose GLP-1 antagonists. I believe there will be technical breakthroughs that will enable these products to be reformulated into oral solid forms. Once brought to fruition, oral formulations of GLP-1s will bring greater patient convenience and compliance. They will also significantly expand market opportunities, and drive growth for CDMOs by increasing demand for specialized manufacturing processes and formulation expertise, ultimately enhancing production efficiency and fostering industry advancements.

Read more views on the future of pharma, biopharma, and healthcare here.

Advancing Mechanism-of-Action Reflective Potency Testing for GLP-1R Agonists

Sascha Karassek,
Scientific Officer, R&D,
Charles River

Review of a scientific approach to improving in vitro assay relevance for GLP-1R therapies

Could you elaborate on the physiological relevance of the mechanism-of-action (MoA) reflective in vitro potency testing for GLP-1 receptor agonists (GLP-1RAs)?
In vitro potency testing that is MoA-reflective is designed to mimic how a drug acts on its biological target. For GLP-1RAs, this means evaluating one of the following events:

- cAMP accumulation (primary signaling pathway)
- β-arrestin recruitment (alternative pathway, associated with receptor desensitization/internalization)
- Receptor internalization
- Insulin secretion (in pancreatic β-cell models)

In general, GLP-1R agonists stimulate insulin secretion and suppress glucagon in a glucose-dependent manner, mainly via cAMP signaling. In contrast, some GLP-1R agonists are designed to be biased and preferentially activate certain signaling pathways (e.g., favoring cAMP over β-arrestin signaling). Therefore, choosing the right MoA reflective in vitro potency assay is important.

Why is it important to have a proof of concept study investigated for different GLP-1 agonists that can activate the reporter system? How does this assay design ensure it is reproducible, sensitive and specific across different agonists?
Conducting a proof of concept (PoC) study for different GLP-1RAs that can activate a reporter system is critical for several scientific and strategic reasons:

- A PoC confirms that the agonists bind and activate the GLP-1R system in a specific way with a good responsiveness
- A PoC allows to investigate if full or partial agonists are able to activate the system.
- A PoC can be used to optimize the general assay conditions
- Once established with a PoC, such assays can be used during development for better development of several lead candidates.

The Promega reporter shown in the poster implements several strategies to give robust results:

- Usage of frozen ready-to-use cells to reduce cell handling and cell aging effects
- A relatively easy to implement assay principle with limited hands-on steps and short incubation times
- A proven downstream reporter gene system that is implemented in several of Promega reporter assay systems

How might your potency assay be integrated into regulatory submissions or quality control workflows for therapeutic GLP-1R agonists? Is this fully GMP-compliant?
Since relative potency is a CQA and therefore mandatory for lot release and stability testing, this Promega reporter is a good alternative to currently available systems on the market. Our PoC study showed that the assay is robust, accurate and precise over a range of 50% to 150% relative potency. It fulfills all points that are requested by the ICH Q2(R2) guideline for potency assay validation. Therefore, it can be used for lot release and stability testing during clinical phases and commercial phase after a product-specific validation has been carried out with a suitable reference material.

Due to the reporter assay design, it is also possible to semi-automate this assay to be used in preclinical phase for lead development and characterization.

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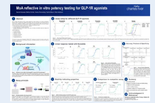

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Analysis and Characterization of GLP-1 Peptides

We ask an expert about the best practices for working with these complicated therapies.

Poor analytical work for GLP-1 peptides during drug development can have serious and far-reaching consequences. One of the most immediate risks is compromised patient safety. If impurities, such as truncated peptides, degradation products, or process related impurities, are not properly identified and controlled, they may lead to adverse immune responses, toxicity, or reduced therapeutic efficacy.

The enormous market for GLP-1 therapeutics is tempting many new biotechs to get involved with this space. However, GLP-1s are not easy products to work with. They are challenging to characterize and analyze because of their inherent complexity and the sophisticated modifications that are often introduced to enhance therapeutic performance. Getting your analytical work wrong can lead to product recalls, reputational damage, or legal action due to quality failures.

