ME-004

A Next-Generation, Tolerated, Highly Potent, Long-Acting Amylin for Monotherapy or Combination Therapy in Obesity and Metabolic Diseases

Non-Confidential Deck

Oct 2025

Executive Summary

1

Unique Pre-clinical Stage Asset: ME-004

- ❑ **ME-004** is a **Long-acting amylin designed for Monotherapy or** Co-formulation with semaglutide (neutral-pH, high solubility) to enable a true single-pen regimen. GLP-1 adoption is limited by intolerabilities, device burden, and weight-maintenance challenges; amylin presents a new alternative monotherapy with higher tolerability and targets deeper, more durable outcomes.
- ❑ Co-formulation chemistry, half-life engineering, and manufacturability (device + supply) de-risked with specialist partners.
- ❑ Preclinical effect data (↓ body weight, ↓ food intake), 1.7× longer half-life than cagrilintide, feasibility data for single-pen delivery.

2

Broad Range of Disease Applications

- ❑ **Obesity / Weight Management:** Amylin agonism is a validated mechanism to enhance satiety, reduce food intake, and support weight loss; >25% weight reduction and >75% food-intake suppression achieved in preclinical combo with Semaglutide.
- ❑ **Type 2 Diabetes:** Amylin complements insulin and GLP-1 by reducing glucagon secretion and slowing gastric emptying, improving glycemic control.
- ❑ **Post-GLP-1 Maintenance:** ME-004 provides a differentiated option for patients discontinuing GLP-1 therapy, addressing rebound weight gain.
- ❑ **Mono or Combination Synergy:** an improved tolerability profile could establish ME-004 as a **next-generation backbone therapy** in the expanding market for obesity and metabolic diseases.

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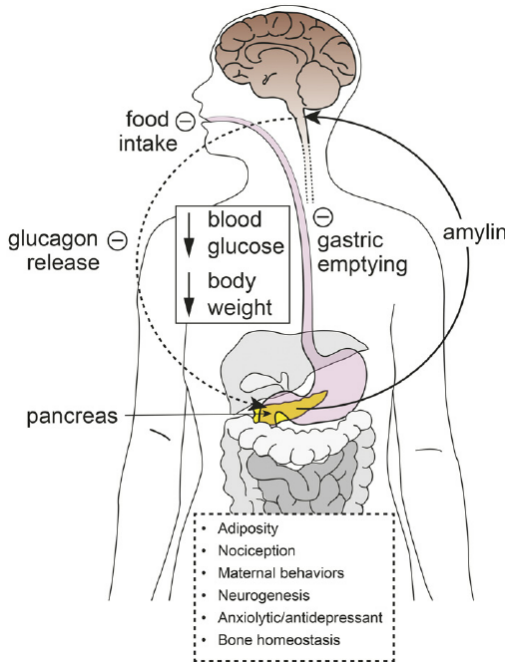
Clear Path to Clinical Milestones

- ❑ **Preclinical:** Repeat-dose efficacy; IND-enabling tox (rodent + NHP), Q2 2026
- ❑ **CMC**: Non GLP material ready**,** yield/scale-up; DS/DP lots for tox & Ph1; release & analytics
- ❑ **Clinical & Regulatory**: IND accepted in Q4 2026; Ph1a SAD/MAD topline in Q2 2027; Ph1b start in Q3 2027
- ❑ **Financing & Roadmap:** $10M seed financing already secured; raising an additional $18M Series A to reach IND acceptance, Ph1a topline, and initiate Ph1b within ~24 months.

