FRACTYL health

The Potential Path to Commercializing Revita®

A Procedural Therapy for Post-GLP-1 Weight Maintenance

September 1, 2026

NASDAQ:GUTS

Revita is for investigational use only in the United States.
Revita has a CE mark in the EU/UK.

Legal disclaimer

The study database has not been locked as this is an ongoing study, and the data are subject to further cleaning and validation.

Forward-looking statements

This presentation contains forward-looking statements about Fractyl Health, Inc. ("Fractyl" or "the "Company") within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this presentation that do not relate to matters of historical fact are forward-looking statements. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will" and variations of these words or similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements in this presentation include, without limitation, statements regarding: the expected initiation, timing, design, endpoints, site activation, and conduct of the REMAIN-1 clinical trial program; Fractyl's regulatory strategy, including submissions to and communications with regulators; the promise, potential impact, and mechanism of action of the Revita DMR system and Fractyl's Revita platform; Fractyl's anticipated financial performance, including cash and cash equivalents, for any period of time; Fractyl's expected cash runway; the promise and potential impact of Fractyl's preclinical or clinical trial data and product candidates, including Revita's potential for maintaining weight loss after glucagon-like peptide (GLP-1) based therapy discontinuation; the design, initiation, timing and results of clinical enrollment and any clinical studies or readouts, including readouts from the REVEAL-1 Cohort, the REMAIN-1 Midpoint Cohort and the REMAIN-1 Pivotal Cohort; the content, information used for, timing or results of any Investigational New Drug (IND)-enabling studies, IND applications, or CTAs; communications with regulators regarding the REVEAL-1 Cohort, the potential launch or commercialization of any of Fractyl's product candidates or products, the REMAIN-1 Midpoint Cohort and the REMAIN-1 Pivotal Cohort; the potential treatment population or benefits for any of Fractyl's product candidates or products; Fractyl's regulatory strategy, including potential use and benefits of the De Novo pathway (U.S. Food and Drug Administration (FDA) pre-submission feedback is advisory and non-binding, and there is no assurance that FDA will accept a De Novo marketing application submission or that the Revita DMR System will receive marketing authorization); Fractyl's commercial readiness activities and the development of commercial infrastructure; Fractyl's strategic and product development objectives and goals; the potential sales and estimated total addressable markets, currently and in the future, for Fractyl's product candidates; the potential timeline for profitability following the launch of Revita;' and the timing of any of the foregoing. 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Today's speakers and agenda

Harith Rajagopalan, MD, PhD
Co-Founder & CEO

Revita: the problem, the opportunity, and the evidence

Folahan Ayoola, MD, FACS, FASMBS
Medical Director, Bariatric Surgery
Texas Health in Flower Mound

Metabolic interventionalist's view on the unmet need in post-GLP-1 patients

Mike Zumdahl
Sr VP of Market Access
& Commercial Strategy

Center of Excellence strategy and Market Access

Lara Smith Weber
CFO

Commercial model and path to profitability

Harith Rajagopalan, MD, PhD
Co-Founder & CEO

Revita: the problem, the opportunity, and the evidence

Revita highlights

A one-time outpatient procedure targeting the biggest unmet need in obesity

- **The problem is maintenance, not weight loss.** Most patients discontinue GLP-1s within a year; there is no approved off-ramp.
- **Existing randomized and open-label data show a durable signal.** Encouraging results from REVEAL-1 and Midpoint 12 month data. Pivotal 6 mo topline is early Q4.
- **The pivotal is built to support a De Novo filing beginning in late Q4 2026.** Class II path, one registrational study, FDA Breakthrough Device.
- **The commercial build is activation, not market creation.** Patients, physicians, rooms, and obesity-procedure payment already exist in a finite set of Centers of Excellence (COEs.)
- **Payment work is already in motion.** Coding, coverage, Transitional Pass-Through (TPT) with favorable tailwinds in payer landscape supporting reimbursement strategy.
- **We believe a focused COE launch can reach profitability 5–8 quarters after launch.** Potentially high gross margin disposable sale without a large field force.

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GLP-1s unlocked weight loss, but durability remains unsolved

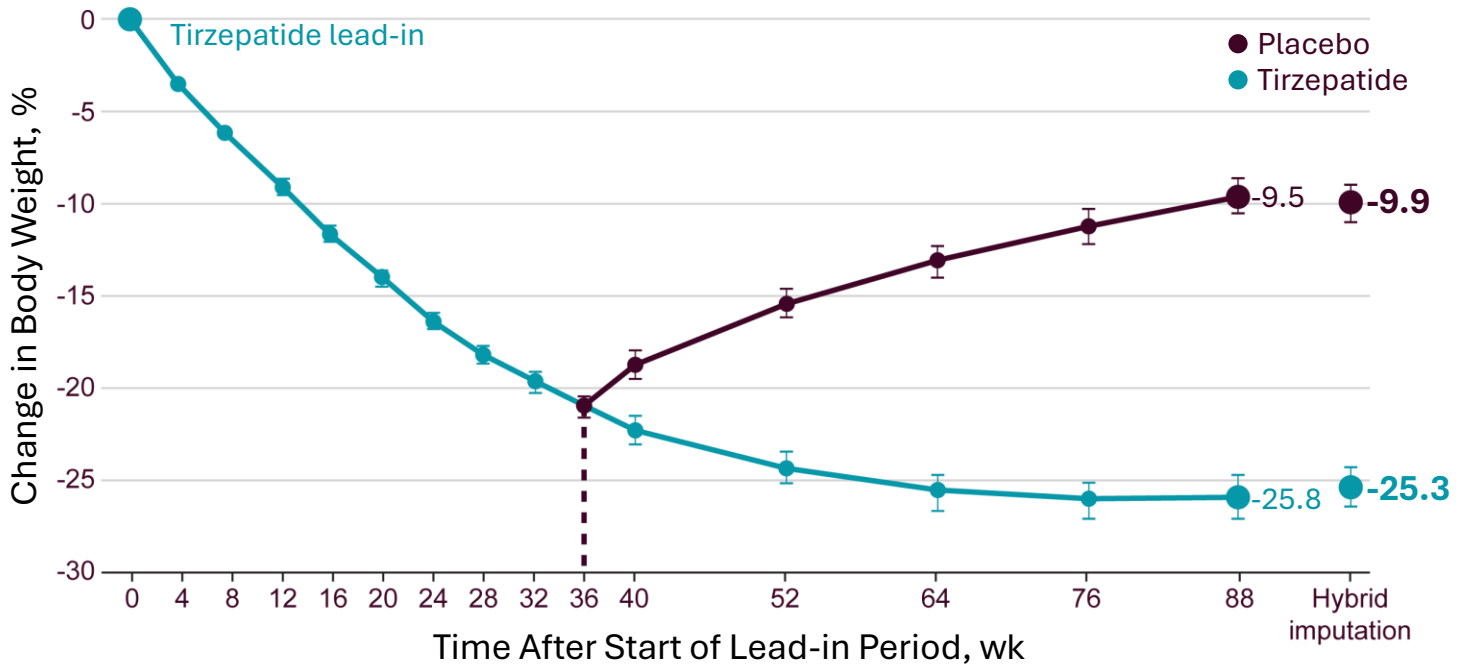
~29M Estimated U.S. patients on GLP-1s[1]

85% Patients regain lost weight after GLP-1 discontinuation[3]

No FDA-approved therapies for post-GLP-1 weight maintenance

Percent change in body weight (week 0-88) from the SURMOUNT-4 Study[3]

Overall mean baseline body weight = 107.3 kg



The next phase of obesity care will be defined by weight maintenance, not weight loss

[1]KFF Health Tracking Poll, Nov 2025: ~1 in 8 adults currently on a GLP-1 [2]Rodriguez, Patricia J., et al. JAMA Network Open 8.1 (2025): e2457349-e2457349. [3]Aronne et al. JAMA. 2023 Dec 11;331(1):38–48.
[4]Revita is currently being studied under an open Investigational Device Exemption (IDE) in the U.S. and holds FDA Breakthrough Device designation for weight maintenance in patients discontinuing GLP-1 therapy.
Abbreviations: GLP-1, glucagon-like peptide-1; wk, week.

