

NDDS Oral G LP-1 Platform

A Novel Excipient Approach for Oral Delivery and Bioavailability

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Abstract

GLP-1 receptor agonists have redefined the treatment of diabetes, obesity, and metabolic disease. They are, without question, one of the most successful therapeutic classes ever developed. But there is a catch: every single one of the leading products requires an injection. For many patients, that's where the story ends.

Attempts to move GLP-1 therapies into oral form have been made, most prominently semaglutide delivered with the SNAC excipient. That experiment proved that oral dosing was possible, but it came at a steep price: extremely low bioavailability (\sim 1%), high patient-to-patient variability, strict fasting requirements, and doses measured in tens of milligrams.

Zoom Biotech's Novel Drug Delivery System (NDDS) represents a clean break from this model. Instead of brute forcing absorption by irritating the stomach lining and altering pH, NDDS protects and guides peptides through a controlled, physiologic pathway. It supports both orally disintegrating tablets (ODT) and capsules, giving patients flexibility and giving clinicians consistent, predictable dosing.

Preliminary data already show that NDDS can deliver clinically meaningful reductions in fasting blood glucose and body weight at microgram-level doses — as low as 0.07 mg/day. That's not just a modest improvement over SNAC; it's a complete reimagining of what oral peptide delivery can be. With a bioavailability target of $\sim 50\%$, NDDS has the potential to bring GLP-1 therapies into oral form at a scale and efficiency that makes them viable for the long term — and to extend that same innovation across other classes of biologics.



Executive Summary

GLP-1 therapies are one of the most valuable franchises in modern medicine, but their reliance on injection creates a gap between what's possible in theory and what's happening in practice. Patients want oral options. Doctors want simpler prescribing. Health systems want scalable, affordable solutions. Yet the only oral product on the market today — semaglutide with SNAC — was built on a flawed delivery concept that limits its success.

NDDS turns that paradigm upside down. By shielding peptides from degradation, stabilizing them through GI transit, and facilitating controlled uptake across mucosal and epithelial surfaces, NDDS achieves levels of efficiency and consistency that SNAC simply cannot match. The ODT format bypasses the GI tract entirely, absorbing through buccal and sublingual mucosa. The capsule format protects the peptide in the stomach and releases it for epithelial absorption under conditions that promote predictability rather than variability.

The result is a platform that can do more than make GLP-1s oral. It can make them *practical*. It can make them *scalable*. And it can open the door to oral dosing for entire classes of peptide therapeutics that have, until now, been locked into injection-only delivery.



Mechanistic Deep Dive

Why SNAC Falls Short

The SNAC mechanism works by raising local gastric pH and transiently increasing membrane fluidity. In simple terms, it irritates the stomach lining to create a temporary window for absorption. This method comes with three problems:

- 1. It is highly variable gastric pH is not the same in every patient, or even within the same patient from day to day.
- 2. It is inefficient only about 1% of the peptide reaches systemic circulation, even at doses of ~ 14 mg per tablet.
- 3. It is inconvenient fasting and water-only requirements create a barrier to patient adherence.

These weaknesses explain why SNAC-based oral semaglutide is not the blockbuster that its injectable counterpart is. It is a workaround, not a solution.

How NDDS Works Differently

NDDS replaces brute force with precision. Its mechanism is a five-stage process:

- 1. **Sub-micronization** reduces particle size, creating dramatically more surface area and faster dissolution.
- 2. **Electrolyte stabilization** shields peptides from enzymatic degradation in the stomach.
- 3. **Mucosal adhesion** ensures that the peptide is held against absorptive surfaces rather than washed away.
- 4. **Transcellular transport** is facilitated by excipients that guide peptides across membranes without disrupting epithelial integrity.
- 5. **Controlled release** ensures that absorption happens predictably, minimizing variability in plasma levels.

The ODT format executes this process in the oral cavity, bypassing the GI tract entirely and eliminating first-pass metabolism. The capsule format executes it during GI transit, stabilizing the peptide until facilitating efficient epithelial uptake through the stomach lining.

The key difference: NDDS works *with* the body's natural physiology, not against it. That makes it not just more efficient, but more sustainable for chronic use.



