BofA SECURITIES

Fractyl Health

Initiate Buy on novel diabesity treatment alternatives to chronic GLP1 therapy

Initiating Coverage: BUY | PO: 26.00 USD | Price: 7.60 USD

Initiating coverage on GUTS with Buy rating and $26 PO

We initiate coverage on Fractyl with a Buy and $26 PO. GUTS is a pre-commercial stage, hybrid medtech/biopharma company that develops treatments for type 2 diabetes (T2D) and obesity. Lead asset Revita (pivotal stage) is a non-invasive endoscopic procedure that restores part of digestive system (duodenum) to a healthier state for better and durable glycemic control. Follow-on asset Rejuva (preclinical) is a one-time, GLP1 gene therapy aims at remission of diabesity, potentially with better tolerability than on-market GLP1 drugs. We like GUTS for actionable catalysts with upside potential in 2024-25 eg pivotal data of Revita that can support approval in multi-bn T2D market.

Endoscopic device in pivotal testing for type-2 diabetes

Revita is being evaluated in a pivotal trial for insulin-dependent T2D. Topline results are expected in 4Q24, and positive data should support approval in the lead indication. Data from prior clinical trials indicate Revita can improve glucose control, lower insulin usage, and induce weight loss in T2D patients. We model 55% likelihood of success (POS) balancing the positive data with imperfections in prior results, including data variability, use of adjunct therapy, and limitations in sham-controlled data.

Endoscopic device could expand into large obesity market

Beyond diabetes, Fractyl plans to evaluate Revita in maintenance of weight loss for patients who have achieved weight loss with a GLP1 drug but wish to discontinue the GLP1 therapy for any reasons (eg drug intolerance due to side effects). The obesity trial is expected to start in 2H24, followed by reporting of initial open-label data thereafter.

Gene therapy early, but with potential to remit diabetes

Rejuva is a GLP1-based gene therapy, leveraging the same therapeutic target as Novo's Ozempic/Wegovy approved for T2D/obesity. The value proposition for Rejuva is two-fold: 1) one-and-done therapy for T2D/obesity, 2) local delivery to the pancreas could isolate therapeutic action to the organ, thereby driving treatment benefits of GLP1 potentially without increasing GLP1 in systemic circulation (avoiding side effects). In animal models, Rejuva can lower blood glucose and reduce weight as good as the active ingredient of Ozempic/Wegovy without safety signals. Fractyl plans to finish preclinical studies in 2H24 and initiate first-in-human clinical trial in 1H25.

Our risk-adjusted SOTP drives PO of $26

Our PO of $26 is based on a SOTP, risk-adjusted DCF of GUTS' key programs. Our SOTP EV ascribes ~60% value to Revita for insulin-dependent T2D, ~20% value to Revita for maintenance of weight loss, and remainder for Rejuva (heavily risk-adjusted given early).

Estimates (Dec) (US$)	2021	2022A	2023E	2024E	2025E
EPS	NA	(31.97)	(33.36)	(2.36)	(2.26)
EPS Change (YoY)	NA	NA	-4.3%	92.9%	4.2%
DPS	NA	0	0	0	0
Valuation (Dec)					
Free Cash Flow Yield*	NA	-12.8%	-12.7%	-27.9%	-35.6%

* For full definitions of iQmethod℠ measures, see page 21.

27 February 2024

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Stock Data

Price	7.60 USD
Price Objective	26.00 USD
Date Established	27-Feb-2024
Investment Opinion	C-1-9
52-Week Range	6.92 USD - 14.50 USD
Mrkt Val (mn) / Shares Out (mn)	362 USD / 47.6
Free Float	0%
Average Daily Value (mn)	NA
BofA Ticker / Exchange	GUTS / NAS
Bloomberg / Reuters	GUTS US / GUTS.OQ
ROE (2023E)	-20,777.2%
Net Dbt to Eqty (Dec-2022A)	-88.8%

GLP1: diabesity drug target
IND: investigational new drug
FDA: US Food and Drug Administration
HbA1c: blood sugar level
KOL: experts

Refer to important disclosures on page 22 to 24. Analyst Certification on page 20. Price Objective Basis/Risk on page 20.
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Timestamp: 27 February 2024 06:00AM EST

iQprofile℠ Fractyl Health

iQmethod℠ **– Bus Performance***

(US$ Millions)	2021	2022A	2023E	2024E	2025E
Return on Capital Employed	NA	NA	-85.6%	-206.6%	-84.3%
Return on Equity	NA	-363.5%	-20,777.2%	NM	-189.8%
Operating Margin	NA	NA	-44,513.3%	NA	-1,107.9%
Free Cash Flow	NA	(46)	(46)	(101)	(129)

iQmethod℠ **– Quality of Earnings***

(US$ Millions)	2021	2022A	2023E	2024E	2025E
Cash Realization Ratio	NA	NM	NM	NM	NM
Asset Replacement Ratio	NA	NA	NA	1.4x	1.4x
Tax Rate	NA	NM	24.0%	NM	NM
Net Debt-to-Equity Ratio	NA	-88.8%	NM	NM	-108.8%
Interest Cover	NA	NA	NA	-19.5x	-27.2x