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Discontinuation is the rule

Real-world persistence data reveals a systemic pattern, not individual failure

Real-world persistence for GLP-1RAs in non-T2D[1]

~65%

of patients without T2D discontinue GLP-1 RA within 1 year[1]

Abbreviations: RA, receptor agonist; TBWL, total body weight loss; T2D, type 2 diabetes. 1. Rodriguez et al., JAMA Netw Open 2025;8(1):e2457349

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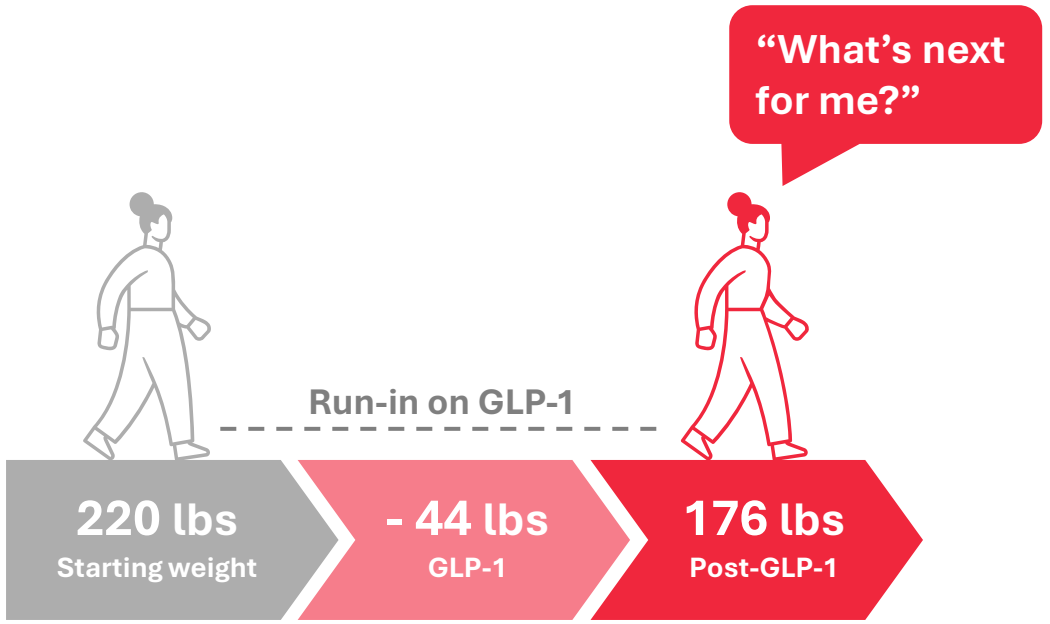
Patient journey post-GLP-1

Patients and physicians are looking for a durable non-drug off-ramp that does not yet exist



Do I have to be on this forever?

‹ I don't want a shot for life.

‹ Why is this lifelong therapy?

Will the weight come back?

‹ Will I gain all of it back?

‹ How fast? weeks or months?

Can I get off it more gently?

‹ Can I taper or microdose?

‹ Is it safe to just stop?

What are my non-drug options

‹ Anything besides another drug?

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Revita®

A one-time, outpatient procedure to ablate duodenal mucosa for durable weight maintenance

- A single outpatient endoscopic procedure
- Designed to complement pharmacology
- FDA Breakthrough Device designation
- Robust IP portfolio protecting first-mover leadership

Revita: a potential new backbone therapy in obesity

Revita is for investigational use only in the United States. Revita has a CE mark in the EU/UK.

Revita Duodenal Mucosal Resurfacing (DMR) procedure

Utilizes familiar skills, does not alter patient's anatomy, complements other approaches

Entire length of the post-papillar duodenum is treated through two primary actions:

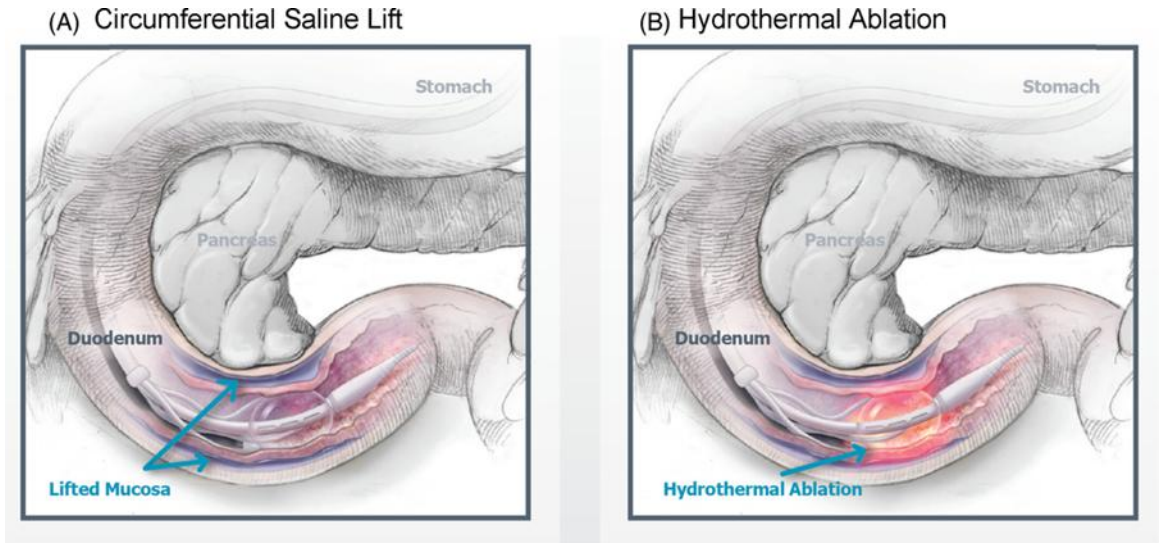
(A) **Circumferential saline lift**

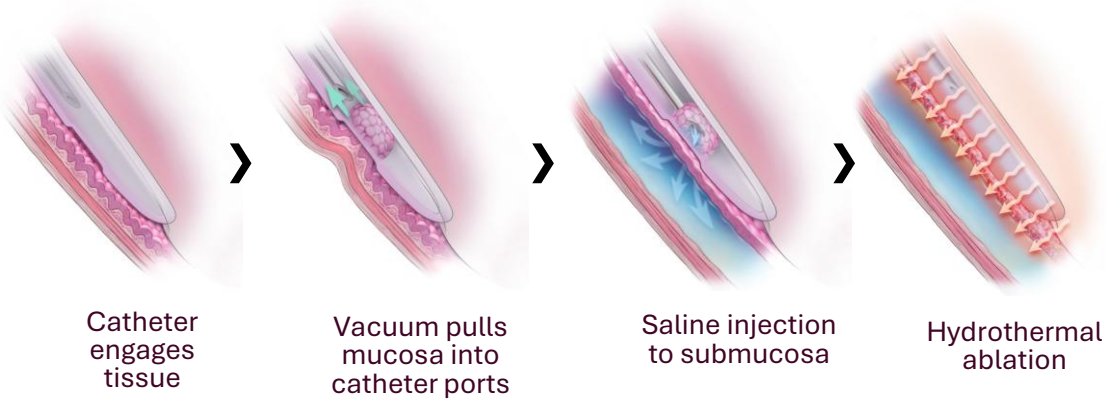
- Balloon engages tissue
- Vacuum pulls mucosa into ports
- Needle injects saline into submucosa

(B) **Hydrothermal ablation**

- Controlled hot water creates precise ablation at each lift site
- Steps repeated along full duodenal length (>14cm)

Utilizes familiar skills.
No implant or anatomy alteration.
Does not preclude any other therapeutic option.