To find out more about the important role of analysis – and how analytical tech companies are reacting to the explosive interest in GLP-1s – we spoke with Matthew A. Lauber, Senior Director – Bioseparations, at Waters Corporation.

What activity are you seeing in the GLP-1 area and what trends interest you?

This space continues to evolve rapidly, with significant innovation beyond traditional GLP-1 receptor agonists. One of the most compelling trends is the shift toward multi-agonist sequences, such as GLP-1/GIP receptor agonists. Dual agonists have demonstrated superior weight loss and glycemic control, making them a key focus in next-generation drug development. Eli Lilly's tirzepatide drugs – Mounjaro (tirzepatide) for diabetes treatment and Zepbound (tirzepatide) for weight loss treatment – outperform active comparators on lowering blood sugar and on weight loss benefits in several trials. Most recently, Novo Nordisk impressed investors with clinical results for amycretin, a GLP-1/amylin dual agonist that showed promising weight loss and metabolic control effects. This drug candidate could represent another wave of peptide drugs. Combined therapies are also on the horizon – this is where more than one peptide is included in a drug product formulation.

Another exciting trend is the push toward oral formulations. While injectable GLP-1 therapies dominate, recent advancements in formulation science are making oral delivery, such as Rybelsus (semaglutide), more viable. Permeation enhancers, nanoparticle carriers, or novel excipients are already being applied and are ripe for breakthroughs.

Overall, we're witnessing a remarkable transformation in this field, with multi-agonists and new delivery formats paving the way for more effective and patient-friendly treatments.

What do you see as the biggest challenge in the analysis and characterization of GLP-1 peptides?

GLP-1 peptides can be challenging to work on because of their complexity, structural modifications, varying bioavailability, and conjugation chemistries, combined with challenging solubility and stability profiles. It is essential to know about each atom ahead of investigational new drug filings, during first-in-human clinical studies, upon seeking approval to go to market, and when completing batch release testing on a commercial product.

To give an example, let's talk about the purity of a drug. GLP-1s

Analysis and Characterization of GLP-1 Peptides (cont...)

"Since the atomic composition and stability of a GLP-1 is so important, it is essential to establish analytical approaches that can precisely and accurately provide information on their exact molecular composition."

can be produced by solid state synthesis or, in some more recent cases, by recombinant expression. When produced synthetically, a drug substance can contain truncated, incomplete peptide species. When produced recombinantly, they can contain host cell impurities. Whatever the manufacturing procedure, impurities must be controlled and carefully examined.

There are also other factors to consider. Peptide drugs are subject to chemical degradation reactions, such as oxidation and deamidation. Many GLP-1 therapeutics also incorporate chemical modifications, such as fatty acid conjugation to enhance half-life, improve receptor selectivity, and enable albumin binding. However, lipidation significantly alters its properties and considerations for how an analyst approaches an experiment.

How do impurities in synthetic peptides affect their overall efficacy and safety profile?

Impurities from incomplete synthesis and chemical degradation can affect efficacy, safety, and stability. Because of the importance of both characterizing and quantifying drug impurities, the FDA recently released product specific guidelines for some synthetic peptides on the market.

Aggregates can be very problematic. If the structure of a GLP-1 peptide drug changes, even just by one atom, there can potentially be a change in receptor binding, lower bioavailability, and diminished therapeutic potency. Some impurities can also trigger immunogenic responses, leading to adverse reactions or neutralizing antibodies that compromise drug effectiveness. This is often the case with aggregates, most especially covalently bonded multimers. Additionally, altered metabolism may produce toxic byproducts or affect clearance, increasing safety risks.

What kind of separation, identification, and analytical processes are important for GLP-1s?

Since the atomic composition and stability of a GLP-1 is so important, it is essential to establish analytical approaches that can precisely and accurately provide information on their exact molecular composition. This necessitates the use of chromatography and instrumentation that uniquely reports on sequence, chemical features, molecular weight, and size.

