BEYOND THE STEP CHANGE

GLP-1s solved the efficacy problem — but in doing so, defined the next set of constraints

What GLP-1s solved and what they didn't

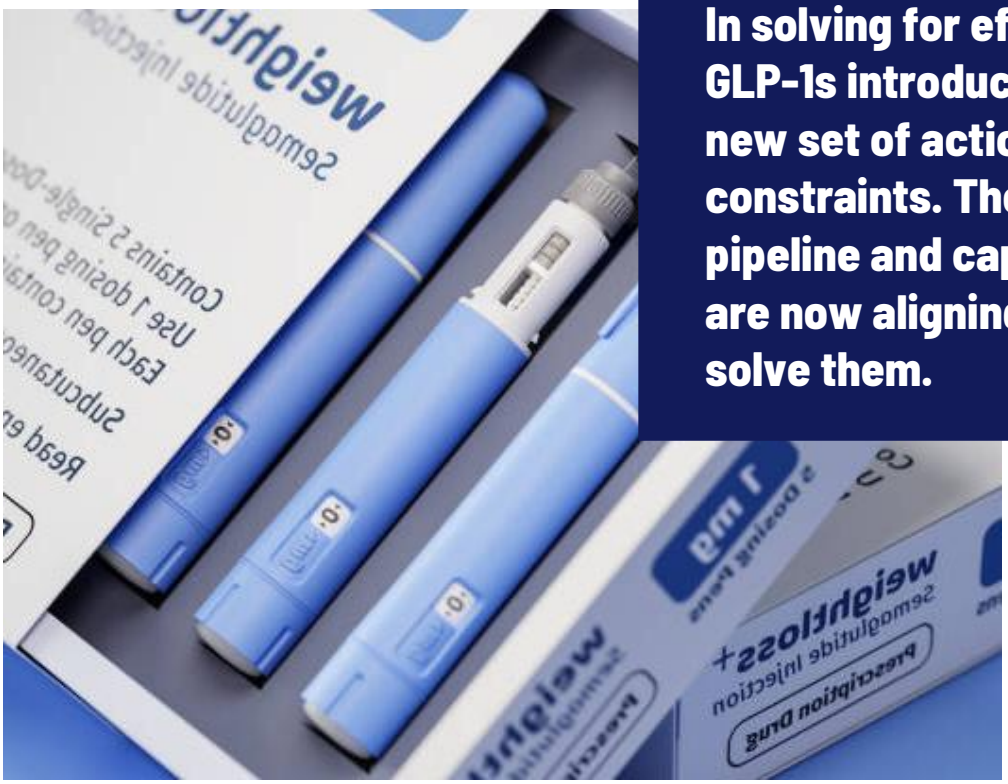
For decades, obesity pharmacotherapy was constrained by modest efficacy and safety setbacks. Incretin therapies — semaglutide, tirzepatide — broke that ceiling, delivering 15–25% weight loss and expanding impact beyond weight alone.

The question now is not whether GLP-1 modulation works, but what it leaves unsolved. Only 14% of physicians view current therapies as sufficient long-term solutions.

The gaps are clear: durability, lean mass loss, tolerability, access, and incomplete comorbidity coverage.

The pipeline — and the capital behind it — is organizing around these constraints. The field is not moving past GLP-1; it is building on it.

> **In solving for efficacy, GLP-1s introduced a new set of actionable constraints. The pipeline and capital are now aligning to solve them.**



The constraints are clear. The market is now organizing to solve them.

GLP-1 success defined the next set of constraints: Weight regain, lean mass loss, GI tolerability, cost and access barriers, and incomplete comorbidity coverage form an interconnected set of gaps that defines the next wave of innovation.

The pipeline is organizing around use cases not mechanisms: Over 230 clinical-stage assets span nearly 80 mechanisms, but the most useful lens is not what these therapies are — it is what problems they are solving: durability, real-world viability, quality of weight loss, and expansion beyond obesity.

Capital is reinforcing the incretin backbone: Investment and partnering activity are consolidating around GLP-1–based platforms. Patent cliffs are accelerating urgency, and the convergence of strategic and financial capital signals where the next wave of differentiation will emerge.

The implications are strategic, not just clinical: Competition is shifting from molecule-level to system-level. The market is segmenting into defined use cases, and the bar for differentiation is rising — anchoring around a specific constraint, designing for combination, and integrating clinical, commercial, and access dynamics are becoming essential.