ME-004 Highlights

Mode of Action (MoA)

- ✓ Long-acting amylin receptor agonist (balanced and AMY3R-unbiased analogues)
- ✓ Engineered for neutral-pH stability & high solubility (pI ~5.5–5.8)
- ✓ Enables co-formulation with Semaglutide in standard pen devices (no dual-chamber limitations)



Source: Hay et al, Amylin: Pharmacology, Physiology, and Clinical Potential, 2015

Competitive Advantage

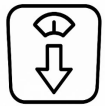
- ❑ **Molecular advantage:** Not a Cagrilintide derivative; structurally differentiated, first-tier progress.
- ❑ **Formulation edge:** Solves fundamental solubility issues → enables co-formulation with GLP-1s in a single dosage form.
- ❑ **Activity profile:** Demonstrates stronger activity vs natural amylin at the GPCR receptor.
- ❑ **Improved Patient Convenience:** Stable at neutral pH, enabling true single-pen co-formulation with GLP-1 (Semaglutide).
- ❑ **Superior Efficacy Potential:** Preclinical data show >25% body-weight reduction and >75% food-intake suppression with ME-004 + Semaglutide combo; lean mass preserved.
- ❑ **Extended Dosing Window:** ME004 shows 1.7× half-life vs cagrilintide in preclinical PK (35h vs 22h).

Market Indication

	ME-004 Role	2024 Market Value	Growth Driver
Obesity / Weight Management	Front-line use; mono-therapy or maintenance option post-GLP-1 withdrawal	~$95B (anti-obesity medicines)	Rising prevalence, GLP-1 combo regimens, high unmet need
Type 2 Diabetes (adjacent)	Improves glycemic control & weight via meal size reduction and glucagon suppression	>$50B global diabetes drug market	Synergy with GLP-1; potential combo backbone
Post-GLP-1 Maintenance	Differentiated therapy preventing rebound weight gain after GLP-1 withdrawal	Emerging sub-segment	Addresses discontinuation gap in long-term management

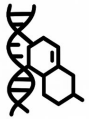
ME-004 – Obesity / Weight Management: Market Potential and Treatment

Disease Overview



Obesity is a chronic, relapsing disease driven by genetic, metabolic, and behavioral factors. It is associated with increased risk of type 2 diabetes, cardiovascular disease, liver disease, and premature mortality.

Common features include excess adiposity, impaired satiety signaling, dysregulated glucose metabolism, and increased cardiovascular burden.



Amylin regulates satiety, gastric emptying, and glucagon suppression. ME-004, a long-acting amylin receptor agonist, enables:
Monotherapy: 8–12% weight loss, option for GLP-1–intolerant patients, simpler regimen.
Combination therapy: 17–18% weight loss, strong option for severe obesity, with higher GI burden and cost

Market	Population	Prevalence	Cases	Market Projection	CAGR
Global	8.2B	742M	342M	8,231M	~12–15%
GLP-1 poor responders (est.)	~300M	-	-	+$15–20B incremental opportunity	-

Obesity / Weight Management

Strategic Reasons

- ❑ Represents a global epidemic: ~890M adults with obesity worldwide
- ❑ GLP-1 therapies validate pharmacologic weight loss; amylin + GLP-1 combinations show superior efficacy in clinical trials
- ❑ Up to ~40% of patients on GLP-1 therapy experience inadequate weight loss and intolerabilities
- ❑ Me004 offers potential option for patients who are GLP-1 intolerant (GI adverse events, etc.)
- ❑ Improved durability: Early data suggest more sustained suppression of appetite and reduced compensatory adaptations (like increased hunger after weight loss)
- ❑ Co-formulation potential simplifies delivery—single-pen administration versus dual-chamber devices.
- ❑ Potential to be the new “gold standard” in pharmacotherapy for obesity,

Competitive Landscape

Stand of Care & Unmet Medical Need

- ❑ Current therapies (GLP-1s: semaglutide, tirzepatide) demonstrate strong efficacy but require chronic use; weight regain is common after discontinuation.
- ❑ No approved long-acting amylin + GLP-1 co-formulated therapy yet.
- ❑ Dual-chamber devices (e.g., CagriSema prototypes) add complexity, patient burden, and cost.