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REMAIN-1 weight maintenance program

Stepwise validation through potential De Novo marketing application submission in late Q4 26[1]

	Open-label exposure	Sham-controlled pilot	Sham-controlled pivotal
	REVEAL-1 Cohort (n≈20)	**REMAIN-1 Midpoint Cohort** (n≈45)	**REMAIN-1 Pivotal Cohort** (n≈315)
Rationale	Post-GLP-1 weight maintenance in a **real-world** setting	Randomized, double-blind, sham controlled	Randomized, double-blind, sham-controlled
Design	• Open-label	• Tirzepatide run-in phase • Revita vs sham (2:1)	• Tirzepatide run-in phase • Revita vs sham (2:1)
Participants	With obesity (BMI > 30 kg/m^2) prior to GLP-1 *and* ≥15% TBWL with GLP-1 drug	With obesity (BMI 30-45 kg/m^2) without T2D *and* GLP-1 drug naïve	With obesity (BMI 30-45 kg/m^2) without T2D *and* GLP-1 drug naïve
Anticipated milestones[1]	✓ 3-mo data: June '25 ✓ 6-mo data: Dec '25 ✓ 1-yr data: Q2 '26	✓ 3-mo data: Sept '25 ✓ 6-mo data: Jan '26 ✓ 1-yr data: Q3 '26	✓ Enrollment: Q2 '25 ✓ Randomization: Feb '26 • **Topline 6-mo data: early Q4 '26** • **Potential De Novo marketing application submission: late Q4 '26** • **Topline 1-yr data: 1Q '27**

[1]These forward-looking statements are based on management's current estimates and expectations.
Refer to the latest disclosures filed with the SEC for a discussion regarding Risk Factors to these and other estimates and expectations.
Abbreviations: BMI, body mass index; GLP-1, glucagon-like peptide-1; T2D, type 2 diabetes; TBWL, total body weight loss.

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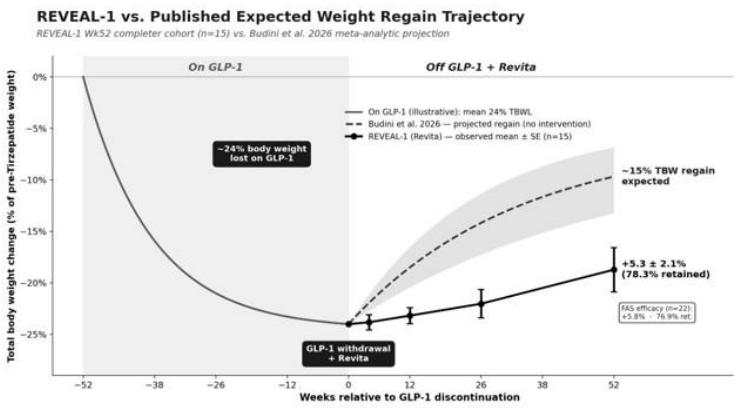
REMAIN-1 Weight maintenance clinical trial program

Stepwise validation through three ongoing clinical cohorts under investigation[1]

Open-label exposure

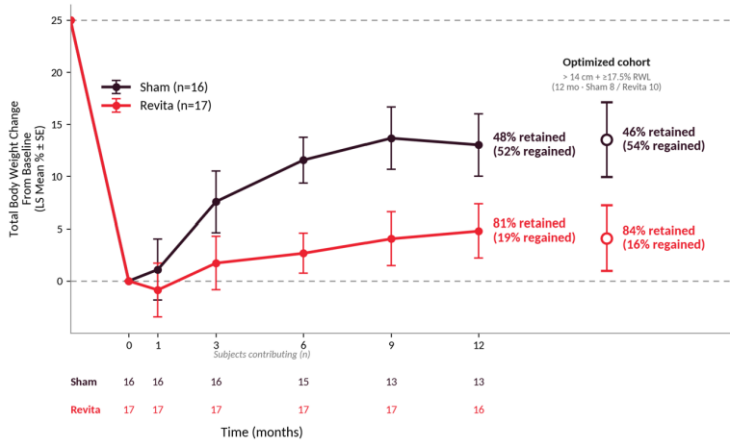
REVEAL-1 Cohort
(n≈20)



Participants retained ~78% of GLP-1 induced total body weight loss one year after discontinuation and a single Revita procedure[1]

Sham-controlled pilot

REMAIN-1 Midpoint Cohort
(n≈45)



Up to 84% of GLP-1 induced weight loss retained with Revita® versus 46% with sham at one year in patients receiving complete duodenal ablations [2]

Sham-controlled pivotal

REMAIN-1 Pivotal Cohort
(n≈315)

Topline 6-mo data:
early Q4 ’26

Topline 1-yr data:
1Q ‘27

1. https://ir.fractyl.com/news-releases/news-release-details/fractyl-health-reports-positive-one-year-reveal-1-open-label
2. https://ir.fractyl.com/news-releases/news-release-details/fractyl-health-reports-positive-randomized-data-remain-1

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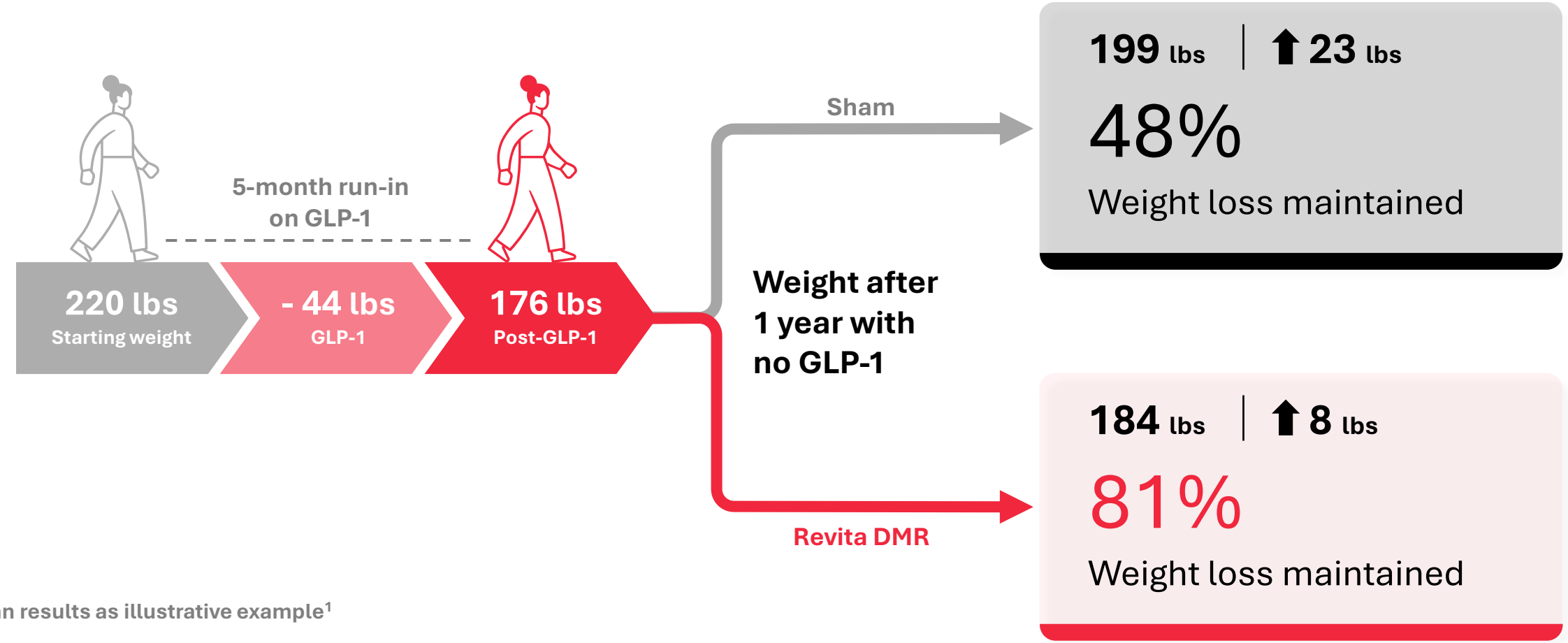
REMAIN-1 midpoint cohort at 1 year

Clinically meaningful effect size



Mean results as illustrative example[1]

[1]Complete ablation population in REMAIN-1 Midpoint Cohort.