Obesity treatment is not new
From limited efficacy to incretin breakthrough

Before GLP-1: limited efficacy and safety constraints

For decades, obesity pharmacotherapy was constrained by modest efficacy and recurring safety setbacks. Agents such as phentermine, orlistat, phentermine/topiramate, and naltrexone/bupropion delivered only 3–7% placebo-subtracted weight loss, while safety-driven market withdrawals — including fen-phen, sibutramine, and lorcaserin — reinforced regulatory and payer caution.

Bariatric surgery remained the only intervention capable of delivering >20% weight loss, but its invasiveness and underutilization left a persistent treatment gap.

After GLP-1: the efficacy ceiling breaks

GLP-1–based therapies changed that equation. While early agents such as liraglutide modestly improved outcomes, the inflection came with semaglutide and tirzepatide. These next-generation therapies delivered 15–25% weight loss, approaching surgical benchmarks for the first time and redefining what pharmacotherapy could achieve.

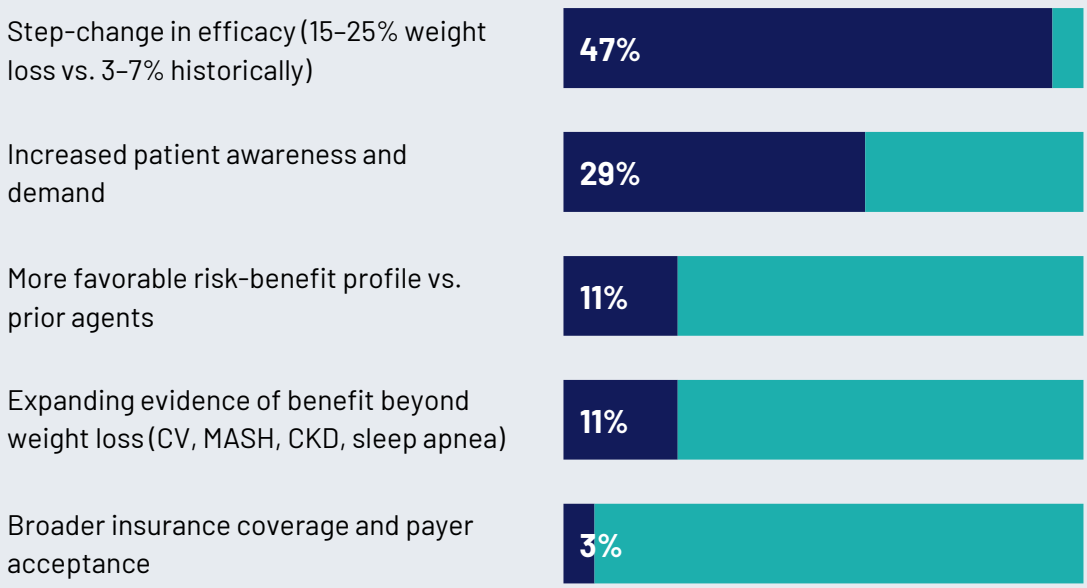
Their improved pharmacokinetics and, in the case of tirzepatide, dual receptor activity, translated into a true step-change in clinical performance.

For decades, the field couldn't close the gap between lifestyle and surgery — until a new approach to targeting the biology emerged.

This breakthrough rapidly translated into real-world impact. Novo Nordisk's Wegovy (semaglutide) and Eli Lilly's Zepbound (tirzepatide) generated approximately $5.7 billion and $4.9 billion in U.S. sales in 2024, compared to ~$345 million for Novo's earlier-generation product Saxenda (liraglutide), reflecting both physician adoption and patient demand.

As shown in Figure 1, the driver of this shift is clear. In an Ipsos survey of 67 U.S. physicians (~1:2 mix of endocrinologists and PCPs), efficacy — specifically the magnitude of weight loss — is the primary reason GLP-1 therapies have succeeded where prior treatments did not. For the first time, physicians have a pharmacologic option that meaningfully closes the gap with surgery without its invasiveness — establishing GLP-1 as the foundation of the modern obesity treatment paradigm.