Income Statement Data (Dec)

(US$ Millions)	2021	2022A	2023E	2024E	2025E
Sales	NA	0	0	0	10
% Change	NA	NA	NA	-100.0%	NA
Gross Profit	NA	0	0	0	8
% Change	NA	NA	NA	NA	NA
EBITDA	NA	(49)	(50)	(77)	(108)
% Change	NA	NA	-1.9%	-53.7%	-39.9%
Net Interest & Other Income	NA	3	(21)	(20)	(19)
Net Income (Adjusted)	**NA**	**(64)**	**(69)**	**(113)**	**(143)**
% Change	**NA**	**NA**	**-8.7%**	**-63.3%**	**-26.4%**

Free Cash Flow Data (Dec)

(US$ Millions)	2021	2022A	2023E	2024E	2025E
Net Income from Cont Operations (GAAP)	NA	(46)	(54)	(98)	(128)
Depreciation & Amortization	NA	0	0	1	1
Change in Working Capital	NA	(1)	1	5	3
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	NA	1	8	(7)	(3)
Capital Expenditure	NA	0	(1)	(1)	(1)
Free Cash Flow	**NA**	**-46**	**-46**	**-101**	**-129**
% Change	**NA**	**NA**	**0.4%**	**-118.8%**	**-27.7%**
Share / Issue Repurchase	NA	0	0	100	350
Cost of Dividends Paid	NA	0	0	0	0
Change in Debt	NA	4	28	0	(55)

Balance Sheet Data (Dec)

(US$ Millions)	2021	2022A	2023E	2024E	2025E
Cash & Equivalents	NA	49	30	34	201
Trade Receivables	NA	0	0	0	2
Other Current Assets	NA	2	2	2	3
Property, Plant & Equipment	NA	0	0	1	1
Other Non-Current Assets	NA	9	10	10	10
Total Assets	**NA**	**61**	**42**	**46**	**216**
Short-Term Debt	NA	0	0	0	0
Other Current Liabilities	NA	7	8	12	18
Long-Term Debt	NA	18	55	55	0
Other Non-Current Liabilities	NA	0	13	13	13
Total Liabilities	**NA**	**26**	**77**	**80**	**31**
Total Equity	**NA**	**35**	**(34)**	**(34)**	**185**
Total Equity & Liabilities	**NA**	**61**	**42**	**46**	**216**

* For full definitions of *iQ*method℠ measures, see page 21.

Company Sector

Biotechnology

Company Description

Fractyl (GUTS) is a clinical stage medtech/biotech company that develops novel approaches to treat type 2 diabetes (T2D) and obesity. GUTS was founded in 2010 and its IPO was in Feb 2024. Lead asset is Revita, an endoscopic device that ablates the duodenal surface with the aim to remove hyperplasia and improve glycemic control. Second asset Rejuva is a GLP1 gene therapy aimed at long-term remission of T2D and obesity. GUTS has royalty-free economics on both Revita and Rejuva.

Investment Rationale

We rate GUTS a Buy for actionable catalysts with upside potential in 2024-25, including pivotal data of Revita that can support approval in multi-billion T2D market. Rejuva (GLP1 gene therapy) is early in development but the program has large upside potential.

Stock Data

Average Daily Volume	NA

Quarterly Earnings Estimates

	2022	2023
Q1	NA	NA
Q2	NA	NA
Q3	NA	NA
Q4	NA	NA

Contents

Executive summary

Fractyl Health is a clinical stage healthcare company focused on developing novel approaches to treat type 2 diabetes (T2D) and obesity. The company was founded in 2010 and its IPO was in February 2024. Lead asset is Revita, an endoscopic device that ablates the duodenal surface with the aim to remove hyperplasia (thickened mucosa) believed to be the byproduct of a life-long high sucrose/fat diet. Mechanistically, the resurfaced mucosa (post Revita) is hypothesized to correct the physiologic nutrient sensing and gut metabolic signaling needed for proper glucose control. Revita is in pivotal-stage evaluating the procedure's impact on glucose control in insulin-dependent diabetics (advanced stage) T2D; trial enrollment is expected to complete in 1H24 followed by topline readout by YE24. Fractyl also plans to advance Revita into a two-part, potentially registrational trial for weight maintenance (obesity) following discontinuation of a GLP1 therapy. Fractyl's second asset Rejuva is a pancreatic selective GLP1 gene therapy aimed at long-term remission of T2D and obesity. The company plans to complete IND-enabling studies Rejuva candidate for T2D (RJVA-001) in 2H24, followed by 1H25 initiation of first-in-human study. GUTS has royalty-free economics on both Revita and Rejuva (wholly-owned programs).