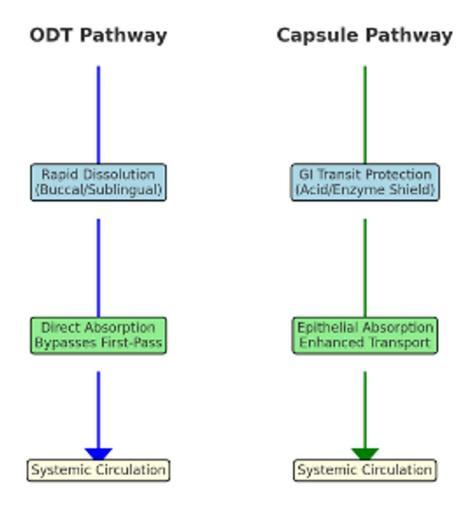


Figure 1 will illustrate ODT vs capsule pathways



PK/PD Modeling and Clinical Translation

What does 50% bioavailability mean in practice? It means that a microgram-level dose of NDDS can achieve the same systemic exposure as milligram-level doses of SNAC. In our preliminary studies, daily doses as low as 0.07 mg produced measurable changes in fasting glucose and body weight.

Pharmacokinetic modeling shows NDDS producing tighter variability bands around its concentration-time curve compared with SNAC. That matters clinically: predictable exposure leads to predictable outcomes. For chronic therapies like GLP-1s, consistency is as important as efficacy.

The pharmacodynamic translation is clear: with NDDS, physicians can prescribe oral GLP-1s with the confidence that patients will achieve steady, reliable systemic exposure — without complex instructions about fasting windows or dietary restrictions.

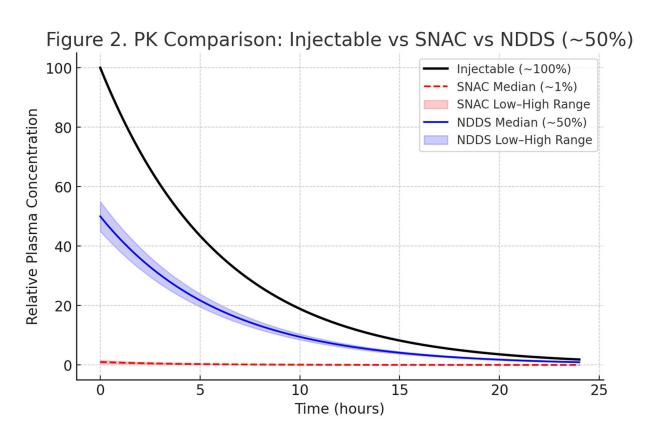


Figure 2 comparative PK curves, highlighting SNAC's variability vs NDDS's consistency.



Case Study: NDDS vs SNAC

A direct comparison underscores just how different NDDS is from the SNAC approach.

- **Dose**: SNAC requires ~14 mg of semaglutide to deliver ~0.14 mg systemically. NDDS achieves clinical effects at \sim 0.07 mg total dose.
- **Bioavailability**: SNAC ~1%. NDDS ~50%.
- **Variability**: SNAC is dependent on gastric conditions, creating wide swings. NDDS minimizes variability through controlled uptake.
- **Patient burden**: SNAC requires fasting and water-only administration. NDDS does not.
- Safety: SNAC relies on gastric pH manipulation and membrane irritation. NDDS protects peptides without disrupting natural physiology.
- **Cost and scalability**: NDDS's efficiency reduces API requirements by 200-fold, lowering manufacturing costs and easing supply chain stress.

Preliminary Human Data

A 30-day pilot study demonstrated that NDDS formulations, even at microgram-level doses, produce clinically meaningful effects. Fasting blood glucose fell by 30–60 mg/dL in participants, and weight trended downward consistently across the group. Importantly, these results were achieved at doses that are hundreds of times smaller than those required by SNAC-based semaglutide. Safety was excellent, with no serious adverse events and only minor, transient gastrointestinal symptoms.