Figure 1. What is the primary reason GLP-1 therapies gained traction where previous treatments did not? (n=67)



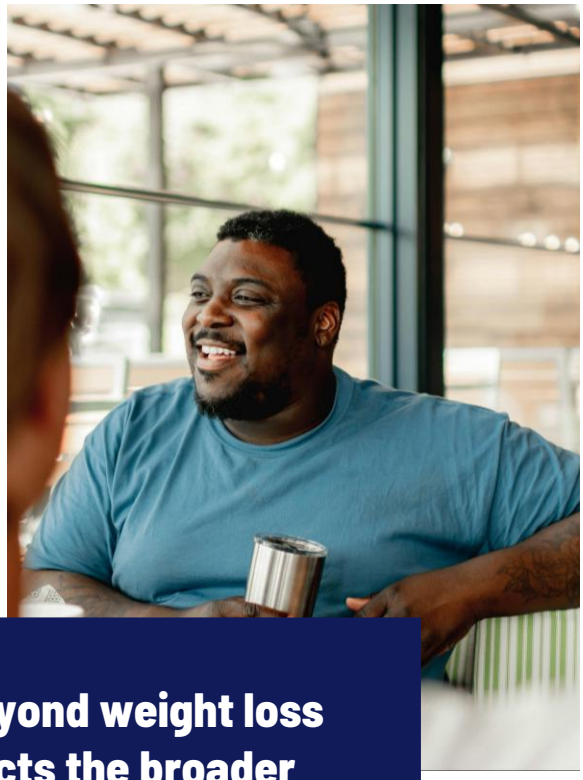
From weight loss to metabolic impact

Semaglutide has expanded beyond weight loss into cardiovascular risk reduction (SELECT), chronic kidney disease, and MASH, while tirzepatide has been approved for obstructive sleep apnea. Together, these developments are repositioning obesity therapies as broader metabolic treatments rather than weight-centric interventions.

Critically, these benefits are not solely an indirect result of weight loss, but reflect direct target engagement and the role of incretin biology across multiple disease pathways. A prespecified mediation analysis from the SELECT trial suggests that semaglutide's cardiovascular benefit is largely independent of both baseline adiposity and the magnitude of weight reduction, with only ~33% of MACE reduction explained by changes in waist circumference. The remainder appears driven by direct anti-inflammatory, vascular, and metabolic effects.

This distinction matters. Prior obesity therapies that achieved weight loss did not demonstrate comparable cardiovascular benefit. GLP-1–based therapies, by contrast, appear to confer broader biological effects that extend beyond weight reduction.

The implication is a structural advantage: incretin-based therapies are not just more effective weight loss agents — they are more complete metabolic interventions, raising the bar for non-incretin competitors.

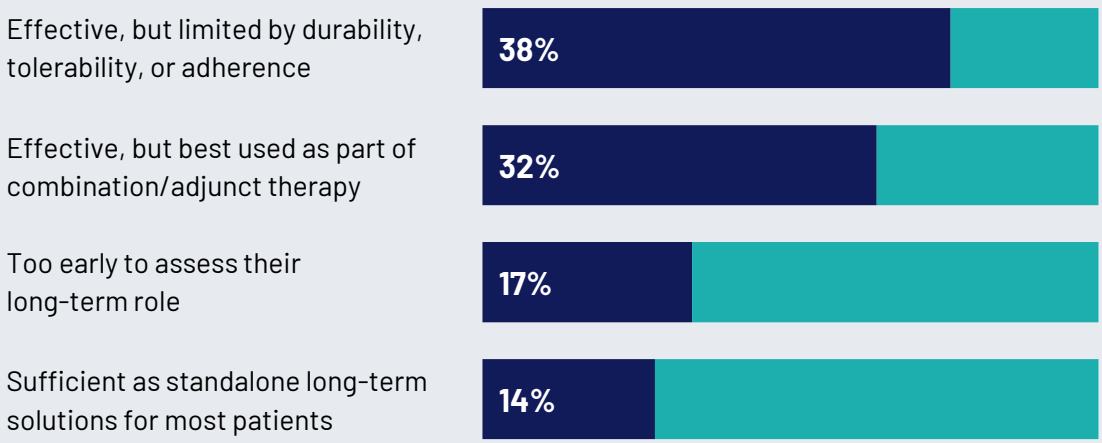


The expansion beyond weight loss is real — and reflects the broader metabolic reach of incretin biology.

GLP-1s solved efficacy — but defined the next set of challenges

While incretin-based therapies represent a clear step-change, they are not viewed as complete solutions. Only 14% of physicians in the Ipsos survey consider current GLP-1s sufficient as standalone long-term treatments (Figure 2), with most instead viewing them as part of a broader, combination-based approach to obesity management.

Figure 2: How do you view the role of current GLP-1-based therapies in long-term obesity management? (n=67)



Physicians aren't questioning whether GLP-1s work — they're questioning whether they're enough.

What efficacy alone cannot solve

An interconnected system of constraints shaping how therapies are used and valued.