The exact mechanism wherein Revita alters gut-brain signaling to drive a therapeutic benefit is not entirely understood, but the approach looks to leverage a) the known benefits of bariatric surgery on glycemic control and weight loss – gastric bypass is a surgical procedure that connects the upper portion of the stomach to the small intestine, thereby bypassing the rest of the stomach and the dysfunction duodenum; and b) Fractyl's own collection of Ph2 datasets for Revita which have shown 0.5 – 1% reduction in HbA1c, 2-4% of weight loss, and/or reduction/elimination of insulin use in 30-60% of patients over a 6-month period or longer. If Revita is successful in development, the potential value-proposition would be a quick (45-min) non-invasive procedure that could replace insulin (for some patients) and/or offer added therapeutic benefit for patients whose pancreas is "burned out" and are struggling to find effective treatment options, including patients who have stepped through multiple anti-diabetic drugs (eg GLP1). Commercially, the US market for insulin has compressed by ~35% over the last 5 years due to broader use of novel anti-diabetic agents (e.g. GLP1 class of drugs) making the weight maintenance study Revita's larger peak sales opportunity.

Fractyl expects pro forma cash inclusive of IPO proceeds (~$130m) will be sufficient to fund operations through Dec 2025. We believe Revita could be commercially available in the US by 2026 and breakthrough device designation of Revita may facilitate CMS (Center of Medicare and Medicaid) reimbursement within 6 months of FDA approval if not sooner around the time of launch. Revita components and subassemblies are to be produced by contract manufacturers and final device assembly and device testing is to be conducted at Fractyl's headquarters in Lexington, MA. If Revita is approved for its lead indication in insulin-dependent T2D patients, the initial strategy would be to place consoles in the leading US academic centers. Barriers to Revita market entry include: 1) diabetologists/endocrinologists would need to refer patients to an endoscopist, 2) endoscopist would need to have an available console and willingness to perform the procedure, and 3) reimbursement – we assume Revita's secondary endpoints around insulin-sparing and/or insulin elimination will strengthen Fractyl's case for pricing.

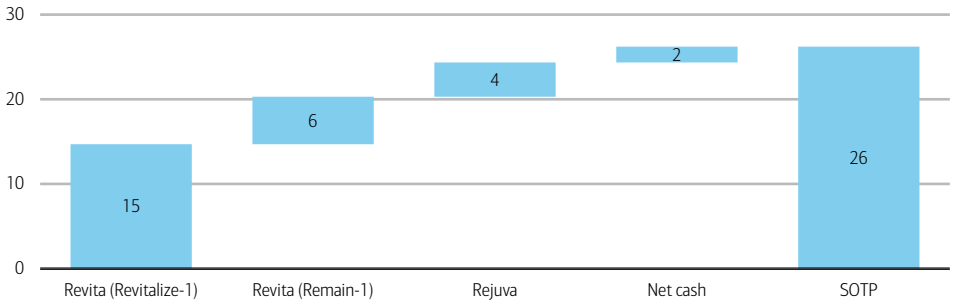
Valuation: $26/shr, primarily Revita-driven

Our $26 per share price objective (PO) is based on a risk-adjusted, SOTP (sum-of-the-parts) DCF. Exhibit 1 illustrates our value assignment for the key segments: 1) Revita for insulin-dependent T2D, 2) Revita for maintenance of weight loss post-GLP1, 3) Rejuva for remission of T2D.

SOTP DCF analysis

We assume: (1) a discount rate of 11% for a clinical stage biopharma with lead asset in late-stage development; (2) likelihood of success (POS) of 55%/20% for Revita in insulin-dependent T2D / maintenance of weight loss post-GLP1; (3) POS of 5% for Rejuva for remission of T2D; and (4) DCF analysis through 2038E and -20% in terminal growth rate, vs issued and expected patents expiring 2032-44 for Revita and 2042-2044 for Rejuva, excluding patent term adjustments.

Exhibit 1: Our SOTP analysis of GUTS
Revita is core value driver in our SOTP



Source: BofA Global Research estimates

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Investment positives: Revita/Rejuva targets significant end-markets

T2D and obesity are sizable end-market market opportunities

There are an estimated ~30m US patients diagnosed with type 2 diabetes (T2D) and an estimated over 100m obese US adults. While Fractyl would target a sub-segment of the overall TAM, we note lead indications in development are still significant under a wide range of scenarios. For example, with Revita's lead indication in insulin-dependent T2D, we estimate ~3m US patients are on insulin each year, which would translate into $1bn+ in peak sales opportunity for Revita even at mid-single digit penetration rate per year. Fractyl's follow-on programs (Revita for weight loss maintenance and Rejuva gene therapy for T2D) have higher ceilings based on disease prevalence.

Lead program Revita has been partially de-risked by prior clinical data + analogs

Fractyl has completed three prior clinical trials to evaluate the efficacy and safety of Revita DMR (duodenal mucosa resurfacing) procedure in T2D patients. Across data generated from prior trials/cohorts, Revita treatment led to 0.5 – 1% reduction in HbA1c (blood glucose level) over a 6-month period and 2-4% of weight loss in 6 months or longer. In trials/cohorts that enrolled insulin-dep patients, over 40% of patients were able to reduce insulin dose and 30-60% of patients were able to eliminate insulin use in 12 months. While the GLP1 class of drugs have shown numerically higher HbA1c reduction in T2D on cross-trial comparisons, we believe Revita's data can stand on its own given the lead indication is focused on late-stage T2D patients who are on insulin despite stepping through multiple anti-diabetic drugs (which may include GLP1). In obesity, Revita's impact on maintenance of weight loss following GLP1 discontinuation needs clinical confirmation in a randomized, controlled trial in obesity. Nonetheless, in general, we expect magnitude of weight loss to be more pronounced in obese patients than T2D based on weight loss results of high-dose semaglutide in T2D (6-10% nominal) vs in obesity (mid-teens % nominal).