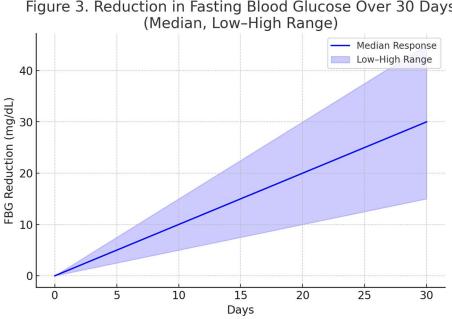


Figure 3. Reduction in Fasting Blood Glucose Over 30 Days



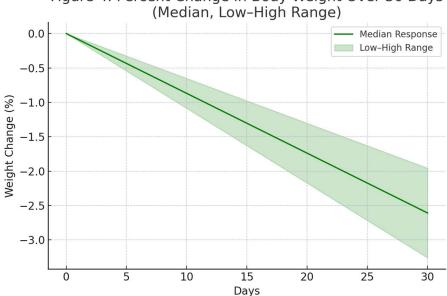


Figure 4. Percent Change in Body Weight Over 30 Days

Figure 3 & 4 Reduction in FBG levels and weight loss in GLP-1 therapy enhanced with NDDS.

Safety and Long-Term Use

Unlike SNAC, NDDS does not irritate the gastric lining or manipulate pH. Its protective, physiologic approach produces a safety profile more compatible with long-term, chronic use. This is critical, because GLP-1 therapies are intended for lifelong conditions like obesity and diabetes. A delivery system that stresses the GI tract every day is not sustainable; NDDS offers a cleaner alternative.

Development Roadmap

Zoom Biotech's path forward is clear. A pharmacokinetic lead-in study will refine dosing and confirm bioavailability targets. A 200-person multicenter trial will validate efficacy and safety at scale. Regulatory submissions under 505(b)(2) will accelerate approval, while 503B pathways open opportunities for earlier commercialization. Manufacturing partnerships are being prepared to ensure supply can scale alongside demand.

Market Impact and Commercial Opportunity

The GLP-1 market is projected to exceed \$150 billion globally by 2030. Oral options are expected to account for a growing share, but only if they can overcome the limitations of existing technologies. NDDS changes the equation by making oral GLP-1s both clinically effective and commercially viable.



With API requirements reduced by 200-fold, NDDS enables lower costs per dose and supports scalable global production. By eliminating fasting restrictions and improving consistency, it also improves adherence — translating into better real-world outcomes and higher market adoption.

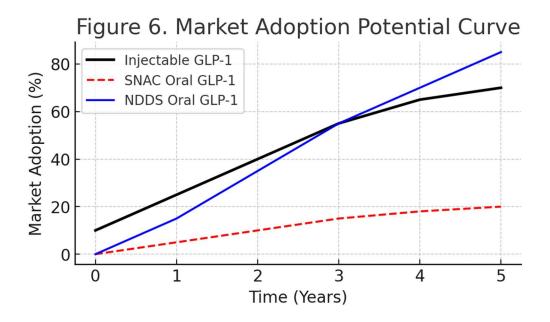


Figure 6 adoption potential: injections vs SNAC vs NDDS.

Beyond GLP-1s: NDDS as a Platform

The barriers NDDS overcomes — enzymatic degradation, first-pass metabolism, poor epithelial permeability — are the same barriers that have held back countless other peptides and biologics. That makes NDDS more than a delivery system for GLP-1s; it makes it a platform for oral biologics in general.

Testosterone replacement therapies, peptide hormones, rare disease biologics, and even peptide-based vaccines could benefit from NDDS. Each of these categories faces the same challenge: how to deliver fragile molecules orally without losing them to degradation. NDDS provides a roadmap.



NDDS Platform ↓ GLP-1 Therapies ↓ TRT ↓ Rare Disease Biologics ↓ Immunomodulators ↓ Peptide Vaccines

Figure 7 pipeline potential, showing GLP-1 as the entry point with arrows branching into other peptide classes.

Conclusion

Zoom Biotech's NDDS is not just another delivery technology. It is the key to unlocking the full potential of GLP-1s and beyond. By protecting peptides, stabilizing them through transit, and guiding them into systemic circulation with efficiency and predictability, NDDS eliminates the compromises of SNAC and establishes a platform that can change how biologics are delivered worldwide.

For patients, it means oral access to therapies once limited to injections. For clinicians, it means reliable prescribing and better adherence. For payors, it means reduced costs and greater scalability. And for the industry as a whole, it means that oral biologics are no longer a dream, but a reality.

Prepared by Zoom Biotech, 2025