Key Players

Several major pharma players are actively investing in obesity and incretin-based combinations:

novo nordisk®, Lilly, AMGEN, Pfizer, AstraZeneca

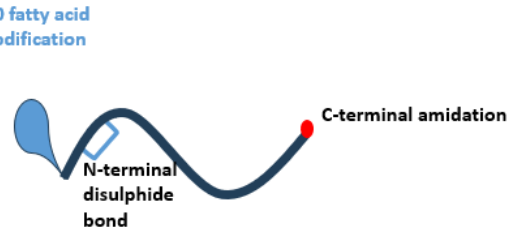
GLP-1 weight-loss segment alone projected ~$49B by 2030. Importantly, ~30–40% of patients show a suboptimal or poor response to GLP-1s (e.g., Semaglutide), creating a significant second-line opportunity for ME-004 in monotherapy or as a combination therapy.

Beyond GLP-1: Tolerability, Durability, and Delivery Open a Lane for Amylin

ME-004 Mechanism and Treatment

Unmet Medical Need for Obesity	❑ Obesity is a chronic, relapsing disease associated with high morbidity (T2D, CVD, fatty liver). ❑ GLP-1s deliver meaningful weight loss but require chronic use; rebound weight gain is common on discontinuation. Gastrointestinal adverse events remain the principal cause of dose reduction or discontinuation, highlighting a tolerability gap ❑ ME004 represents a promising alternative or adjunctive approach ❑ Dual-chamber device limitations hinder the adoption of amylin + GLP-1 combinations.
Potential Indications	❑ Weight loss without muscle loss ❑ Diabetes ❑ NASH ❑ CV benefits ❑ Chronic renal disease

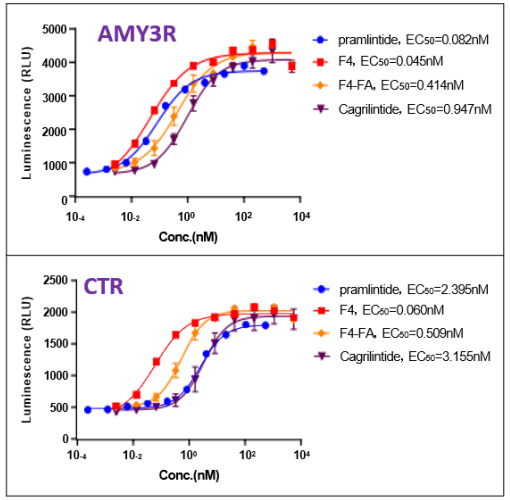
AI-powered Drug Design



- **M004 modification in the mid-sequence**, preserving full potency at both CTR and AMY3
- **Comparable cellular potency to cagrilintide** (Novo Nordisk benchmark)
- **No patent constraints** on the terminal residue
- **Fully synthetic chemistry** supports scalability and control
- **Isoelectric point (pI) 5.75**, ensuring high solubility at neutral pH