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Midpoint cohort: favorable safety through 12 months

No device-related serious AEs: a mild, periprocedural profile that supports outpatient use

- **No new device-related TEAEs between 6 and 12 months**
- **No device-related SAEs:** one SAE (blocked bile duct) adjudicated as unrelated to the device or procedure
- **No excess AEs with Revita:** any-TEAE rates matched sham (24% vs 25%)
- **Mild and periprocedural:** all 4 related events were Grade 1, on procedure day, and transient
- **1 new diagnosis of Type 2 Diabetes in sham arm vs zero in Revita arm**

Treatment-Emergent Adverse Events	**Revita** (n=29)	**Sham** (n=16)	**Total** (N=45)
Patients experiencing any TEAE n, (%)	**7 (24)**	**4 (25)**	**11 (24)**
TEAEs by grade, n (%)	**12**	**5**	**17**
Grade ≥3 TEAEs	1 (8)	0	1*
Grade 2 TEAEs	1 (8)	1 (20)	2**
Grade 1 TEAEs	10 (83)	4 (80)	14 (82)
Related TEAEs, n**	**4**	**0**	**4**
Abdominal discomfort	1	0	1
Nausea	1	0	1
Dry mouth	1	0	1
Sore throat	1	0	1

Exploratory REMAIN-1 Midpoint Cohort analysis; not powered for formal inference.
*1 SAE: blocked bile duct (Grade IIIb, day 65); unrelated to device or procedure. **2 Grade 2 AEs: Revita worsening hypertension (day 258); Sham urinary tract infection (day 239); both unrelated. Related TEAEs = probably related to device/procedure; all Grade 1, onset day 0. Two Sham AEs previously ungraded in EDC: nausea (day 0), Type 2 diabetes (day 363) are now classified Grade 1.REMAIN-1 Stage 2a, through 52 weeks (12 months). Abbreviations: AE, adverse event; TEAE, treatment-emergent adverse event; SAE, serious adverse event.

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REMAIN-1 randomized pivotal study in weight maintenance

Patient population

- Adults with obesity (BMI 30-45 kg/m^2)
- GLP-1 naïve; no T2D
- n≈315

Co-primary endpoints

- % TBW regain: Revita vs sham at 6 months *and*
- Responder rate: % participants who maintain weight loss at 12 months

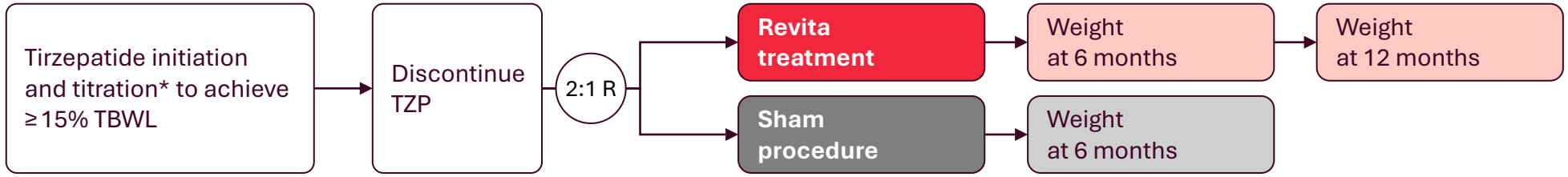
Study design

- Randomized (2:1 Revita vs Sham), double-blind, sham-controlled
- TZP administration to achieve ≥ 15% TBWL, then discontinued
- Diet and lifestyle counseling throughout

Anticipated milestones[1]

- **Complete randomizations:** Feb '26
- **Topline 6-month pivotal data:** Early Q4 '26
- **Potential De Novo marketing application submission:** Late Q4 '26

Study design



Top line results expected early Q4 2026 – de novo marketing submission to follow

*Tirzepatide run-in modeled from SURMOUNT-4 trial. 1These forward-looking statements are based on management's current estimates and expectations.
Refer to the latest disclosures filed with the SEC for a discussion regarding Risk Factors to these and other estimates and expectations.
Abbreviations: BMI, body mass index; GLP-1, glucagon-like peptide 1; R, randomization; TBW, total body weight; TBWL, total body weight loss; TZP, tirzepatide; T2D, type 2 diabetes.

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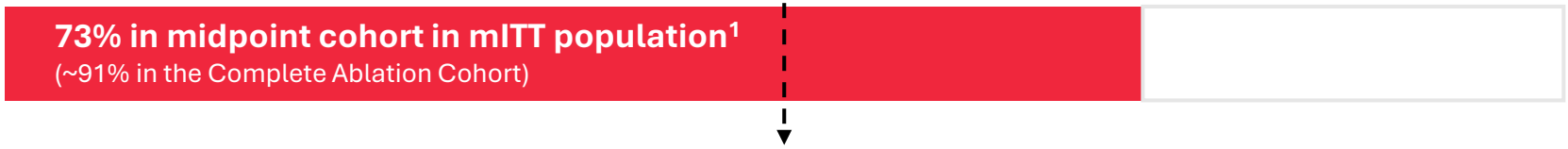
Co-primary endpoints well powered for pivotal trial success

First co-primary:
% TBW regain: Revita vs sham at 6 months

Illustrative sham 6-mo regain in mITT[1]	Revita regain needed to win[1,2]	Observed in midpoint cohort[1,3]	Projected pivotal p-value[4]
10%	≤ 7.4%	5.1%	*p<0.05*
11.6% (base case, current)	≤ 9.0%	5.1%	*p<0.05*
12.5%	≤ 9.9%	5.1%	*p<0.05*

Second co-primary: Responder rate:
% of Revita patients maintain ≥ 5% TBWL at 12 months



50% = FDA-mandated pre-specified performance goal (single-arm)

[1]Values shown are model-based estimates (mITT MMRM at the 20% run-in weight-loss reference). REMAIN-1 Midpoint Cohort, exploratory. [2]Maximum Revita weight regain at which the pivotal reaches statistical significance vs the sham scenario shown (~ 2.5-point gap at pivotal N=315). [3]5.1% = LS-mean percent total body-weight regain from post-run-in baseline at 6 months (Week 26); mITT MMRM at 20% run-in weight-loss reference; n=29 Revita. REMAIN-1 Midpoint Cohort, exploratory. [4]Two-sided; Revita vs sham, pivotal N=315, randomized 2:1 (Revita:sham). Sham values illustrative.
Abbreviations: LS-mean, least-squares mean; mITT, modified intention-to-treat; MMRM, mixed-model repeated measures; TBW, total body weight; TBWL, total body weight loss; .

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Advancing toward a more efficient US regulatory path

FDA pre-submission feedback received; de novo submission planned late Q4 2026

- Received favorable pre-submission feedback from the FDA in March 2026
  - Safety profile of the Revita DMR System is consistent with a Class II (de novo) device classification
- One pivotal study is the registrational package
- A successful de novo would make Revita the reference device for the category
- Company intends to submit de novo marketing application in late Q4 2026[1,2]

FDA regulatory pathways: De novo vs. PMA

	De novo classification	PMA (premarket approval)
Intended device risk	Class I or II (low to mid risk)	Class III (high risk)
Clinical evidence required	"Reasonable assurance of safety and effectiveness"	"Valid scientific evidence"
Statutory FDA review timeline	150 FDA days	180 FDA days
Downstream optionality	Creates predicate for future 510(k)s	No predicate created
Capital efficiency	Potentially more capital-efficient	Potentially capital-intensive

[1]These forward-looking statements are based on management's current estimates and expectations. Refer to the latest disclosures filed with the SEC for a discussion regarding Risk Factors to these and other estimates and expectations [2]FDA pre-submission feedback is advisory and non-binding, and there is no assurance that FDA will accept a De Novo marketing application submission or that the Revita DMR System will receive marketing authorization
Source: FDA device classification regulations (21 CFR); FDA device classification regulations (21 CFR). Both De Novo and PMA pathways require demonstration of reasonable assurance of safety and effectiveness.
Abbreviations: FDA, Food and Drug Administration; PMA, premarket approval.