Follow-on Rejuva (GLP1 gene therapy) has big upside potential, but early

Rejuva is a GLP1-based gene therapy program aimed at helping patients achieve remission of T2D or obesity as a one-time therapy. We believe the goal with Rejuva is more than simply an injection-sparing approach based on early animal data suggesting

that GLP1 modulation can be isolated to the pancreas, thereby driving the therapeutic aspects of GLP1 potentially without increasing GLP1 in systemic circulation (avoiding side effects), though this hypothesis needs clinical confirmation. At current trading levels, we believe company valuation implies the Street is ascribing heavily risk-adjusted value for Rejuva due to its early-stage/uncertainties (in preclinical stage). Nonetheless, Fractyl is on track to advance its first Rejuva candidate into a human clinical trial in 2025, assuming completion of preclinical studies in 2H24 and subsequent regulator approval of clinical trial initiation (e.g. IND [investigational new drug] or equivalent). We look to first-in-human data for initial safety and early signs of efficacy of Rejuva, and we see upside potential if Rejuva shows early promising data in 2025.

Investment risks: Revita requires paradigm shift + Rejuva is very early-stage

Clinical trials of Revita carry clinical risks due to caveats with prior clinical data

While Revita treatment led to positive impact on glucose control, insulin use, and weight loss, there were some confounding factors that complicate our analysis of the past datasets including: 1) most of the trials conducted did not have a sham control for head-to-head benchmarking Revita's effectiveness; 2) the adjunctive use of (add-on) anti-diabetic agents such as liraglutide (GLP1) and empagliflozin (SGLT2) in two single-arm studies further complicate our analysis of the Revita datasets. In the only sham-controlled study which enrolled T2D patients on a steady regimen of oral anti-diabetic medications, Revita led to more modest 0.3% placebo-adjusted reduction in HbA1c in the overall population, but the sham-adjusted effect is modestly higher at 0.5% if the analysis is narrowed to the per protocol EU population, excluding study sites in Brazil where protocol deviations around glucose monitoring and management. In the Ph3 Revitalize-1 study, we believe a sham-adjusted HbA1c improvement of 0.5% would be clinically meaningful based on KOL feedback vs 0.3% bar for FDA approval consideration, and the commercial use-case would be bolstered by solid secondary endpoints around insulin consumption. We model 55%/20% POS for Revita in insulin-dependent T2D/obesity reflecting the above risk factors.

Expansion of GLP1s may reduce lead opportunity in insulin-dependent T2D

The GLP1 class of drugs have become the standard of care in early line T2D and the class was more recently approved for treatment of obesity. The broader and earlier use of GLP1 drugs in obesity, prediabetic, and early T2D patients could slow or halt patients' progression into late stage T2D and reduce the addressable market of insulin-dependent T2D population. That said, Fractyl is pursuing follow-on indications that would be complementary to the increasing penetration of GLP1 drugs in US population: 1) Remain-1 trial, which evaluates Revita in helping patients maintain weight loss after patients discontinue their GLP1 therapy, 2) Rejuva, a one-time, GLP1-based gene therapy for remission of T2D/obesity.

Revita utilization at scale requires a paradigm shift

Endocrinologists manage and treat T2D patients and are accustomed to prescribing pharmaceutical agents including GLP1 drugs to T2D patients. For Revita to be commercially successful, an endocrinologist would need to refer an eligible T2D patient to a qualified gastroenterologist / endoscopist to perform the DMR procedure. Based on our KOL checks, Revita would likely require an advanced endoscopist to handle given complexity of the procedure. Revita will likely see initial adoption in large US academic centers which can facilitate cross-department physician referral and likely have advanced endoscopist(s) in-house. Lastly, while bariatric surgery represents an analog for device-alternative to T2D/obesity management, it was introduced decades ago prior to GLP1 becoming standard of care in T2D/obesity; furthermore, bariatric surgery in rare instances can result in significant complication (eg stomach leakage and inflammation) which has likely dampened usage.

Catalysts: Pivotal Revitalize-1 + initial Rejuva GT safety

We expect the pivotal topline results of Revitalize-1 in insulin-dependent T2D to be the biggest catalyst for Fractyl this year, as positive trial results could support US approval of Revita in insulin-dependent T2D. Fractyl indicated the FDA's regulatory bar is sham-adjusted 0.3% reduction in HbA1c reduction for the approvability in Revita. Our KOL checks suggest sham-adjusted 0.5% HbA1c lowering would be clinically meaningful, and the commercial use-case would be bolstered by solid secondary endpoints around insulin consumption. Beyond Revitalize-1, we look to 2H24E initiation of a new clinical trial called Remain-1 which will evaluate Revita in obesity, for maintenance of weight loss post-GLP1 discontinuation. We assume initial open-label data (Reveal-1 cohort) in 2025E assuming 6-month study evaluation on HbA1c reduction.