Unbiased Amylin Analogue

A human amylin-derived molecule with balanced potency at both CTR and AMY3

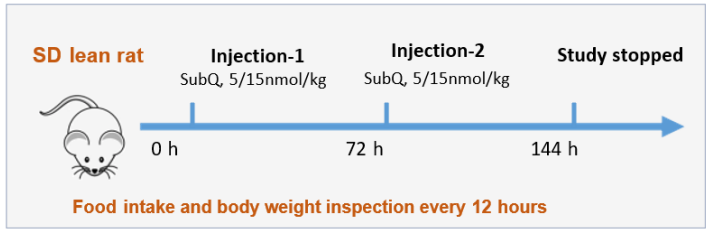


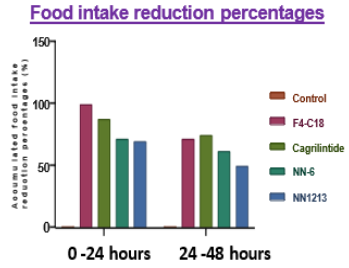
Clinical Target Product Profile

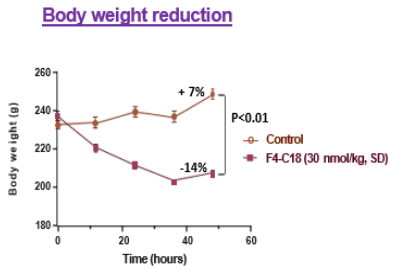
Indication	❑ ME-004 is intended for the treatment of obesity and weight management in adults, with potential expansion to type 2 diabetes and maintenance post-GLP-1 withdrawal
USP	❑ Monotherapy with improved tolerability ❑ Single-pen co-formulation with Semaglutide – no dual-chamber device limitations ❑ Enhanced efficacy potential vs GLP-1 monotherapy (superior weight reduction in preclinical combo studies) ❑ Addresses post-GLP-1 discontinuation rebound
Efficacy	❑ Clinically validated target: amylin agonism improves glycemic control and weight outcomes ❑ Preclinical synergy with Semaglutide: >25% weight reduction vs baseline ❑ Expected to match or exceed CagriSema benchmarks (~22.7% weight loss at 68 weeks)
Safety	❑ Amylin receptor agonists generally well tolerated ❑ Neutral-pH formulation improves solubility and stability, reducing injection-site issues ❑ Favorable safety profile anticipated relative to older pramlintide class
Treatment Mode	❑ Subcutaneous injection (single-pen, mono or co-formulated with Semaglutide) ❑ Potential for maintenance dosing after GLP-1 withdrawal ❑ Suitable for chronic management of obesity and metabolic disease

Preclinical Data Package

Single-dose Rat Study



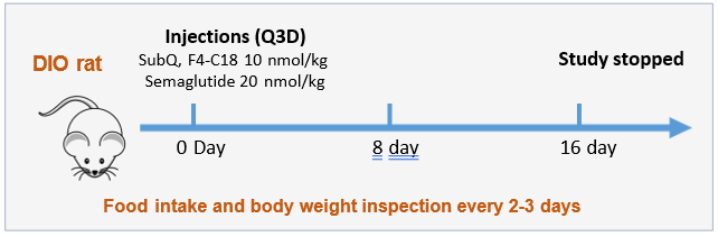


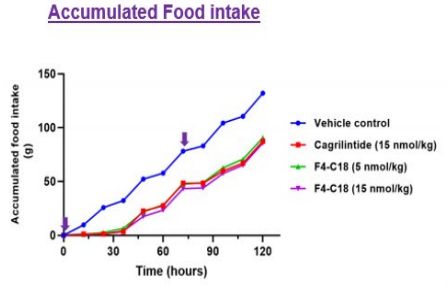


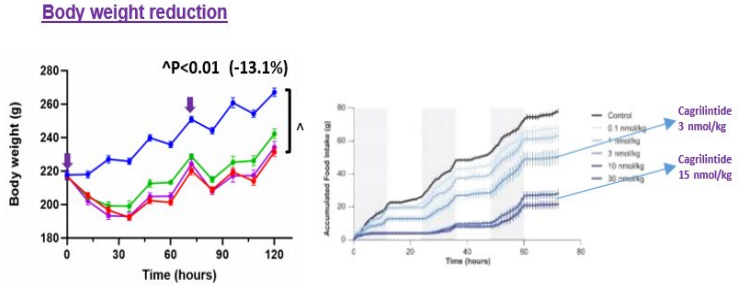
Molecules	0-24 hours	24-48 hours
Control	0	0
F4-C18	100%	72%
Cagrilintide*	88%	75%
NN-6*	72%	62%
NN1213*	70%	50%

- Demonstrates dose-dependent reductions in food intake and body weight
- At 15 nmol/kg, ME004 shows comparable efficacy to cagrilintide
- Notably, similar levels of food-intake reduction were achieved at both 5 and 15 nmol/kg, suggesting potential for effective outcomes at lower doses