Advanced analytical techniques, such as HPLC and UHPLC, mass spectrometry, and light scattering, are essential for detecting, quantifying, and controlling impurities to ensure consistent drug performance and patient safety.

If I picked two chromatographic separation modes to focus on, it would be reversed-phase (RP) and size-exclusion chromatography (SEC). Each provide unique insights into peptide quality, purity, and stability. RP, commonly coupled with liquid chromatography-mass spectrometry (LC-MS), is used to assess peptide purity, detect impurities, and characterize modifications, such as oxidation, deamidation, and truncation. It relies on hydrophobic interactions to separate GLP-1 and its variants based on differences in polarity, making it ideal for detailed structural analysis and impurity profiling.

This approach is used in preclinical animal studies as a so-called inlet technique for quantitative dosing and metabolism studies. It is also used in a simpler capacity, with just a UV detector to confirm identity and test for impurities during batch release testing because it is particularly effective at resolving and detecting oxidation, deamidation, and incomplete sequences.

SEC, on the other hand, is essential for evaluating the aggregation and size distribution of GLP-1 peptides by separating molecules based on their hydrodynamic radius rather than chemical interactions. This technique helps assess formulation stability, detect higher-order structures, and monitor degradation pathways. Together, RP and SEC provide a comprehensive analytical approach, ensuring GLP-1 therapeutics meet stringent quality, safety, and efficacy requirements.

Read the full article online.

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AI Approach to Transdermal GLP-1s

How do you design, refine, and optimize novel GLP-1 drugs that could improve patient experiences? With a computer, of course.

Traditional drug discovery often relies on high-throughput screening and iterative lab-based modifications. ImmunoPrecise Antibodies (IPA) is taking a different path by using a computational platform to design, refine, and optimize GLP-1-like sequences. By analyzing conserved evolutionary patterns and structural motifs, their AI-driven approach aims to predict optimal sequence and structural characteristics in silico, enhancing stability, improving receptor engagement, and optimizing pharmacokinetics. The goal? To develop GLP-1 therapies that are longer-lasting, more effective, and potentially easier to administer with fewer side effects.

In this Q&A, IPA CEO Jennifer Bath explains how AI-designed GLP-1 therapeutics using a transdermal approach could overcome some of the challenges of current treatments.

How do AI-designed therapies address common challenges associated with current GLP-1 treatments?
Traditional GLP-1 therapies degrade quickly because of enzymatic breakdown by the enzyme dipeptidyl peptidase-4 (DPP-4), requiring frequent injections. AI-designed sequences can incorporate predicted structural modifications that may enhance resistance to degradation, improve binding affinity, and extend half-life without relying on chemical modifications or external stabilizers. By selecting a construct carrying the sequence that may be well suited for alternative delivery methods, including potentially transdermal delivery with sustained, controlled release, the aim is to reduce the need for frequent administration.

Why could a transdermal approach be so beneficial for GLP-1s?
Transdermal delivery offers a non-invasive alternative to injections, which could improve patient compliance and eliminate injection-related discomfort. Sustained absorption through the skin could ensure a steady plasma concentration, which could reduce fluctuations in drug levels, leading to more consistent therapeutic effects. Additionally, the use of targeted technology for optimized gene expression may support long-term drug production, further enhancing the feasibility of a low-frequency dosing regimen.

What are the scientific and technical challenges of delivering GLP-s transdermally? How is the company approaching these?
Because the skin is a natural shield, it can be hard for biologic/large molecule drugs to pass through, which is why transdermal delivery is rare. Specific to GLP-1 drugs is that they break down easily from skin enzymes and body processes, losing effectiveness, plus storing them at room temperature is difficult. This creates another challenge in that patches need to release medicine slowly over days while delivering enough to work. One approach will be to focus on molecular redesign using advanced engineering to create smaller, more stable versions of GLP-1 tailored for skin absorption, creating delivery enhancements that will combine skin-friendly formats (e.g. patches or gels) with methods to improve drug penetration. We also plan to explore gene-based platforms to enable the body to produce therapeutic molecules internally, reducing dosing frequency.