On Rejuva GT (gene therapy), we expect progression into a first-in-human trial will boost investor visibility to the program. We believe initial clinical data starting 2025E would first offer safety de-risking in human followed by an initial read on efficacy signals.

Exhibit 2: GUTS catalyst tracker
We summarize GUTS catalyst path in 2024-25

Pipeline		
Program	Event	Timing
Revita	Pivotal topline data of Revitalize-1 in insulin-dependent T2D	4Q24E
Revita	Initiation of open-label Reveal-1 trial in obesity	2H24E
Revita	Open-label Reveal-1 data in obesity	2025E
Rejuva	Completion of IND-enabling studies or equivalent in T2D	2H24E
Rejuva	Initial Ph1 data in T2D	2025E
Corporate, regulatory		
Drug or type of event	Event	Timing
Revita	Submission of IDE in obesity (Reveal-1 / Remain-1)	1H24E
Rejuva	Submission of IND-equivalent ex-US	2H24E
Revita	FDA approval and commercial launch in insulin-dependent T2D	Late 2025E / 1H26E

Source: company filing, BofA Global Research estimates

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Revita: multiple applications in T2D and obesity

Revita is an endoscopic device that ablates the patient's duodenal surface to improve gut metabolic signaling, with an aim to help patients lower blood glucose and lose weight. Fractyl has completed three clinical trials that evaluated the efficacy and safety of Revita in T2D, which showed positive impact on glucose lowering as well as reduction in insulin dose and/or insulin sparing. These data were leveraged to help inform the advancement of Revita into an ongoing pivotal trial in insulin-dependent T2D, with enrollment completion expected in 1H24 (topline by YE24). Based on post-hoc analyses of prior trials which suggest weight loss impact of Revita, Fractyl is planning a separate clinical trial to evaluate Revita in maintenance of weight loss for obese patients who have achieved initial weight loss with a GLP1 drug but want to discontinue their GLP1 treatment. Fractyl plans to file an IDE (Investigational Device Exemption) for the obesity trial in 1Q24 and would initiate the obesity trial in 2H24. We assume 55%/20% POS for Revita in insulin-dependent T2D/obesity and $1.5bn/$2bn nominal peak sales in those respective settings; our POS assumption is higher in T2D vs. obesity given prior clinical data were limited to T2D.

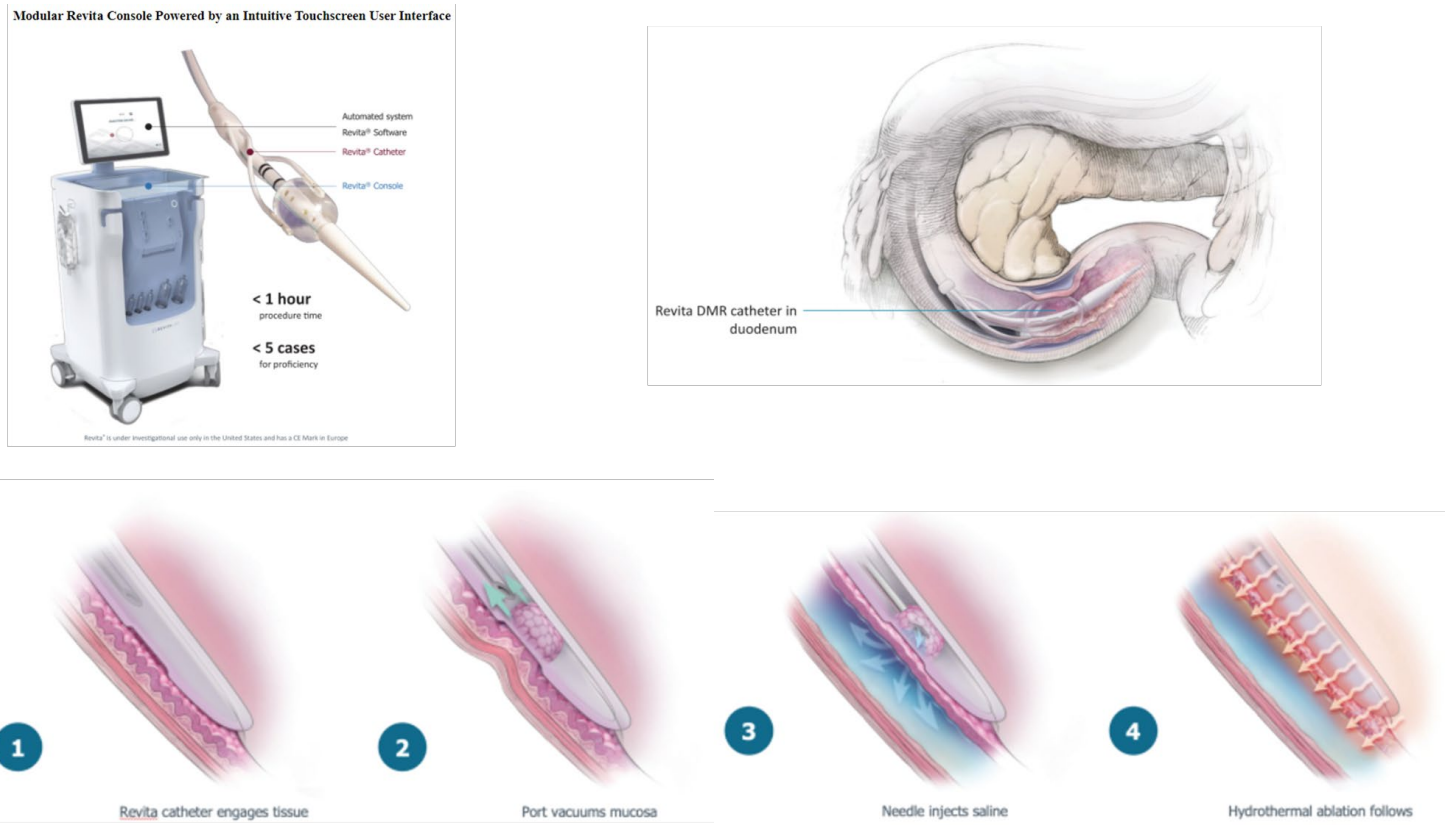
Revita is a quick, non-invasive outpatient endoscopic procedure