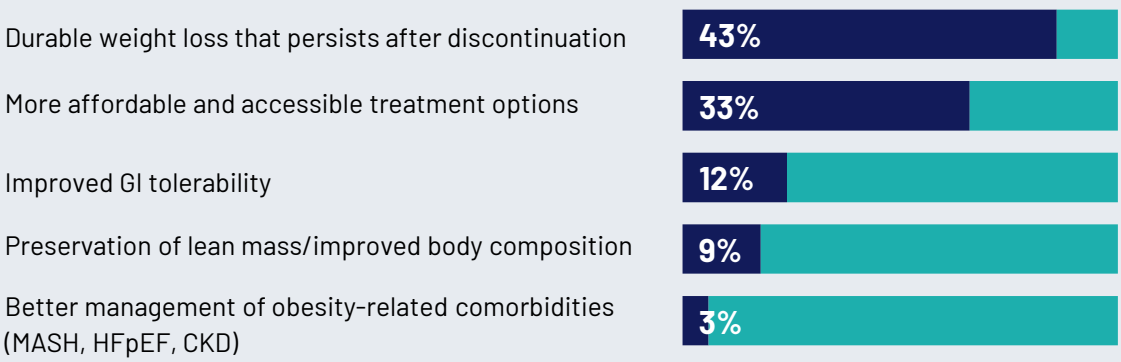
CORE CONSTRAINTS

- **Durability and access now define the primary constraints in obesity treatment.** Sustained weight loss after discontinuation remains the leading unmet need, as current therapies require continuous use and weight regain is common once treatment stops (Figure 3). A BMJ analysis (January 2026) shows patients discontinuing semaglutide or tirzepatide regain weight four times faster than those stopping conventional dieting.
- **Affordability and access have emerged as central barriers.** Cost, coverage limitations, and payer dynamics continue to determine who can initiate and sustain therapy, underscoring that clinical efficacy alone does not translate into real-world impact.

EMERGING CONSTRAINTS

- **GI tolerability continues to constrain persistence,** with nausea, vomiting, and diarrhea remaining leading drivers of discontinuation — reinforcing the need for improved tolerability or combination approaches to enable dose optimization.
- **Body composition is also emerging as a critical concern.** A meaningful proportion of GLP-1–driven weight loss comes from lean mass (e.g., ~45% with semaglutide vs. ~25% with tirzepatide; Apovian et al., 2025), raising concerns around functional outcomes — particularly in older populations where muscle and bone loss accelerate with age.

Figure 3: Which of the following do you consider the highest unmet need in the management of patients with obesity? (n=67)



From constraints to use cases: Four priorities define the next wave

The constraints identified above are not just problems to solve — they will define what the market rewards.

Rather than organizing the pipeline by mechanism — which can obscure how therapies will ultimately compete — it is more useful to organize around use cases: how therapies are expected to perform in clinical practice.

01

Make treatment durable

Sustain weight loss beyond active treatment. Address weight regain, metabolic adaptation, and the ability to persist on therapy over time.

02

Make treatment viable in the real-world

Enable access, adherence, and scale. Overcome cost barriers, payer friction, and the practical limitations of chronic injectable therapy.

03

Improve the quality of weight loss

Shift from weight loss to outcomes. Preserve lean mass, protect function, and redefine success beyond the number on the scale.

04

Expand beyond weight loss

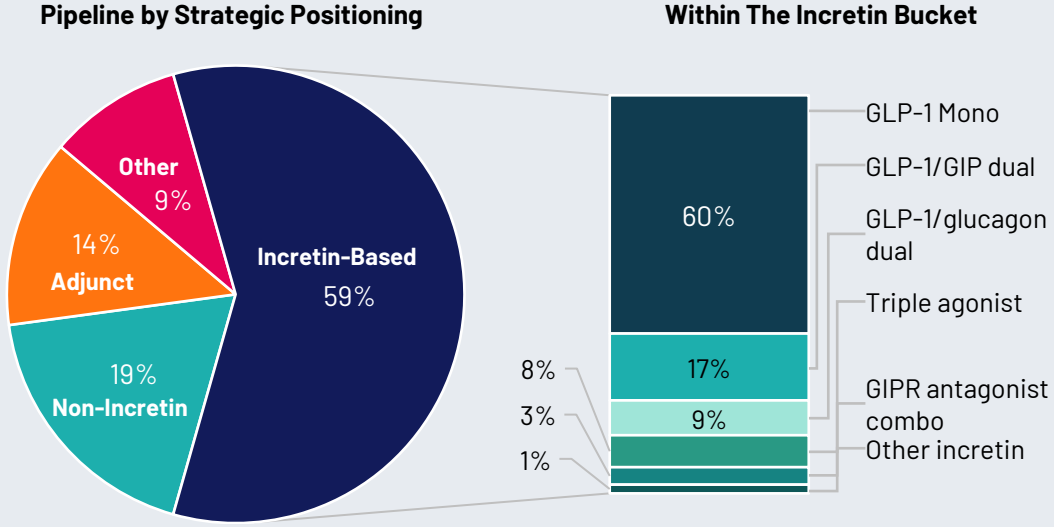
Treat systemically. Target cardio-renal-hepatic outcomes for defined patient subsets and enable combination-based market expansion.