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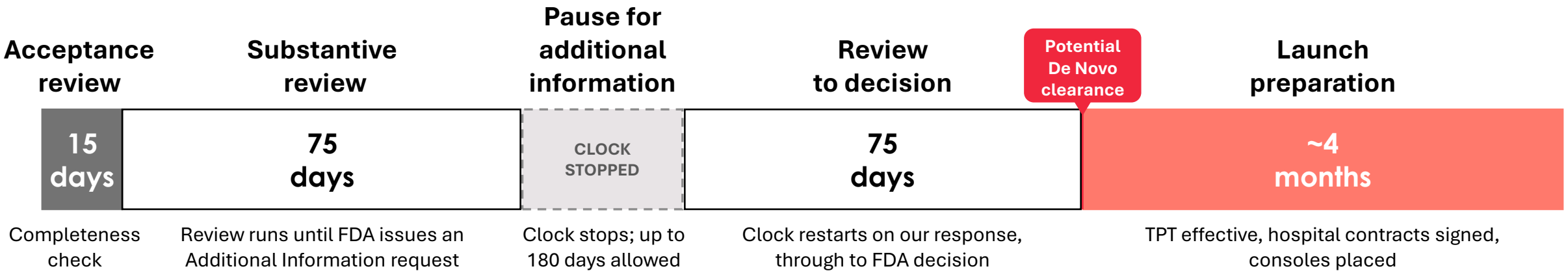
Potential pathway from de novo filing to commercial launch

Illustrative review path



Illustrative only; durations are assumptions, not FDA commitments. FDA days are calendar days between receipt and decision, excluding time on hold for an Additional Information request; the acceptance review falls within that count. Under MDUFA V the goal is a decision within 150 FDA days for 70% of De Novo requests. A refusal to accept would restart the clock. Timing of TPT, coverage and launch is not assured.

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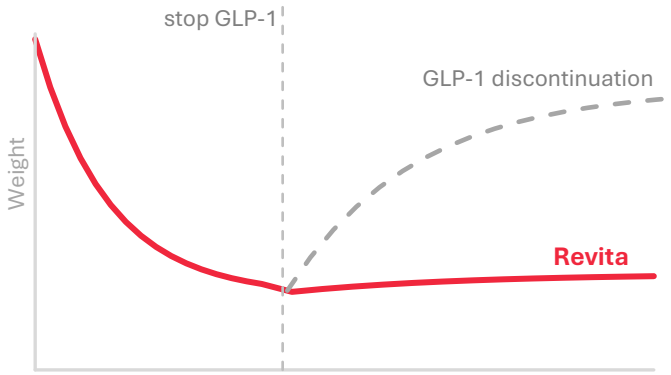
One metabolic reset, three potential use cases in obesity

Step 1 · Prove it

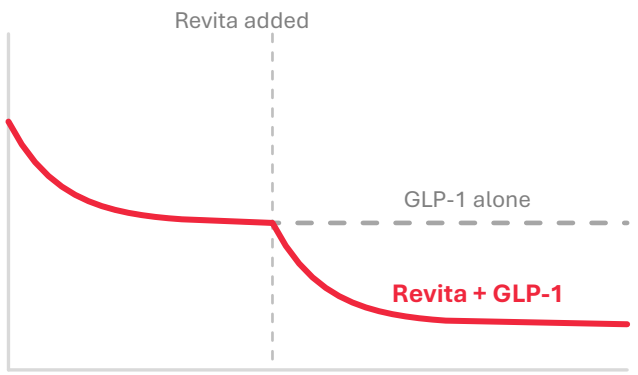
Maintenance after GLP-1



Off-ramp: preserve weight and metabolic benefit after discontinuation

Step 2 · Combine

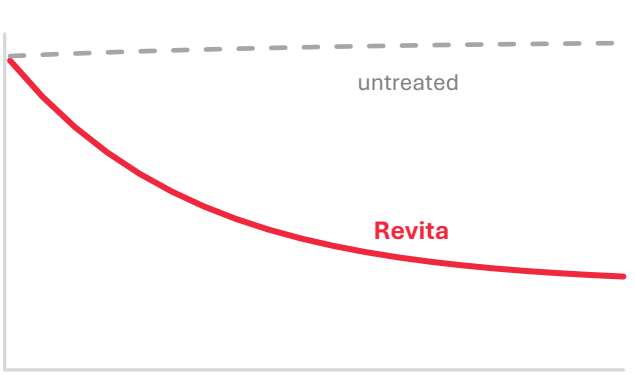
Adjunct to orals, injectables, procedures



Add-on: Pair with drugs to deepen and sustain response, enabling lower doses, drug holidays, and durable step-down

Step 3 · Front line

Front-line, drug-free



Kick-start : An earlier one-time option for patients who can't tolerate, afford, or stay on chronic drugs.

Illustrative and hypothetical; schematic, not clinical data; contingent on pivotal results

Illustrative, forward-looking expansion framework contingent on pivotal success and future studies; not FDA-assessed. Timelines are management estimates. Subject to the risks described in the Company's SEC filings.

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Folahan Ayoola,
MD, FACS, FASMBS
Medical Director, Bariatric Surgery
Texas Health in Flower Mound

A metabolic interventionalist's perspective on the unmet need in post-GLP-1 patients

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Mike Zumdahl
Sr VP of Market Access
& Commercial Strategy

Commercial Strategy and Market Access

The potential commercial build is an activation exercise in centers that are already prepared

Open high-quality centers

High-volume metabolic centers already exist today and are built for Revita

Select appropriate patients

Motivated GLP-1 discontinuers are already in the interventionalists' clinic

Perform great procedures

Leverage interventionalists' skillset and validated Revita training program

Secure payment

Align patient, provider, payer, and Fractyl economics

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~4M eligible patients for Revita translates to $40-120B opportunity*

US GLP-1 users → patients clinically eligible for Revita (post-GLP-1 weight maintenance)

Bars: ● share of prior step retained (point estimate)

~4M

eligible patients

~$40–120B TAM

@ estimated cost of 10K – $30k / procedure

* TAM is an internal figure developed by management based on certain assumptions that management believes to be reasonable as of the date hereof. Please refer to the disclaimer titled "Market Data, Estimates and Industry Information" set forth on Slide 2 of this presentation.[1]Gallup 2026 — ~11% of ~262M US adults currently on a GLP-1 for weight loss. [2] 65% discontinuation rate is for individuals without T2D - Rodriguez et al., JAMA Netw Open 2025;8(1):e2457349. [3]30% base · Monte Carlo median 29.3% based on Fractyl market estimates. [4]On-label BMI 30–45 (~70%; RWE / Fractyl est.) Abbreviations: TAM, total addressable market

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Ready centers already have necessary infrastructure — only missing the GLP-1 off-ramp

Already in place

- Comprehensive metabolic program
- Metabolic interventionalists who already manage GLP-1 patients
- Nutrition and lifestyle counseling
- Prior-authorization machinery
- Endoscopy and fluoroscopy suite time
- The interventional skillset
- Registry participation

›

Still missing
An approved, reimbursed, durable off-ramp procedure

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Targeted and efficient COE launch strategy

Focused on top 10-20% high volume comprehensive metabolic centers across the U.S.

~1,000

Accredited centers, U.S. and Canada[1]

100–200

Early launch starts with top 10–20% of potential COEs

First wave includes Revita clinical centers and established ASMBS COEs

Locations approximated from the ASMBS center locator. Illustrative. 1 https://www.facs.org/quality-programs/accreditation-and-verification/metabolic-and-bariatric-surgery-accreditation-and-quality-improvement-program/

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Precision launch: depth before breadth

High-touch activation of ready sites

Phase 1

Year 1

30–50 highest-readiness centers of excellence: trial sites and centers already in dialogue

Training, pathway integration, economic proof

Phase 2

Year 2

60-90 centers: early sites become regional training and referral hubs

Replication of a proven pathway

Phase 3

Year 3 onward

100-200 centers: at scale, representing 10- 20% of potential COE distribution

Broader rollout as the procedure becomes routine and coverage solidifies

Scale on established policy

Phase 1 centers include REMAIN-1 trial sites, Everself (Bariendo) centers, and ASMBS Centers of Excellence [overlapping set of criteria]

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Revita is delivered by metabolic interventionalists

Proceduralists who already treat obesity with procedures and manage patients in clinic

300–400

GI endoscopists with bariatric practices[1]

2–3K

Bariatric surgeons[1]

Physicians who already have these patients in their own obesity clinics

Motivated proceduralists

Expected revenue per physician is high and recurring

A finite, nameable target list

A field force of tens, not hundreds

[1]Physician counts are company estimates of the addressable operator pool.