Revita duodenal mucosa resurfacing (DMR) is a minimally invasive, <1-hour endoscopic procedure performed by a GI (gastro) physician skilled at routinely performing endoscopy in an outpatient setting. Patients can go home after 60-90minutes in a recovery room and resume routine activities the day after the procedure. Patients then follow a liquid diet, and they can resume normal foods 1-week after the procedure. Per KOLs, commonly performed endoscopy procedures involve at least a few days of post-procedural diet modification.

The Revita device consists of a console that operates the endoscopic device and a catheter that ablates the duodenal surface. The console offers imaging guidance and progress of the procedure for the physician and is designed to monitor temperature, pressure and location to reduce risk of physician error and improve safety of the procedure. During the procedure, the catheter is inserted through the mouth, past the stomach, and into the duodenum. The ablation steps involve 1) establishing a connection between the catheter and the duodenum mucosa, 2) delivering saline to lift the mucosal surface and create a thermal barrier between the mucosa and the inner (muscular) layer to avoid unintended thermal injury, 3) apply heat to ablate the lifted mucosa. These steps are repeated sequentially along the length of the duodenum.

Earlier iterations of Revita targeted a shorter length ablation at 3-9cm from the Ampulla of Vater to end of the duodenum, but the pivotal stage approach involves ablating longer length at 10-14 cm covering areas from the Ampulla of Vater to ligament of Treitz to have more areas of duodenum treated. In theory, the longer the treatment length, the higher the likelihood of improving efficacy, but also the greater the risk of thermal injury. On efficacy, Fractyl reported a dose response finding in an early study (Rajagopalan et al. Diabetes Care 2016) in which longer ablation (~9cm) led to ~2x more potent HbA1c lowering than shorter ablation (~3cm). On safety, Fractyl noted submucosal lift that precedes each ablation serves as a mitigation strategy to risk of thermal injury. Importantly, Fractyl has not seen any dose (length)-related increased incidence of adverse events and Revita has not reached a maximum tolerated dose (length).

Exhibit 3: Illustration of Revita device and procedure
Revita is an endoscopic device that ablates the duodenal surface for the treatment of T2D and obesity



Source: company filing at SEC.gov

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Mechanism of action: gastric bypass offers indirect analog

The duodenal mucosa (surface) is thought to control metabolic response to food intake in human, and chronic exposure to high-fat/high-sugar diets is thought to drive hyperplasia (thickening) of the duodenal mucosa and disrupt physiologic nutrient sensing and gut metabolic signaling, subsequently leading to poor glucose control. Fractyl believes ablating the duodenal mucosa could improve gut metabolism and glucose control. Mechanistically, gastric bypass (bypassing part of stomach and duodenum) is an (indirect) analog that suggests duodenal resurfacing may help patients improve glucose control and lose weight. Duodenal mucosa resurfacing could offer patients a non-invasive alternative to gastric bypass to achieve glucose control and weight loss.

Pivotal data by YE24 for lead indication targeting insulin-sparing

Fractyl is in a pivotal trial (Revitalize-1) evaluating Revita for glucose control and insulin sparing in inadequately controlled T2D patients who are on insulin (20-100 units per day) and up to three anti-diabetic agents. The pivotal trial is expected to randomize 320 patients 1:1 onto Revita or sham. The primary endpoint is the change from baseline in HbA1c (blood sugar level) at 24 weeks. The study is >90% powered for detecting a 0.5% treatment difference in HbA1c. Per Fractyl, the FDA has stated the minimum clinical difference in HbA1c for approvability of Revita is 0.3%. Key secondary endpoints include % patients achieving HbA1c of no higher than 7%, % change from baseline in insulin dose, % patients without the need of insulin, and weight loss. Based on correspondence with the FDA, Fractyl believes successful Revitalize-1 results can support PMA

(Premarket Approval; expected to file 1H25). As part of the PMA, Fractyl plans to submit the 24-week primary endpoint data (supporting a finding of effectiveness) and additional follow-up data through 48 weeks.