How does IPA plan to collaborate with other stakeholders to integrate these therapies into existing diabetes treatment protocols?
IPA is working with Aldevron to produce the constructs that can deliver the therapy. We're also exploring collaborations with pharmaceutical companies and research institutions to align AI-discovered therapeutics with current treatment standards. By integrating potential stakeholder insights early in the development process, the aim is to ensure seamless adoption within existing diabetes and metabolic disease management protocols.

Read the full article online.

Link
Online Article

Revolutionizing GLP-1 delivery: Excipient innovation for a patient-centric future

As GLP-1 therapies evolve, patient-friendly delivery formats - from oral tablets to inhalation systems - are gaining momentum. This shift is driven by patient preferences and the limitations of traditional injections, such as needle anxiety, disposal challenges and cold chain requirements. At the same time, expiring patents are opening doors for next-generation formats that improve usability and logistics.

The role of excipients in innovation

Success in this new landscape requires more than a novel API. It demands smart formulation strategies and the right excipients to ensure stability, bioavailability, and ease of use. At DFE Pharma, we recognize the critical role excipients play in enabling this transition. Our comprehensive portfolio of high-performance excipients combined with deep formulation expertise enables innovation across oral solid dose (OSD), inhalation, and biopharma platforms.

Case study: inhalable semaglutide

As a part of the INTO (Inhalation Together) alliance, DFE Pharma conducted a comprehensive study exploring an inhalable alternative to injectable or oral semaglutide using spray-drying techniques. The resulting dry powder inhalation formulation maintained semaglutide stability without refrigeration. During pre-formulation, three excipients – sucrose, trehalose dihydrate, and mannitol — were evaluated. BioHale® Trehalose dihydrate emerged as the most effective, delivering superior aerodynamic performance and achieving a fine particle fraction of 60%, indicating strong potential for deep lung deposition and systemic absorption.

This breakthrough highlights the promise of inhaled semaglutide as a needle-free, cold-chain-independent therapy – offering greater convenience and supporting long-term adherence.

Enabling patient-centric therapies

Excipients are key enablers of patient-centric innovation. While oral and inhalation routes offer clear benefits, they also present formulation challenges. Oral biologics must overcome digestive breakdown and absorption barriers, while inhaled therapies require excipients that ensure drug stability and targeted lung delivery. Addressing these challenges requires right excipient solutions tailored to each route of administration.

DFE Pharma's broad excipient portfolio supports multiple non-invasive routes, including OSD, and pulmonary delivery. Our global technical and regulatory experts work closely with development teams of pharmaceutical companies worldwide to accelerate development timelines, reduce risks associated with regulatory complexities and production failures, and streamline commercial scale-up.

From concept to impact

Creating GLP-1 therapies that patients prefer requires a holistic approach – combining formulation science, delivery innovation, and excipient functionality. DFE Pharma is your partner across the development journey, helping you bring smarter, safer, and more accessible therapies to life.

Are you exploring non-invasive GLP-1 formulations?

Discover how DFE Pharma supports innovation through excipient expertise, collaborative studies, and purpose-built solutions like BioHale® Trehalose Dihydrate.

Your medicines, our solutions. Moving to a healthier world.

Learn more

GLP-1s: Going Beyond Diabetes and Obesity

What other therapeutic indications could GLP-1s make an impact in? We took a look at the research to find out.

Alcohol-Use Disorder

In the US alone, around 178,000 deaths every year can be attributed to alcohol – which can cause liver disease and cardiovascular disease. A significant proportion of people will meet the criteria for alcohol use disorder (AUD) at some point in their lives, but many do not seek or receive treatment.