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Site-level volume potential is material and credible

Initial target centers

100–200

High-volume systems

GLP-1 patients/center/year

>2000

Patients at ready COEs[1]

Potential procedures /center/year

250–500

Procedures during ramp[1]

1. Company estimates

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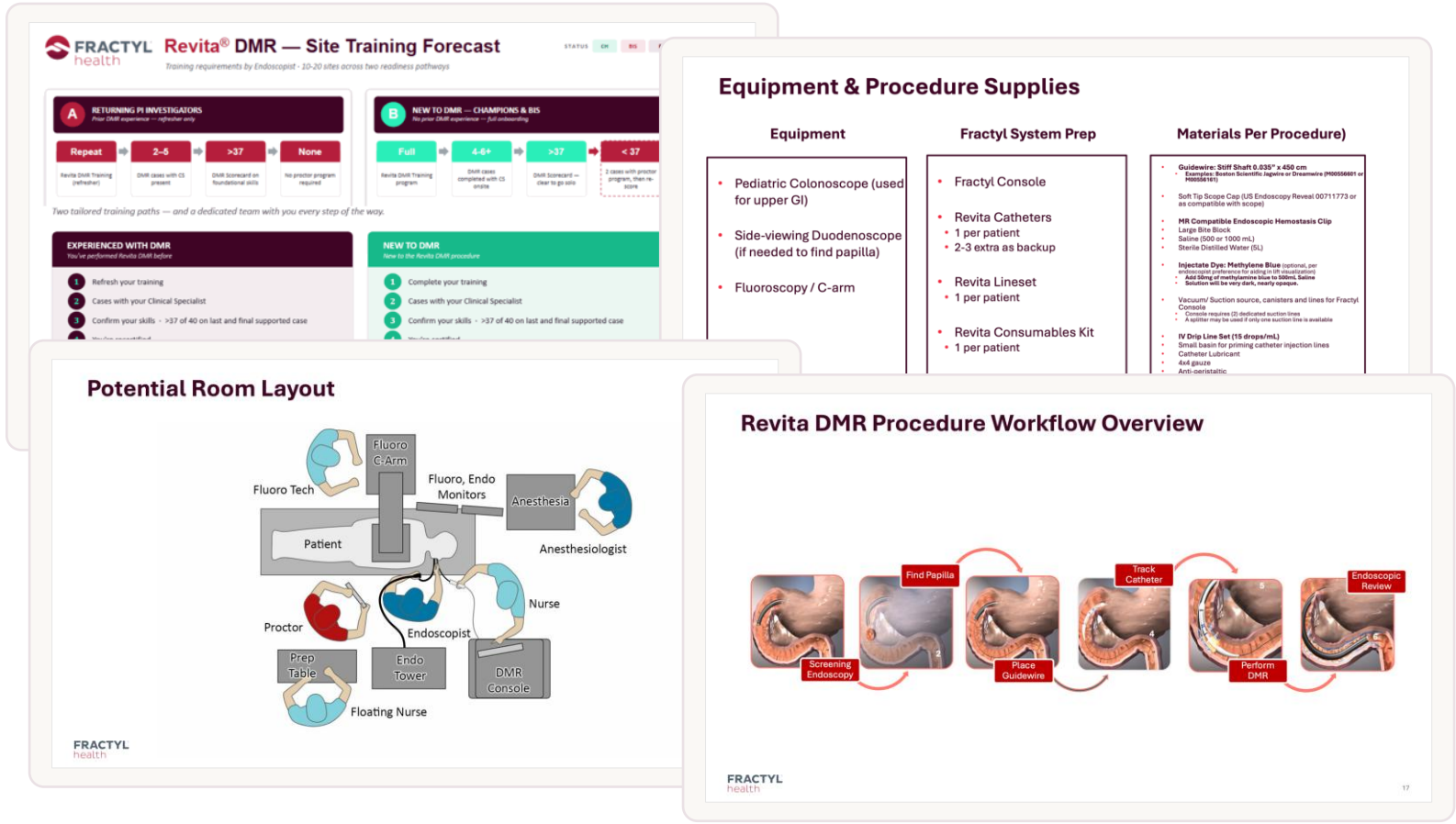
Training is short and built on existing endoscopic skills

REMAIN-1 protocol training requirements

REMAIN-1 trial:

- Half-day didactic + ~4 cases with Fractyl clinical specialist for physician & staff proficiency
- Protocol-defined technical success = complete ablation of entire duodenum (>14 cm ablation covering the post-papillary duodenum)



Three reimbursement tracks all underway

1. Coding

- **Filed:** CPT Category III application submitted Jun'26
- **Category III CPT code:** Anticipate going into effect in 2027

2. Coverage

- **Medicare:** Leverage FDA Breakthrough Designation and TCET/RAPID pathways to aim for early national coverage aligned with timing of FDA approval/clearance
- **Commercial:** Medical policy informed by value dossier & HEOR. 3rd party prior auth/appeal support planned to facilitate early coverage with commercial payers

3. Payment

- **Facility:** Potential Transitional Pass-Through (TPT)* to make hospitals whole on day one
- **Physician:** professional payment established through CPT valuation over time

* CPT, APC, and TPT outcomes are subject to AMA and CMS review cycles and are not assured.
Abbreviations: APC, ambulatory payment classification; MAC, Medicare administrative contractor; NCD, national coverage determination; OPPS, outpatient prospective payment system.

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Major payers already cover obesity procedures

Bariatric surgery + GLP-1 coverage provide tailwinds for potential Revita coverage

Payer	2025 commercial lives[1]	GLP-1s for obesity[2]	Bariatric surgery[3]
United Healthcare	~35M	Prior Auth + opt-in	Covered
Elevance Health	~30M	Prior Auth + opt-in	Covered
aetna™	~20M	Prior Auth + opt-in	Covered
Cigna	~18M	Prior Auth + opt-in	Covered
HCSC Health Care Service Corporation	~14M	Prior Auth + opt-in	Covered
CMS (Medicare)	~68M[4]	GLP-1 Bridge	Covered

~190M lives sit with the six payers already reimbursing bariatric surgery

[1]Total U.S. medical enrollment, all lines — Mark Farrah Associates / Peterson–KFF, 2025; CMS row is Medicare Part D enrollment, not commercial. [2]Obesity indication; PA + employer election typically required (CVS Caremark 7/25; Evernorth 5/25). [3]Payer commercial medical policies; typical criteria BMI ≥40 or ≥35 + comorbidity (UnitedHealthcare policy, 2026). [4]Medicare GLP-1 Bridge: CMS §402 demonstration, Jul 1 2026–Dec 31 2027, outside Part D payment flow; $50/mo copay, central processor for PA (CMS, 2026). BALANCE Model indefinitely delayed. Bariatric surgery per NCD 100-1.1.