The pipeline is large — but not random

Development is converging around a discrete set of use cases

The clinical pipeline spans more than 230 assets across nearly 80 mechanisms — but the signal is not fragmentation, it is convergence. Innovation is consolidating around an incretin backbone, with differentiation shifting toward solving specific clinical constraints. The question is shifting from how many assets are in development to what they are designed to do.

Figure 4: Obesity pipeline composition by strategic positioning and incretin sub-type breakdown (n=233 active clinical-stage assets, Phase 1–3; GlobalData, May 2026)



> **The question is shifting from how many assets are in development to what they are designed to do.**

Four use cases are now structuring the pipeline:

01 Durability	02 Real-world viability	03 Quality of weight loss	04 Beyond weight loss
Sustain outcomes	**Enable access & adherence**	**Preserve lean mass**	**Expand into systemic disease**
Retatrutide (Lilly · triple agonist)	Oral Wegovy (Novo · approved Dec '25)	Bimagrumab (Versanis / Lilly)	Semaglutide (Novo · CV outcomes)
CagriSema (Novo · amylin combo)	Orforglipron (Lilly · oral, scalable)	Cagrilintide (Novo · amylin analog)	GLP-1/glucagon (MASH & metabolic)
Orforglipron (Lilly · adherence driver)	PF-08653944 (Pfizer · monthly)	Enobosarm (Veru · SARM)	Multi-target agents (pipeline broadly)

The clinical pipeline spans more than 230 assets across nearly 80 mechanisms — but the signal is not fragmentation, it is convergence.

Use case 1: bolster treatment durability

Sustain weight loss by addressing biological and practical drivers of persistence

Durability is emerging as the central constraint in obesity treatment. Current therapies require continuous use, with weight regain driven by biological adaptation and real-world discontinuation. The pipeline is responding along two dimensions: deepening response and improving persistence.

Next-generation incretins are pushing the efficacy ceiling higher. **Eli Lilly's retatrutide**, a GLP-1/GIP/glucagon triple agonist, has demonstrated up to 28.7% weight loss in Phase 3 (TRIUMPH-4; Jastreboff et al., NEJM, 2024), with the glucagon component introducing mechanisms such as increased energy expenditure and hepatic fat oxidation that may begin to shift the metabolic set point.

Combination approaches are also emerging. **Novo Nordisk's CagriSema** combines semaglutide with cagrilintide, a long-acting amylin analog, achieving 20.4% weight loss versus 14.9% for semaglutide alone.

By engaging parallel satiety pathways, these approaches aim to deepen and potentially stabilize response over time. **Novo's amycretin**, a unimolecular GLP-1/amylin dual agonist, further reflects this trend, with both subcutaneous and oral formulations advancing into Phase 3.

Durability is also being addressed through persistence. **Eli Lilly's Foundayo (orforglipron)**, approved April 2026, is now the second oral GLP-1 competing directly with **Novo's oral Wegovy** (approved December 2025). At the same time, early launch data suggest that despite Foundayo's convenience advantage — no food or timing restrictions — brand equity and first-mover advantage may matter as much as ease of use in driving real-world persistence.

More broadly, combination strategies may also support durability by enabling comparable outcomes at lower incretin exposure — improving tolerability and persistence over time. **Looking further ahead, durability may ultimately extend beyond combination pharmacotherapy, with early approaches pointing toward more sustained, system-level solutions rather than continuous management.**

Use case 2: make treatment viable in the real-world

Improve access, affordability, and scalability at population scale

Real-world viability is becoming a limiting factor on growth. Even with strong efficacy, adoption is constrained by cost, access, and the practical realities of chronic therapy. The pipeline is responding by redesigning how these therapies are delivered and scaled.