Multi-dose Rat Study

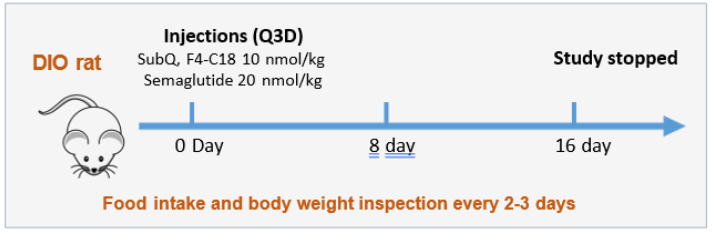


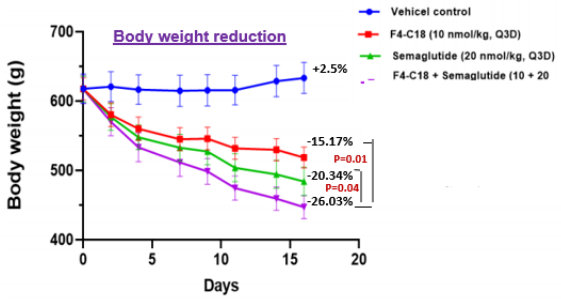


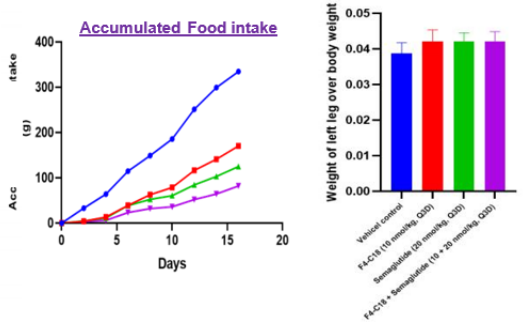


- ME004 induces dose-dependent reductions in food intake and body weight
- At 15 nmol/kg, ME004 shows comparable efficacy to cagrilintide
- Similar food-intake reduction at 5 and 15 nmol/kg, suggesting effective outcomes are possible at lower doses