A small clinical trial led by researchers at the University of North Carolina and the USC Institute for Addiction Science has reported that semaglutide may reduce alcohol consumption and craving in people with AUD under certain conditions.

The trial enrolled 48 non–treatment-seeking adults with AUD in the US, with participants randomized to receive either semaglutide or placebo over nine weeks. The primary endpoint was alcohol self-administration in a lab setting, designed to capture changes in voluntary drinking behavior under controlled conditions. Secondary and exploratory outcomes included weekly self-reported consumption and craving.

Participants who received semaglutide consumed less alcohol during the post-treatment lab session compared to the placebo group. Statistical models indicated medium to large effect sizes for both the quantity of alcohol consumed and peak breath alcohol concentration.

Semaglutide did not reduce the overall number of drinking days or drinks per day in naturalistic settings, but it did significantly reduce the amount consumed on drinking days, with participants saying they had decreased alcohol cravings.

A notable secondary outcome was observed among participants who also smoked cigarettes. In this subgroup, those receiving semaglutide showed a greater reduction in cigarettes per day over time relative to placebo. The researchers cited preclinical studies suggesting that GLP-1 receptor agonists may dampen reward-related behaviors beyond alcohol, including nicotine use.

The study population consisted of individuals with moderate AUD severity who were not actively trying to reduce their drinking, which the investigators argue may better reflect the majority of patients receiving GLP-1 therapies in general practice settings.

"The focus on non–treatment-seeking participants has important considerations, one being that semaglutide-related reductions in drinking quantity occurred absent volitional attempts to reduce drinking," write the authors. "In contrast to treatment-seeking participants, this sample is arguably representative of the majority of those with AUD exposed to GLP-1RAs in general medical settings . . . In this context, the broad uptake of GLP-1RAs presents an ideal scenario for medication repurposing, with potential to help reduce the wide treatment gap associated with AUD."

MASH

Novo Nordisk's ESSENCE phase III trial evaluated the efficacy and safety of semaglutide in adults with metabolic dysfunction-associated steatohepatitis (MASH) and liver fibrosis stages. The study assessed subcutaneous semaglutide 2.4 mg administered weekly over a period of 72 weeks.

Original image sourced from: Adobestock.com

GLP-1s: Going Beyond Diabetes and Obesity (cont...)

"The slower loss of brain volume suggests liraglutide protects the brain, much like statins protect the heart."

The trial met its primary endpoint, with 62.9 percent of patients receiving semaglutide achieving resolution of steatohepatitis without worsening of liver fibrosis, compared to 34.3 percent in the placebo group. A key secondary endpoint, improvement in liver fibrosis by at least one stage without worsening of steatohepatitis, was achieved in 36.8 percent of patients in the semaglutide arm versus 22.4 percent in the placebo arm. An additional composite endpoint – the proportion of patients achieving both resolution of steatohepatitis and improvement in fibrosis – was reached by 32.7 percent of patients treated with semaglutide compared to 16.1 percent of those on placebo.

The safety profile of semaglutide observed in the study was consistent with its known safety characteristics, with gastrointestinal events being the most frequently reported adverse events. The results have been published in *The New England Journal of Medicine*.

Dementia

A meta-analysis conducted by authors in Ireland examined whether glucose-lowering drugs recommended for cardiovascular protection might also lower the risk of dementia. Published in JAMA Neurology, the study reviewed data from 26 randomized clinical trials involving more than 164,000 participants to assess the impact of four drug classes – SGLT2 inhibitors, GLP-1 receptor agonists, metformin, and pioglitazone – on dementia and cognitive impairment outcomes. The authors concluded that while glucose-lowering therapies as a group were not clearly associated with reduced dementia risk, GLP-1RAs warranted further investigation. GLP-1s appeared to be associated with a statistically significant decrease in dementia cases.