Oral formulations are the most visible shift. Following the approval of **Novo's Wegovy** in December 2025 — the first oral GLP-1 for chronic weight management — the category is expanding rapidly. **Lilly's Foundayo (orforglipron)**, approved April 2026, extends this trend as the first oral GLP-1 that can be taken without food or timing restrictions — now competing directly with Novo's oral Wegovy for market share

Dosing innovation is also reshaping persistence. **Amgen's MariTide (maridebart cafraglutide),** a monthly injectable now in Phase 3 across six global studies (MARITIME program), is the most advanced monthly-dosing candidate in obesity — combining GLP-1 activation with GIP receptor blockade, a notably different approach from tirzepatide's dual agonism. **Pfizer's PF-08653944 (Phase 2b)** is also pursuing monthly dosing. Together, these programs reflect a broader move away from weekly administration toward less frequent, more manageable regimens.

At the system level, competitive dynamics are beginning to shift. China-originated GLP-1 assets licensed for global development **(e.g., Kailera/Hengrui, YaoPharma/Lilly)** are expanding supply and introducing pricing pressure, while looming patent expirations — semaglutide around 2032 and tirzepatide in the mid-2030s — will further alter access through generics and biosimilars.

Real-world viability is becoming a limiting factor on growth.

Use case 3: improve the quality of weight loss

Preserve lean mass and functional outcomes

GLP-1–driven weight loss introduces a critical trade-off: meaningful fat loss accompanied by significant lean mass reduction. This is not a secondary issue — it directly affects functional outcomes, particularly in older and sarcopenic populations.

The pipeline is responding by targeting body composition as a distinct therapeutic objective, not just an outcome of weight loss. A growing class of adjunctive therapies is focused on preserving muscle while enabling fat loss. Many of these approaches target the myostatin/activin signaling pathway, reflecting a broader shift toward mechanisms originally developed for muscle-wasting disorders now being repurposed for obesity.

Eli Lilly's bimagrumab, an anti-activin type II receptor antibody, provides a clear proof point. In Phase 2b, when combined with semaglutide, it achieved 22.1% weight loss with 92.8% derived from fat mass, compared to 71.8% with semaglutide alone. As monotherapy, bimagrumab delivered 10.8% weight loss with 100% from fat — directly addressing concerns around lean mass loss.

Other approaches are advancing in parallel. **Regeneron's trevogrumab plus garetosmab** (anti-myostatin plus anti-activin A) is in Phase 2, while **Veru's enobosarm**, a selective androgen receptor modulator, has demonstrated meaningful reductions in lean mass loss when combined with semaglutide.

The emerging model is combination-based: incretins drive weight loss, while adjunctive therapies shape how that weight is lost. Importantly, some combination approaches are not designed to exceed GLP-1 efficacy, but to achieve comparable outcomes at lower incretin exposure — improving tolerability and enabling more sustainable long-term use.

This shift is beginning to segment the market into more defined patient subsets — for example, those where muscle preservation and functional outcomes are paramount — signaling a move toward a more mature, stratified treatment paradigm.

Use case 4: expand beyond weight loss
Address metabolic and organ-level disease

The expansion beyond weight loss reflects a shift in how obesity is understood — from a standalone condition to a systemic metabolic disease affecting multiple organs. Incretin-based therapies are leading this transition.

Retatrutide's glucagon component introduces mechanisms such as increased energy expenditure and hepatic fat metabolism, positioning it for indications like MASH. Similarly, **Boehringer Ingelheim's survodutide** (GLP-1/glucagon dual, Phase 3) is being developed with a clear focus on liver disease, representing one of the first major challengers outside the Novo Nordisk and Eli Lilly ecosystem.

Clinical data reinforce this broader therapeutic scope. Mediation analyses from the SELECT trial suggest that semaglutide's cardiovascular benefit is largely independent of weight loss, pointing to direct metabolic and vascular effects. This shifts the competitive frame — from weight reduction alone to multi-system disease modification.

Alongside incretin expansion, non-incretin mechanisms are emerging to address specific gaps. These approaches are more targeted and earlier stage, often focused on defined patient segments rather than broad populations.

Examples include **MGAT2 inhibitors** targeting hepatic fat metabolism, **GDF-15/GFRAL agonists** acting through central energy regulation, and peripherally restricted **CB1 inhibitors** designed to revisit a validated pathway with improved safety.

These programs represent a strategic hedge beyond the incretin paradigm. They are not positioned to replace GLP-1-based therapies, but to expand the therapeutic toolkit — offering alternatives for patients who do not respond, cannot tolerate, or require more targeted intervention.

The expansion beyond weight loss reflects a shift in how obesity is understood

Combination as the emerging model
Not replacement, but augmentation

Across the four use cases, a clear pattern emerges: the pipeline is not fragmenting — it is converging.

The same assets appear across multiple use cases, reflecting a shift from single-mechanism solutions toward multi-dimensional problem solving. **Retatrutide** spans durability and comorbidity expansion, orforglipron bridges durability and real-world viability through its oral formulation, and **bimagrumab** improves body composition while enabling combination strategies that may address tolerability.