ME-004+Semaglutide



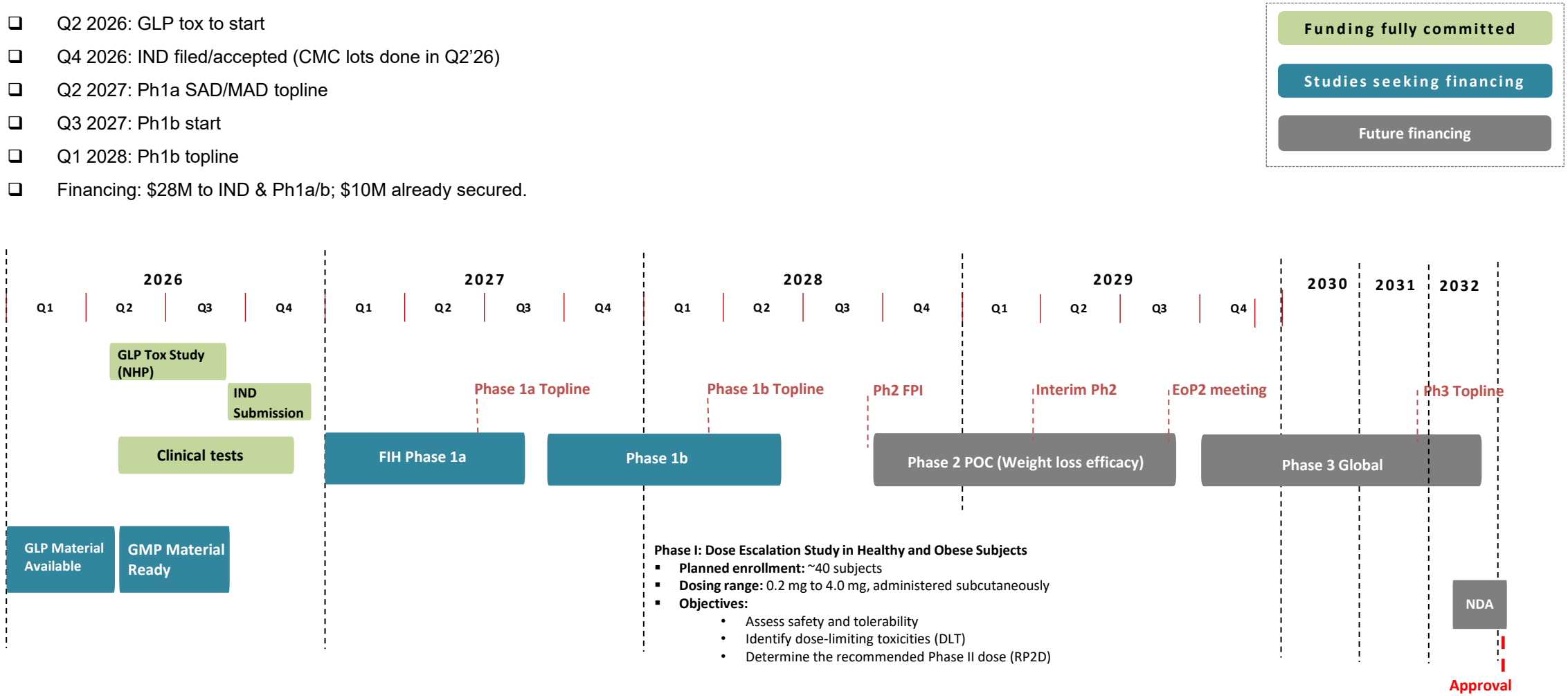




- ME004 demonstrates strong synergy with Semaglutide in reducing body weight
- Combination of 10 nmol/kg ME004 + 20 nmol/kg Semaglutide achieved:
  - >25% body-weight reduction
  - >75% suppression of food intake
- Importantly, no additional lean mass loss was observed in the combination group

Clinical Development Timeline

- ❑ Q2 2026: GLP tox to start
- ❑ Q4 2026: IND filed/accepted (CMC lots done in Q2'26)
- ❑ Q2 2027: Ph1a SAD/MAD topline
- ❑ Q3 2027: Ph1b start
- ❑ Q1 2028: Ph1b topline
- ❑ Financing: $28M to IND & Ph1a/b; $10M already secured.



AI-powered Operational Model

Lean Core, Extended Network

- Core team (≤6 FTEs): CEO/BD, CSO/Translational, VP Reg/Ops, PM/AI, fractional CMO/CFO/QA/Stats
- Outsourced: CMC, GLP tox, Phase 1 sites, stats/DM/QA
- AI enables small footprint with scalable execution

AI-Generated Regulatory Documents

- Highly pretrained AI engine drafts Protocols, IBs, IND modules, and Charters in days, not weeks
- Continuously updated with regulatory precedents and submission structures

Automated Quality & Compliance

- eTMF/EDC QC bots flag inconsistencies and gaps
- Automated SDTM/ADaM readiness validation
- Ensures GxP traceability and audit readiness

Vendor & Trial Oversight

- KPI dashboards monitor budget, burn, and cycle times
- Deviation heatmaps highlight operational risks in real time
- Improves governance with predictive monitoring

Competitive & Literature Radar

- AI-curated digests of emerging science and competitor disclosures
- Provides continuous updates for decision-making and governance
- Reduces manual tracking burden

ME-004 NewCo Team

Mark Ma, MD, Ms.

Dr. Ma has dedicated more than two decades to advancing preclinical and clinical development. His career includes leadership as VP and Head of Translational Sciences and Early Development at Rallybio, as well as senior roles at Alexion (AstraZeneca) and Amgen. Beyond the industry, he is an active leader in the scientific community, currently serving as a long-time leader of the AAPS Pharmacokinetics Working Group since 2014.

John Morton, MD, MPH, MHA

Dr. Morton has 18 years of experience in the field of obesity. He currently serves as Medical Director of Bariatric Surgery for the Yale School of Medicine and Yale New Haven Health System. He is a past president of the American Society for Metabolic and Bariatric Surgery. He presently serves as National Chair of the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program.