Other studies have also suggested a potential link between GLP-1s and a reduced risk of dementia and Alzheimer's disease. For instance, a phase IIb clinical trial presented at the Alzheimer's Association International Conference 2024 found that liraglutide slowed cognitive decline by 18 percent over one year in patients with mild Alzheimer's disease, compared to a placebo group. The study also reported nearly 50 percent less brain shrinkage in areas related to memory, language, and decision-making among those treated with liraglutide

The mechanisms by which GLP-1RAs might influence dementia risk remain speculative, though animal studies and prior observational research suggest roles for anti-inflammatory effects, reduced oxidative stress, and direct neuroprotection.

"The slower loss of brain volume suggests liraglutide protects the brain, much like statins protect the heart," said Paul Edison, professor of science from Imperial College London and study lead for the work presented at the conference. "While further research is needed, liraglutide may work through various mechanisms, such as reducing inflammation in the brain, lowering insulin resistance and the toxic effects of Alzheimer's biomarkers amyloid-beta and tau, and improving how the brain's nerve cells communicate."

The Golden Ticket For Obesity Drug Development

We speak to the 2025 winner of Novo Nordisk and Pioneer Group's Golden Ticket program.

The Golden Ticket program targets early-stage biotechs that "want to change the world," with a focus on cardiometabolic health and rare blood and rare endocrine disorders. The prize includes rent-free space, mentoring and support from both Novo Nordisk and the Pioneer Group, and access to Pioneer's venture programs. Entry closed in November 2024, with shortlisted companies invited to a pitching event.

And the winner? Meet Melio Bio – a new company that was established to discover and develop novel inhibitors that target a receptor associated with obesity. We caught up with Zoë Johnson, Co-founder and Executive Chair of Melio Bio, to find out more about the company, its work, and how it will make the most of this golden opportunity to push obesity research forward.

Congratulations on winning the Golden Ticket! Can you give us an introduction to the science and R&D that Melio Bio is working on?

While GLP-1 receptor agonists have transformed obesity treatment, many patients remain underserved because of side effects, non-response, or limited efficacy. With strong human genetic evidence linking GPR75 loss-of-function variants to lower body weight and reduced obesity risk, we believe this represents a breakthrough opportunity for a new class of cardiometabolic drugs. In addition to treating obesity, we are also focusing on co-morbidities – particularly metabolic-dysfunction associated steatoic liver disease (MASLD), one of the most common forms of chronic liver disease.

What is the story behind the creation of the company?

I have spent over 25 years working in the pharma/biotech/start up space and have had the opportunity to work on several highly innovative programs in a range of therapeutic areas. This experience has taught me what it takes to build a company: great science, a great team and a large dose of passion and perseverance! At Molecule to Medicine, my role is focused on building new companies that deliver high quality drug R&D programs based on innovative science with strong genetic validation, working with our team of expert scientist-entrepreneurs and company scalers.

Melio Bio was developed internally at Molecule to Medicine, where my co-founder, David Miller, a medicinal chemist with deep expertise in GPCR drug discovery, highlighted a publication that detailed the target, GPR75, having a very strong association with obesity. We were looking for new opportunities for a next generation program in obesity and associated co-morbidities, and this target was an ideal fit with our expertise. Additionally, we have a long-standing relationship with Sygnature Discovery who agreed to work with us on the program to advance the screening to a point where we could raise external funds to support the ongoing development of the company.

What have been the biggest challenges in the early stages of the company?

From a scientific point of view, establishing the hit finding screen was challenging. We could not replicate some of the published literature around the putative endogenous ligands of GPR75 and so we had to devise an assay to screen our compound library in

The Golden Ticket For Obesity Drug Development (cont...)

the absence of a known ligand. Fortunately, Sygnature Discovery helped us to make excellent progress in a short time.]

From a corporate point of view, we are capital raising for an early-stage company in a challenging economic climate. We anticipate that the benefits of the Golden Ticket prize will give us a boost in our fundraising efforts and we look forward to accelerating our preclinical development plans in the coming months.

A lot of companies are now trying to enter the obesity therapeutic space. In a competitive area, what makes your research stand out?