This overlap is not incidental — it reflects a structural shift. The next generation of therapies is being designed to address multiple constraints simultaneously, not sequentially. The model is no longer monotherapy, but incretin-based combinations with adjunctive agents layered to solve for durability, adherence, body composition, and systemic disease.

> **The next generation of therapies is being designed to address multiple constraints simultaneously, not sequentially.**

The capital confirms the signal
investment is reinforcing – and enabling the trajectory of the field

Capital allocation from both biopharma and institutional investors is concentrating around a consistent thesis: the future of obesity treatment will be built on an incretin backbone, with differentiation driven by what gets layered on top. The focus is not on replacing GLP-1s, but on extending them – improving durability, enabling more convenient delivery, preserving lean mass, and expanding into systemic disease.

Patent timelines are accelerating this dynamic. With **semaglutide** facing loss of exclusivity around 2032 and **tirzepatide** following in the latter half of the decade, market leaders are acting now to secure future assets and defend franchise value – raising the bar for innovation while setting the stage for longer-term pricing pressure.

Deal-making reflects this urgency. **Novo Nordisk** and **Eli Lilly** are both building depth around their incretin franchises, layering in combinations and adjacent assets to address durability, adherence, and body composition while hedging beyond the core mechanism.

Beyond the incumbents, the same pattern holds: recent transactions and capital formation across the space reinforce a market consolidating around incretin-based combination strategies, not fragmenting away from them.

The focus is not on replacing GLP-1s, but on extending them

From pipeline to capital to practice
Independent signals, one direction

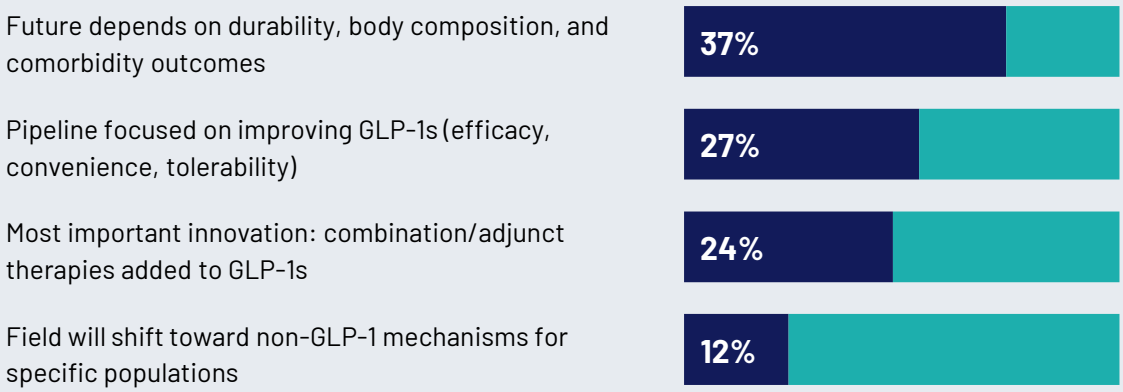
Three independent signals — pipeline, capital, and clinical practice — are converging on the same conclusion.

The pipeline is organizing around the incretin backbone, with innovation focused on solving key constraints: durability, adherence, body composition, and systemic disease. Capital is reinforcing that direction, with investment concentrated on assets that extend rather than replace GLP-1–based therapies.

As further support for this trend, Ipsos survey data reveals that only 12% of physicians anticipate a meaningful shift away from GLP-1 mechanisms. The majority point to the same priorities emerging from the pipeline: improving durability, body composition, and comorbidity outcomes, along with combination and adjunct therapies.

Taken together, these signals reinforce a consistent direction: innovation is concentrating on extending GLP-1–based therapies rather than moving beyond them.

Figure 5: When you look at the obesity pipeline, which statement best reflects how you see the field evolving? (n=67)