Jay Ma, MBA,MS,PMP

Jay has 16 years of cross-functional experience in global program management, clinical development, and business development across biotech and pharma. He has held leadership roles at Alexion and Kira Pharma, where he drove strategy, execution, and competitive intelligence. Jay specializes in aligning R&D and business operations to accelerate IND through early clinical development.

Wei Zhang, PhD

Over 15 years of unique insights and extensive successful experience in recombinant protein refolding technology, recombinant protein molecule & formulation design, and recombinant protein drug manufacturing process development. During his tenure at Novo Nordisk, he led a team to solve core technical bottlenecks in protein manufacturing, process scaling-up, and formulation modification for multiple global R&D projects, ensuring the smooth transition of these projects to the clinical phase.

Jackie Schumacher

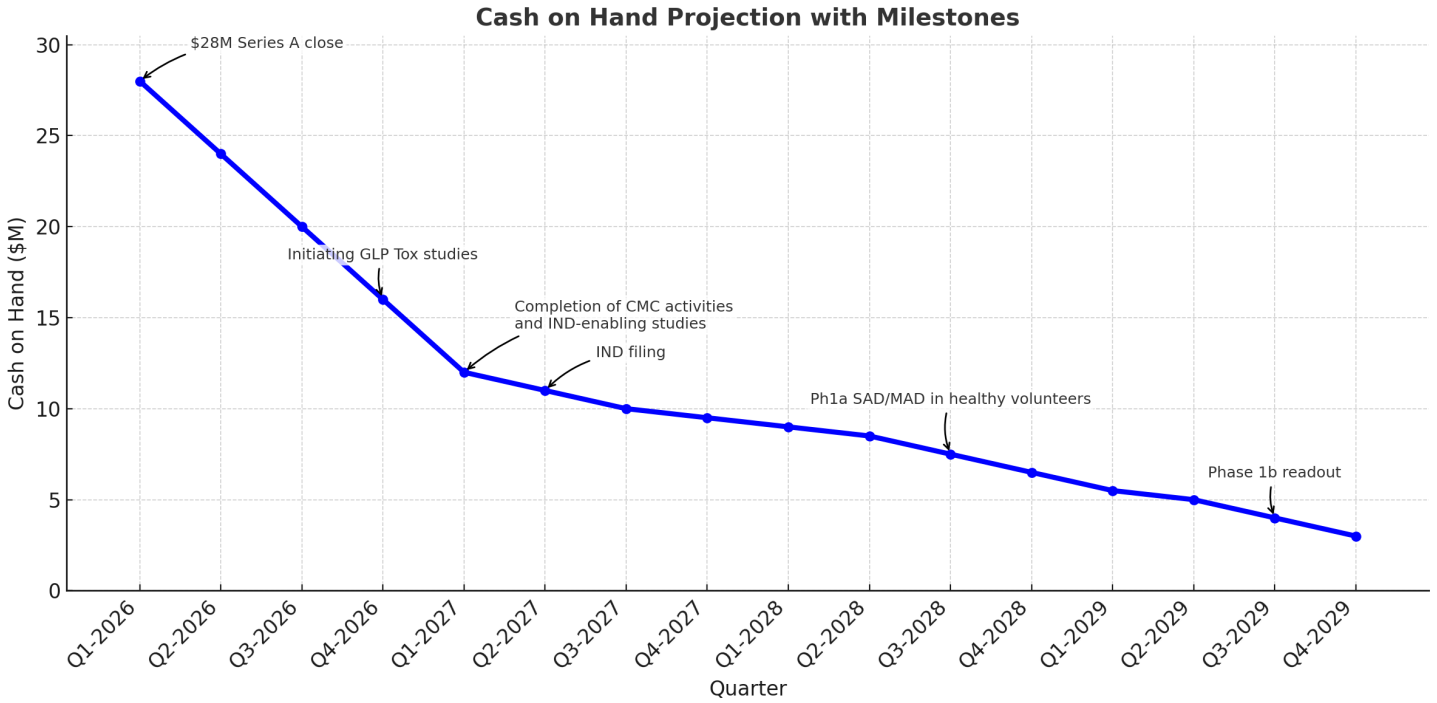
Jackie has 30+ years of leadership in global regulatory and quality strategy across biotech and pharma. She was SVP, Head of Regulatory and Quality at Rallybio, with prior senior roles at Lyndra Therapeutics and Pfizer, where she advanced regulatory submissions, CMC strategy, and portfolio optimization. She now advises companies through her consultancy and serves as a mentor and board member supporting biotech innovation.