It is true that the space is increasingly crowded, but a lot of the competition is still focused on the clinically validated incretin class, offering incremental improvements on the first generation GLP-1 agonists. We believe that real breakthroughs require new approaches, so we are focusing on next generation molecules that will address some of the limitations of current and emerging therapies. The GPR75 target has been identified relatively recently, and the field is wide open – the team that is able to deliver a high-quality program at pace will win, and we believe we have all the tools to succeed.

How did you and the team react when you first found out you had won the Golden Ticket program?

We found out just before Christmas, so it was like receiving the best gift early! In early-stage discovery there are a lot of ups and downs, so this was really welcome news!

What will you be receiving?

We receive a number of benefits; the two principle ones being space and advice. The early support and guidance we will receive from Novo Nordisk's world-class pharma team represents a unique opportunity to refine and strengthen our approach. We are excited to leverage this collaboration to drive meaningful impact and bring new solutions to patients globally. Secondly, having space in a biotech focused hub in a central London location, along with the associated support from the Pioneer Group team, is a huge boost for us. Being surrounded by like-minded scientist entrepreneurs in the heart of London's knowledge quarter is exactly the environment we want Melio Bio to be in to flourish and grow. We would have struggled to secure this space at our pre-fundraising stage, and we intend to remain in this location for many years to come.

A competitive pitch process was involved. What lessons did you learn during this? And what advice would you offer to other young companies when it comes to getting pitches right?

The experience was great because it gave us an opportunity to think about how to communicate the value of our early-stage company to large pharma as well as an investor in a concise way.

Read the full article online.

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Packaging innovation for GLP-1 therapies: Powering Scalable Obesity Treatment

As GLP-1-based therapies redefine chronic weight management, the demands on primary packaging are changing rapidly, requiring smart solutions that ensure patient safety, drug stability, and global scalability.

GLP-1 receptor agonists are transforming chronic weight management. Originally developed for diabetes, these biologics now show remarkable promise in driving sustained weight loss, improving metabolic health, and reducing cardiovascular risk. With over 870 million adults affected by obesity globally (World Obesity Federation), these therapies must be scaled safely and efficiently, starting with smarter primary packaging.

As demand surges, packaging must do more than contain. It must protect sensitive molecules, support frequent self-administration, and enable global scalability without compromising on patient safety and regulatory compliance.

Matching molecule to material

GLP-1 drugs are delicate proteins that must remain stable throughout shelf life. Container interaction, especially with silicone oil, tungsten residues, or extractables from elastomeric components, can negatively impact protein stability. That's why Borosilicate glass remains the gold standard for drug containment, offering superior chemical resistance and minimizing interaction risks.

For high-volume manufacturing, Type I glass syringes and cartridges are the preferred formats. Not only are they compatible with existing fill-and-finish lines, they also demonstrate proven performance with biologics.

Supporting frequent use medication: syriQ BioPure® glass syringes and cartriQ® ready-to-use cartridges

Unlike one-time treatments, GLP-1 medications are often self-administered weekly or even daily. This demands primary packaging that integrates seamlessly into user-friendly devices. syriQ BioPure® prefillable glass syringes (PFS) are designed for optimal functionality and seamless device integration with autoinjectors and safety systems, offering simplicity and confidence for patients with limited dexterity. Meanwhile, cartriQ® ready-to-use (RTU) cartridges provide the flexibility needed for reusable pens, allowing multiple doses from a single container and therefore a format gaining traction for its environmental and economic advantages.

Device integration brings new challenges. Plunger performance, break-loose and glide forces, and dimensional precision must be tightly controlled to ensure consistent dosing. SCHOTT Pharma offers cartridge and syringe platforms optimized for specific drug viscosities and dosing volumes, critical as the industry moves toward higher-concentration formulations to reduce injection volume.