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Medicare alone is a multi-billion dollar opportunity

GLP-1 Bridge program may create a massive discontinuation pool Revita is designed to help

~4M

Medicare beneficiaries expected to access GLP-1s through the Bridge[1]

2–3M

expected to discontinue within a year | Bridge expires 12/31/2027[2]

600–970K

an estimated will achieve a deep response before stopping[3]

510K – 830K CMS beneficiaries eligible for Revita & TPT[3]

[1]https://www.kff.org/medicare/nearly-four-million-medicare-beneficiaries-met-the-eligibility-criteria-in-2023-for-the-medicare-glp-1-bridge . [2]CBO estimates 65% discontinuation - Publication 60441. [3]Company estimates

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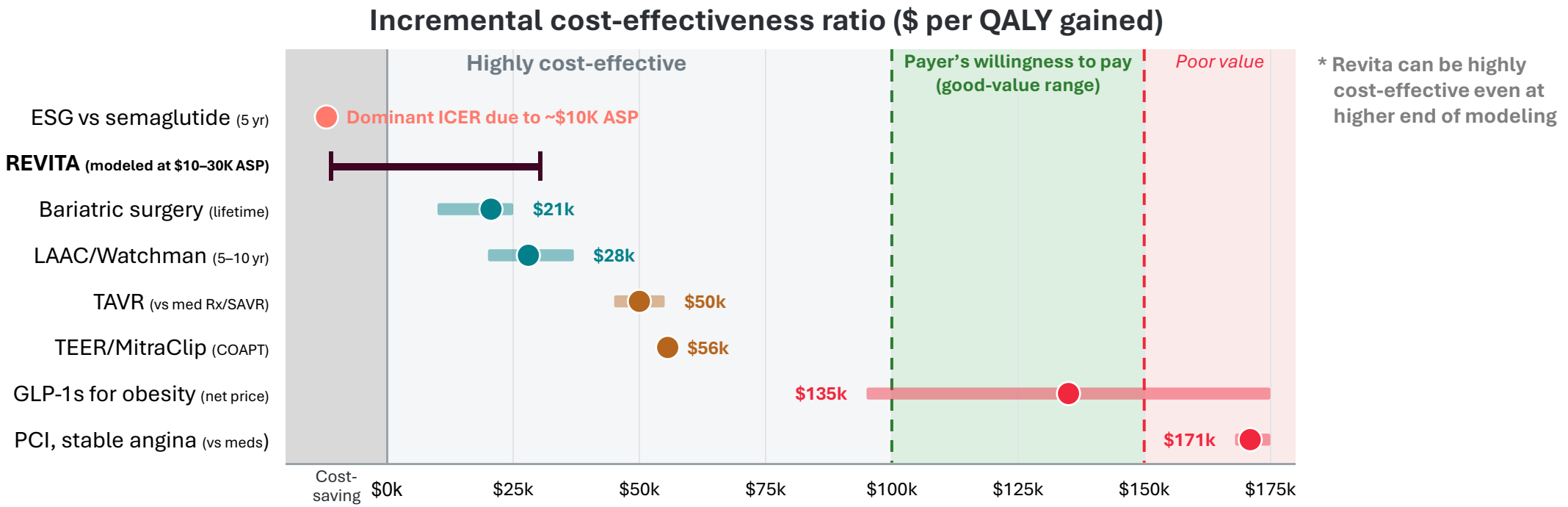
A one-time procedure that maintains post-GLP-1 weight loss can be highly cost-effective

We believe Revita's modeled cost-effectiveness is highly favorable: Better cost per QALY than widely covered CV procedures, bariatric surgery, and comparable to ESG-vs-GLP-1 at lower ASP



Based on published cost to payers and cost-effectiveness benchmarks for obesity therapies and other device-based interventions

Sources: JAMA Netw Open 2024 (ESG vs semaglutide, dominant at ~$10K ASP); ACS Clinical Congress 2024 & lifetime CE literature (bariatric surgery $10k–$25k/QALY); Stroke 2018 / PROTECT AF (LAAC); PARTNER economic substudies (TAVR); COAPT (TEER); ICER 2025 net-price review (GLP-1s); COURAGE (PCI). Revita value is internal model, not peer-reviewed. IVL omitted — no published ICER. Cross-study comparisons are directional: populations, comparators, & horizons differ.

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The commercial field team is potentially tens of people, not hundreds

Open high-quality centers

Business development managers focused on site selection and activation

Select appropriate patients

Account managers focused on site execution and procedure growth

Perform great procedures

Clinical specialists focused on clinical excellence and outcomes

Secure payment

HEMA experts focused on payer engagement, prior authorization, and billing support

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Lara Smith Weber
CFO

The model and path to profitability

Precedent: Focused high-volume CoE launches work

Company	Focus	Key quantitative signals	Investor outcome
Inari (VTE)	Specialized interventional centers; LimFlow → ~200[2] high-vol COEs	Rapid account growth then deeper penetration; >50 of ~200 target COEs accessed in year 1 for LimFlow[2]	**Stryker, $4.9B – ~8x sales[3,10]** $277M[1] → $603M[2] (30% CAGR)
Shockwave (IVL)	High-volume PCI centers (>750 PCIs/yr) [5]	1–1.5 new accounts/ territory/month; reorder rates 83–92% quickly; majority of targets in ~2 yrs[5]	**J&J, $13.1B – ~14x sales[6,10]** $237M[4] → ~ $920M[4] (~ 57% CAGR)
Watchman (LAAC)	Structural/EP centers	Median hospital vols ~40–70/yr (high-vol quartile >100) [7,8]; programs scale to hundreds; >700 programs, >500k pts[9]	**Boston Scientific,** Revenue quickly scaled past $1B a year[9]

What drives value for shareholders

- Finite list of high-volume centers
- Deep utilization per site
- Strong growth

Sources : 1. Inari FY2021 results, 23 Feb 2022. 2. Inari Q3 2024 earnings call, 29 Oct 2024. 3. Stryker press release "Stryker completes acquisition of Inari Medical, Inc." 19 Feb. 2025. 4. Shockwave FY2021 results, 17 Feb 2022; FY2023 results and FY2024 guidance. 5. Shockwave quarterly earnings calls, 2021–2022. 6. J&J press release, 5 Apr 2024. 7. Freeman et al., JACC 2020;75:1503 (NCDR LAAO Registry). 8. Friedman et al., Circ Cardiovasc Interv 2024;17:e013466. 9. Boston Scientific 2024 Annual Report; BSX quarterly earnings calls. 10. Revenue multiples calculated on forward revenue — Inari FY2024 (~$603M), Shockwave FY2024 guidance midpoint ($920M).

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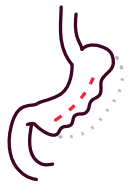
Revita pricing corridor

Bracketed by the endoscopic and surgical benchmarks that payers already pay



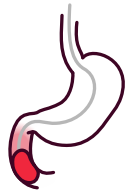
Endoscopic sleeve gastroplasty

~$11,600[1]+

CPT 43889 – APC 5362
Category I code effective Jan 1, 2026

Medicare, hospital outpatient
$10,860 facility + $720 physician

Self-pay market
$8,000 – $15,000, bundled



Revita DMR

Pricing to be determined

Outpatient endoscopic
Under one hour, same-day discharge

No resection or anatomic change
Repeatable; no permanent implant

Duodenal target
Distinct mechanism from restriction

Bariatric surgery

Up to $33,000[2]

Sleeve gastrectomy, CPT 43775
Inpatient only under Medicare

Commercial/uninsured
$20,000 – $33,000

[1] ESG Lower bound is the CY2026 Medicare national average in the hospital outpatient setting: $10,860 facility (OPPS APC 5362, a Comprehensive APC — device cost is bundled, not separately paid; CMS-1834-FC) plus $720 physician (PFS at a $33.40 conversion factor; CMS-1832-F), before the 2% sequestration reduction. Upper bound is the published US self-pay range for ESG, typically $8,000–$15,000 as a bundled package.
[2] Bariatric surgery Lower bound is CY2026 Medicare for an uncomplicated laparoscopic sleeve gastrectomy: MS-DRG 621 at $10,976 (IPPS) plus $1,000 physician (CPT 43775); MS-DRG 619 with a major complication or comorbidity pays $21,011. Upper bound is self-pay and uninsured list pricing from published market surveys — a charge, not a payer-allowed amount. Published commercial episode payments sit materially below it.

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Potentially attractive unit economics at the center and at the company

Unit economics potentially favorable for hospital and Fractyl

The hospital's view

- Endoscopy and bariatrics are major drivers of hospital contribution margin
- TPT enables positive contribution margin by passing disposable costs through to CMS
- No new capital footprint to justify

Fractyl's view

- High gross margin of ~80%
- Capital-light: no high cost, long lead-time sales cycle per site
- Commercial cost scales with sites, not linearly with volume

Recurring, high-margin procedure revenue concentrated in high-throughput centers

Hospital economics assume pass-through plus facility payment.