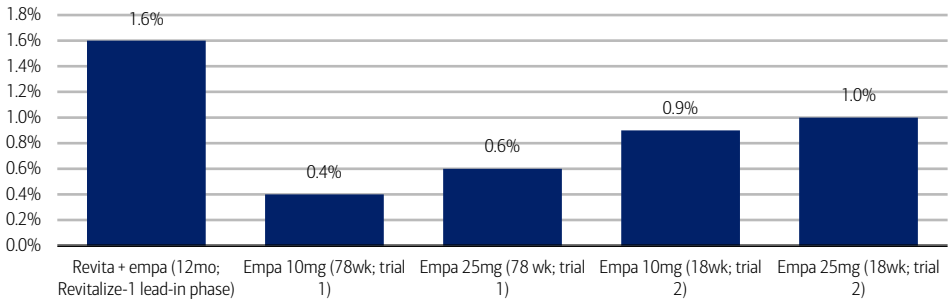
Prior data suggest impact on A1c/insulin use, though trial designs have caveats

Fractyl has previously evaluated Revita in T2D patients in three clinical trials (Exhibit 5; Revita-1, Revita-2, Inspire). In addition, Fractyl tested Revita in a small, open-label, lead-in phase of Revitalize-1 prior to conducting the ongoing randomized portion of the pivotal study. Across data generated from these trials and cohorts, Revita treatment led to 0.5 – 1% reduction in HbA1c over a 6-month period and 0.2 - 1.6% over a 12-month period and 2-4% of weight loss in 6 months or longer. In trials/cohorts that enrolled patients dependent on insulin, over 40% of patients were able to reduce insulin dose and 30-60% of patients were able to eliminate insulin use in 12 months.

Importantly, in the open-label phase that precedes the ongoing pivotal Revitalize-1 trial, Revita + empagliflozin (SGLT2) led to 1.6% reduction in HbA1c. While the sample size was small (n=7) and use of empagliflozin may have contributed to HbA1c lowering, we are encouraged to see that the magnitude of improvement compares favorably to HbA1c reduction reported for empagliflozin alone in insulin-dependent T2D trials (0.4-0.7%) on cross-trial comparisons. In the randomized, registrational portion of Revitalize-1, Revita (alone) is compared to a sham control for reduction in HbA1c.

Exhibit 4: Cross-trial comparisons of HbA1c lowering data in insulin-dependent T2D

Revita + empa led to higher HbA1c reduction than empa along on cross-trial comparisons



Source: company filing, Jardiance package insert

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While Revita treatment led to positive impact on glucose control, insulin use, and weight loss, there were confounding factors (variability in data and trial designs) that complicate our analysis of the datasets. Most of the trials conducted did not have a sham control for comparison. Further complicating the results from the single-arm studies were adjunctive use of (add-on) anti-diabetic agents such as liraglutide (GLP1) and empagliflozin (SGLT2) in Inspire and lead-in portion of Revitalize-1. In the only sham-controlled study which enrolled T2D patients on a steady regimen of oral anti-diabetic medications (Revita-2; Revita vs Sham), Revita led to modest 0.3% placebo-adjusted reduction in HbA1c in overall population, but the sham-adjusted effect is modestly higher at 0.5% if the analysis is narrowed to the per protocol EU population, excluding study sites in Brazil where “implausible large improvements” in glucose control across Revita and sham arm could be linked to variability in medication uses and more intensive glucose monitoring and nutritional guidance vs EU sites.

Exhibit 5: Clinical trial data of Revita in T2D
Trial subjects achieved blood glucose lowering and insulin reduction after REVITA treatment, though datapoints were confounded by lack of sham control, protocol violation (REVITA-2, Brazil), and/or use of adjunct glucose lowering medications