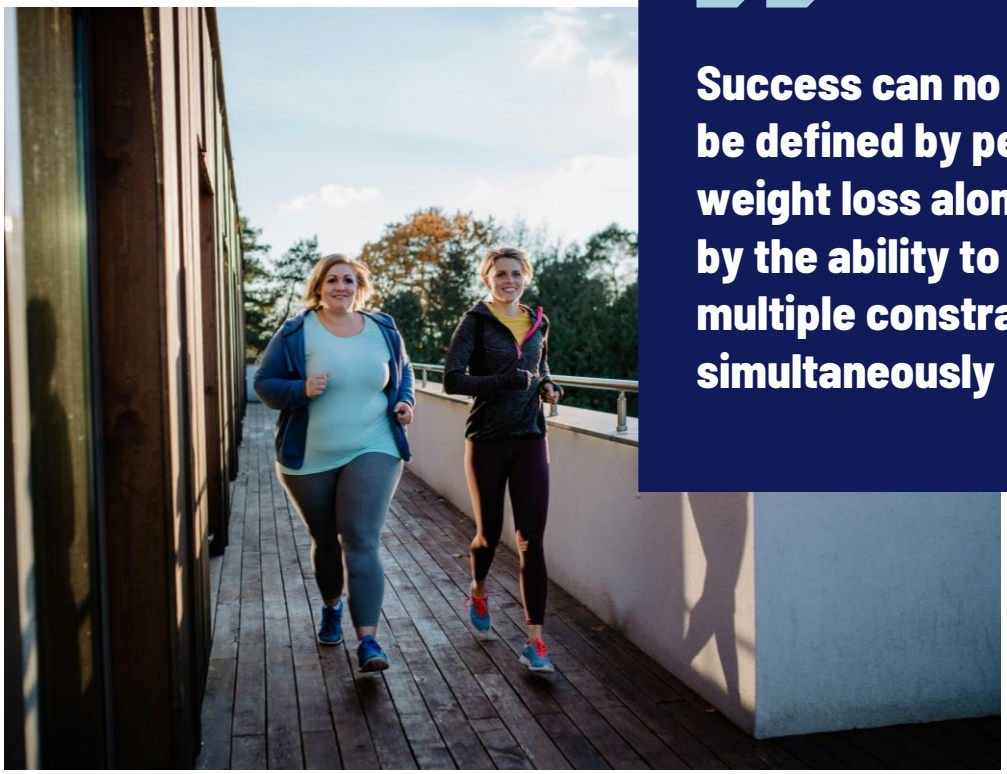
Implications for the next wave

What this means for competition, differentiation, and the road ahead

Competition is shifting from molecule-level to system-level. Success can no longer be defined by percent weight loss alone, but by the ability to address multiple constraints simultaneously — durability, tolerability, body composition, access, and comorbidities. As a result, the market is segmenting into defined patient use cases, with therapies increasingly differentiated by which constraints they solve — and for whom.

The market is segmenting into defined use cases. Obesity is no longer a single category, but a set of patient profiles — each requiring a different solution.

The question is no longer "how much weight does it reduce?" but "which constraint does it solve — and for whom?"



Success can no longer be defined by percent weight loss alone, but by the ability to address multiple constraints simultaneously

What this means for different players

Strategic implications vary by position across the biopharma ecosystem.

For incumbents (Lilly, Novo):
The priority has shifted from defending a single asset to extending a system. With patent cliffs looming, the imperative is to build layered portfolios around the incretin backbone — combining novel mechanisms, formulations, and adjunctive therapies to sustain leadership beyond exclusivity. Current deal-making reflects this shift: not filling gaps, but reinforcing a multi-asset architecture designed to solve multiple constraints simultaneously.

For emerging biotechs:
Differentiation requires focus. The path forward is not to compete broadly, but to anchor around a specific constraint from the outset — durability, body composition, tolerability, or access — and design assets explicitly for combination with incretins. Success depends not just on clinical performance, but on how clearly an asset fits into a defined use case and integrates into the emerging treatment model.

For later-stage entrants (Pfizer, Boehringer, Roche, AZ, Amgen):
Time is the constraint. The window to establish a durable position is narrowing as incumbents consolidate around the most valuable adjacencies. Defensible positions will not come from incremental efficacy gains, but from solving constraints the leaders have not yet fully addressed — whether through differentiated mechanisms, novel delivery models, or access-driven innovation.

Looking ahead, the direction is clear. The next phase of obesity treatment will not be defined by what replaces GLP-1, but by how effectively the field builds on it — solving for durability, composition, access, and comorbidities in combination. The competitive advantage will lie not in any single mechanism, but in how well therapies integrate into a system designed to deliver sustained, real-world outcomes.

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BEYOND THE STEP CHANGE

GLP-1 established the foundation — the next wave will be defined by who solves the constraints it revealed.

Authors:

Joel Sandler, PhD
Associate Partner, Healthcare,
Ipsos in the US

Lauren Barry, MPH
Senior Consultant, Healthcare,
Ipsos in the US

Acknowledgements:

Chareen Lim
Senior Vice President, Healthcare,
Ipsos in the US

Devon Reimer
Senior Vice President, Healthcare,
Ipsos in the US

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