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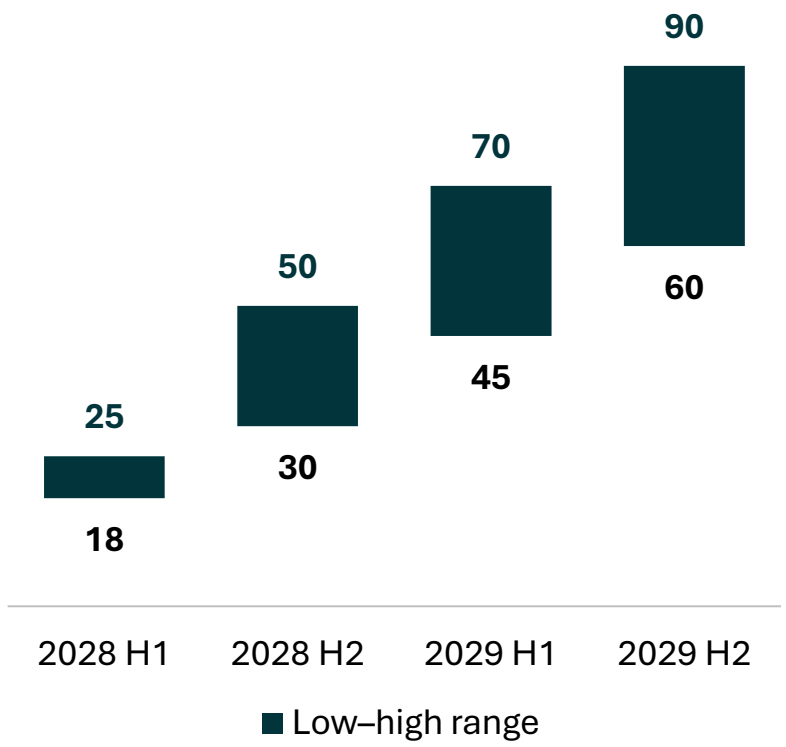
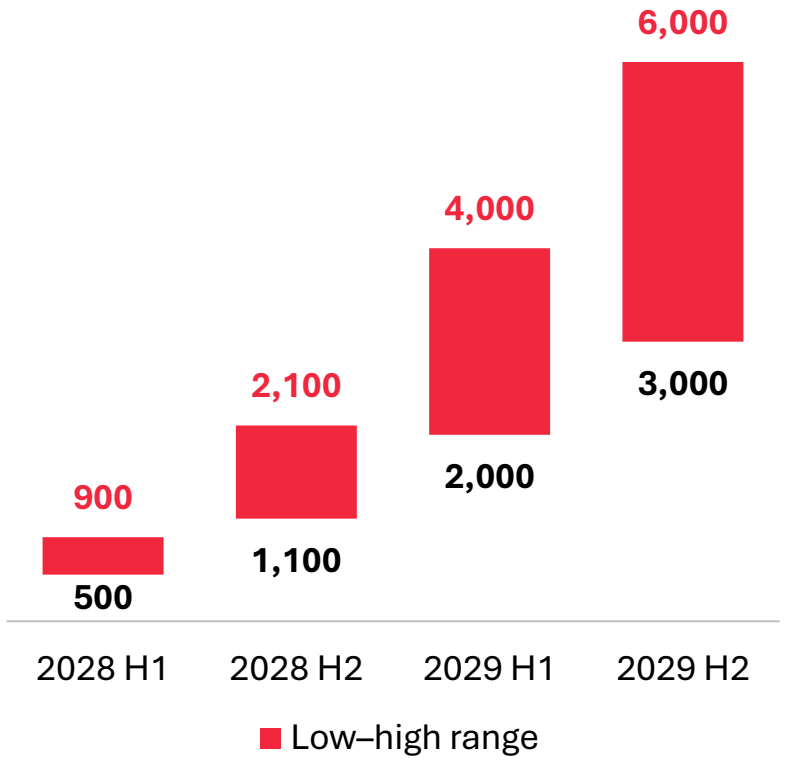
Potential launch expected early 2028: Center-led ramp with ~1,600–3,000 procedures by EOY 2028 and 5,000–10,000 procedures in 2029

Centers live (cumulative)[1]



Procedures (per half-year)[1]



Centers of excellence[1]

30-50
live at the end of 2028

60-90
live at the end of 2029

Procedure volume[1]

1,600 to 3,000
procedures in 2028

5,000 to 10,000
procedures in 2029

1. Figures presented are management estimates contingent on pivotal results and on FDA marketing authorization, neither of which is assured, and they are not guidance

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Potential Revita unit economics and breakeven

Potential 80% gross margin leads to cash break even 5-8 quarters after launch

Price per procedure

$11–33K

Published benchmark range

ESG: $11,600 Medicare

Bariatric: $20,000 private payer

Bariatric: $33,000 self-pay list

×

Gross margin at scale

~80%

Held constant across scenarios

Margin held flat across scenarios rather than modeled; higher-ASP cases would carry higher margin and earlier break-even than shown

›

Procedures to breakeven

80% gross margin, $22M quarterly operating cash burn

ASP	GP/proc	Procedures/qtr	Break-even
$10,000	$8,000	2,750	**2H 2029**
$20,000	$16,000	1,375	**1H 2029**
$30,000	$24,000	920	**Q1 2029**

Every date assumes | De novo approval in late 2027 — CMS coverage and transitional pass-through early 2028

Price benchmarks: CY2026 Medicare national averages (OPPS APC 5362; IPPS MS-DRG 621) and a derived private-payer estimate. Gross margin, operating cash run-rate and center productivity are Fractyl assumptions. Break even quarters are contingent on De Novo authorization, coverage and financing, and are not guidance.

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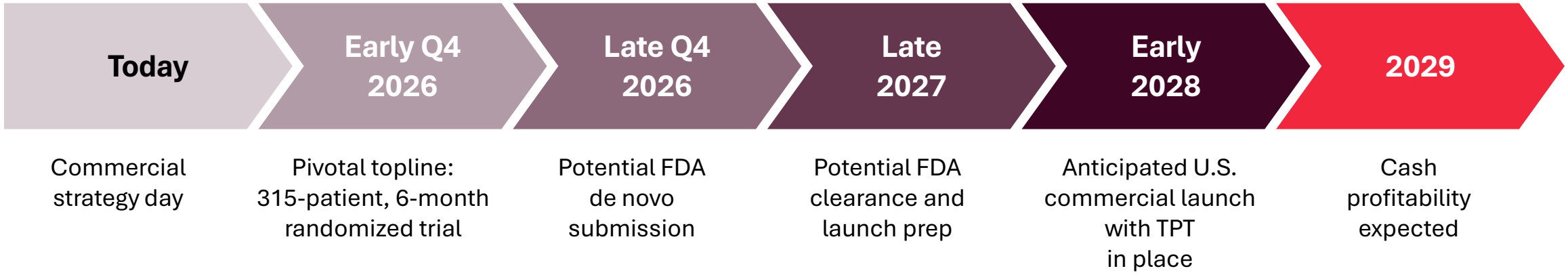
Clear commercial strategy to potential cash profitability within 5–8 quarters of launch



Timelines are management estimates and forward-looking; actual events may differ. Revita is investigational — commercialization is subject to REMAIN-1 results and FDA marketing authorization, neither of which is assured.

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Revita highlights

A one-time outpatient procedure targeting the biggest unmet need in obesity

- **The problem is maintenance, not weight loss.** Most patients discontinue GLP-1s within a year; there is no approved off-ramp.
- **Existing randomized and open-label data show a durable signal.** Encouraging results from REVEAL-1 and Midpoint 12 month data. Pivotal 6 mo topline is early Q4.
- **The pivotal is built to support a De Novo filing beginning in late Q4 2026.** Class II path, one registrational study, FDA Breakthrough Device.
- **The commercial build is activation, not market creation.** Patients, physicians, rooms, and obesity-procedure payment already exist in a finite set of Centers of Excellence (COEs.)
- **Payment work is already in motion.** Coding, coverage, Transitional Pass-Through (TPT) with favorable tailwinds in payer landscape supporting reimbursement strategy.
- **We believe a focused COE launch can reach profitability 5–8 quarters after launch.** Potentially high gross margin disposable sale without a large field force.

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Q&A

NASDAQ:GUTS