Scaling with safety

The success of GLP-1 drugs depends not only on medical efficacy but also on the ability to reach patients quickly and safely. That means packaging solutions must support high-throughput, automated production, and meet stringent regulatory standards across global markets. Using SCHOTT iQ® RTU containers, which are supplied sterile and, if necessary, siliconized, reduce contamination risk and support faster, more agile manufacturing.

Vials in focus: EVERIC® pure is a foundational format for flexibility

While much of the innovation in GLP-1 packaging is focused on self-administration formats like syringes and cartridges, vials remain essential, especially in early-stage development, institutional settings, and cost-sensitive markets. Their flexibility, ease of filling, and compatibility with a wide range of administration techniques make them a practical choice for clinical trials and hospital use. Moreover, in regions where cost efficiency is a top priority, vials offer a more economical solution without compromising on safety or performance. EVERIC® pure vials offer low delamination risk and outstanding extractable and leachable performance, making them a trusted choice for safe, scalable delivery. As global access to GLP-1 therapies expands, vials remain a vital format for ensuring equitable distribution and scalable treatment delivery.

Enabling the future of obesity treatment

GLP-1 therapies are reshaping obesity treatment—and packaging must evolve in lockstep. Whether through robust syringes, versatile cartridges, or flexible vials, the right primary packaging is critical to ensuring drug stability, patient adherence, and global reach.

For pharmaceutical manufacturers, now is the time to invest in scalable, biologics-ready packaging platforms designed with the patient in mind. The SCHOTT iQ® platform delivers on all fronts—safety, speed, and simplicity—empowering the next generation of obesity care.

Learn more

Semaglutide's Origins: A Breakthrough for Type 2 Diabetes

An interview with Novo Nordisk's Stephen Gough.

With GLP-1 receptor agonists like semaglutide gaining widespread attention for their powerful effects on weight loss, it's easy to forget where their story began. Long before headlines focused on obesity management, semaglutide was developed and approved to treat type 2 diabetes, which remains a leading cause of cardiovascular complications. As the spotlight shifts toward the drug's weight-loss benefits, it's critical not to lose sight of its foundational role in blood glucose management and cardiovascular risk reduction.

In this interview, originally conducted during the early rollout of oral semaglutide, Stephen Gough, Chief Medical Officer at Novo Nordisk, discusses the evolution of diabetes treatment, the challenges patients still face, and why cardiovascular disease remains one of the most pressing – and under-addressed – threats to people living with type 2 diabetes. The insights remain highly relevant today, as the medical community continues to push for broader adoption of therapies that do more than just lower blood sugar. They save lives.

How has the treatment of diabetes evolved?

The pharmaceutical industry has come a long way in its ability to address diabetes. At Novo Nordisk, for example, we developed our first insulin products in 1923 and continue to produce treatments for both type 1 and type 2 diabetes today. Metformin, DPP-4, SGLT-2 inhibitors, and recent innovations like GLP-1 RAs are especially effective in blood glucose-lowering in comparison to previous treatments, but there are still issues for pharma to address. For example, we need to innovate on the drug delivery front. Injectable therapies, though useful, aren't suitable for everyone. Exploring new options will help us better support patients.

What challenges do patients face?

Diabetes is associated with many other conditions – including cardiovascular disease, the leading cause of death and disability in type 2 diabetes patients. We conducted a study, CAPTURE, to address a gap in the knowledge of the global prevalence of cardiovascular disease, as well as its risk and management in people with type 2 diabetes. Nearly 10,000 participants took part in the global study. We found that one in three people with type 2 diabetes have established cardiovascular disease (CVD), and 90 percent of those had atherosclerotic CVD (a build-up of fat, cholesterol, and other substances in the artery walls). The study also showed that only 20 percent of people with type 2 diabetes and atherosclerotic CVD are receiving a glucose-lowering treatment with proven cardiovascular benefits.

These data show that people with type 2 diabetes need to be more aware of their risk factors, and that physicians need to not only actively screen for them, but also prescribe blood glucose-lowering therapies with proven cardiovascular benefit if patient outcomes are to be improved.

Read the full article online.

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