Dao-An Sun, PhD

Dr. Sun is a seasoned pharmaceutical development leader with over 15 years of experience spanning discovery, CMC, and commercialization of biologics and advanced therapeutics. He has successfully led 5 BLA/NDA submissions and 4 IND-enabling programs across monoclonal antibodies, bispecifics, ADCs, enzymes, and fusion proteins.

Cash Need from 2026-2029

Clinical Cost Breakdown by Year	
Cash Required (2026-2029)	**Total**
GLP tox start (NHP), IND-enabling CMC lots complete	16
IND filed/accepted, Ph1a SAD/MAD topline	7
Ph1b dose-ranging readout (weight-loss % and lean-mass preservation)	5
Total	**28**
Investors	**Total**
Secured	**10**
Series A Financing	**18**
Total	**28**



Obesity / Weight Management: Competitive Landscape

Company	Drug	Mechanism	Efficacy	Dosing Route / Frequency	Edge / Limitation
NewCo	**ME-004**	Long-acting **unbiased amylin analogue**; neutral pH stability; co-formulation with Semaglutide	>25% body-weight reduction and >75% food-intake suppression in preclinical combo with Semaglutide; lean mass preserved	SC injection (co-formulated with Semaglutide)	Single-pen co-formulation (no dual-chamber); unbiased receptor profile; addresses GLP-1 withdrawal weight regain
novo nordisk	**Cagrilintide**	Long-acting unbiased amylin analogue	~22.7% mean weight loss with CagriSema at 68 weeks (Phase III)	SC injection, weekly (co-administered with Semaglutide)	Requires dual-chamber co-administration with Semaglutide
novo nordisk	**Amycretin**	Oral long-acting GLP-1 + amylin dual agonist (unbiased)	Early Phase I data; dual agonism promising	Oral, daily	Oral SNAC delivery formulation challenges; very early stage
novo nordisk	**NN1213 / Amylin 355**	NN1213: biased; Amylin 355: possibly unbiased	Preclinical/Phase I, limited clinical data	SC injection, early-stage (likely weekly)	Potency / receptor balance still unclear
AstraZeneca	**AZD6234**	Long-acting AMY3-biased amylin analogue	Phase II trials ongoing	SC injection, weekly	Reduced CTR activity; uncertain balance of efficacy vs safety
Lilly	**DACAR QW II**	Long-acting biased & unbiased amylin analogue mix	Early Phase I	SC injection, weekly (QW)	Receptor balance uncertain, in very early stage
abbvie	**GUB014295**	Long-acting unbiased amylin analogue	Phase I	SC injection, frequency not disclosed (likely weekly)	Licensed to AbbVie
Roche	**Petrelintide**	Long-acting unbiased amylin analogue	Phase I	SC injection, weekly	Licensed to Roche
Metsera	**MET-233i**	Long-acting unbiased amylin analogue (DACR class, monthly SC injection)	Preclinical / early clinical; ~19-day half-life supports once-monthly dosing; early tolerability promising	SC injection, weekly (preclinical assumption)	Recently acquired by **Pfizer ($4.9B upfront; up to $7.3B with milestones)**; strong funding; efficacy/safety still being established
VIKING THERAPEUTICS	**Viking DACARs**	Long-acting unbiased amylin analogue	Preclinical	SC injection, once monthly (Q4W)	Still preclinical; efficacy not yet shown