	REVITA-1	REVITA-2	INSPIRE	US pilot study	REVITALIZE-1
Study (N)	Single-arm open-label, multicenter (EU) (n=34 per protocol [PP])	Randomized, sham-controlled, multicenter (EU n=75, Brazil n=33)	Single-arm open-label, single-center (Netherlands) (n=16)	Randomized, sham-controlled study (US n=3)	Open-label training phase of pivotal study (US n=9)
Treatment	Revita	Revita vs sham	Revita + GLP1 (liraglutide)	Revita vs sham	Revita + SGLT2 (empagliflozin)
Screening criteria	HbA1c 7.5% –10%, BMI: 28-40 kg/m2 Oral anti-diabetic (OAD) ≥ 1 Glucose-lowering medication kept stable for ≥ 6 months post-Revita	HbA1c 7.5% –10%, BMI: 28-40 kg/m2, OAD and/or metformin (no change in medications in 12 weeks prior to study entry)	HbA1c ≤8%, BMI: 28-40 kg/m2, Long-acting insulin	HbA1c 7.5% –9.5%, BMI: 28-40 kg/m2, 1-2 OADs + metformin (no change in medications in 12 weeks prior to study entry)	HbA1c 7.5% –9.5%, BMI: 28-40 kg/m2, Insulin (20-60 U/day) + 2 additional glucose-lowering agents
HbA1c (blood glucose) reduction	0.9% in 6 months (n=34 per protocol [PP]) 1% in 12 months (PP)	1.0% Revita vs 0.7% sham in 6 months (overall n=108) 0.6% Revita vs 0.3% sham in 6 months (EU mITT n=71) 0.8% Revita vs 0.3% sham in 6 months (EU PP n=64)	0.5% at 6mo 0.2% at 12mo 0.4% at 18mo	0.33% Revita vs 0.7% sham in 6 months (n=3), very small sample size as study ended early due to COVID19	1.6% in 12 months (n=7)
Weight loss	2.3% or 2kg in 6 months (PP) 3.5% or 3.1kg in 24 months (PP)	2.4kg Revita vs 1.4kg sham in 6 months (EU mITT n=72) 2.5kg Revita vs 1.4kg sham in 6 months (EU PP n=69)	8% or 7kg in 12 months, 8% or 7kg in 18 months	---	---
% patients eliminated insulin use	Not applicable	Not applicable	69% at 6mo (n=16), 56% at 12mo (n=16), 53% at 18mo (n=15)	---	29% in 12 months (n=7)
% patients reduced insulin daily dose	Not applicable	Not applicable	---	---	44% in 12 months (n=7)

Source: company filings, medical meeting presentations

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Revita procedure has good trial safety data after device modification

Revita procedure generally appears safe in the hands of trained trial investigators using the latest version of the Revita device. With the first iteration of the Revita device which requires two catheters for a procedure, there were three cases of stenosis reported in initial trial experience. The issue was linked to the time gap between lifting the duodenum surface with the first catheter and tissue ablation with the second. In 2016, Fractyl updated the device to a single-catheter system and had not observed a single case of stenosis since the modification (>200 procedures). Beyond that, only procedure-related serious adverse events (SAEs) were reported in the Brazil cohort of Revita trial, which was attributable to a training problem with an inexperienced surgeon. Since then, there was no procedure-related SAEs reported in clinical trials.

Exhibit 6: Clinical safety data of Revita
Revita procedure appears generally safe based on more recent clinical trial results

	REVITA-1	REVITA-2	INSPIRE	REVITALIZE-1 (lead-in)
Safety				
n	46	39 DMR vs 37 sham (EU) 17 DMR vs 16 sham (Brazil)	16	9
Device/procedure related AE	3 events reported in 1 subject	33% vs 27% (EU)	Data not reported	2 (22%)
GI disorders	---	28% vs 22% (EU)	---	---
Abdominal pain	Reported in 1 subject	18% vs 5% (EU)	---	1 (11%)
Diarrhea	---	3% vs 5% (EU)	---	1 (11%)
Nausea	Reported in 1 subject	3% vs 0% (EU)	---	0
Vomiting	---	3% vs 0% (EU)	---	0
Device related SAE	0%	0%	---	0%
Procedure related SAE	1: elevated body temp, increased c-reactive protein	12% DRM-arm in Brazil cohort	---	0%

Exhibit 6: Clinical safety data of Revita
Revita procedure appears generally safe based on more recent clinical trial results

	REVITA-1	REVITA-2	INSPIRE	REVITALIZE-1 (lead-in)
Other SAE unrelated to device/procedure	9 events in 6 patients	---	---	3 (33%): Covid-19, hypertension, euglycemic ketoacidosis

Source: company filing

BofA GLOBAL RESEARCH

KOL feedback: 0.5%+ lowering in HbA1c, reduction in insulin requirement

Our KOL checks suggest the commercial bar for Revitalize-1 data in insulin-dependent type-2 diabetes as following:

- **0.5%+ reduction in HbA1c, sham-adjusted**: while in clinical trials the GLP1-class of drugs (standard of care) has shown 1-2% placebo-adjusted lowering in HbA1c in insulin-dependent T2D, our KOL checks indicate 0.5%+ lowering in HbA1c (sham-adjusted) could help commercial adoption of Revita for a couple of reasons, given the revitalize-1 study population is difficult to treat (insulin-dependent T2D receiving up to 3 background anti-diabetic agents) and the likely target commercial market for Revita is insulin dependent despite being treated with multiple anti-diabetic agents (which may include GLP1).

- **Reduction in insulin use would be a plus**: while reduction in insulin use is a secondary endpoint, KOLs we spoke with see value from Revita if it can help patients reduce insulin dependency. KOL opinions are somewhat diverse on this topic, with some satisfied with reductions in mean insulin dose while others wanting to see elimination of insulin use in one-third of patients and/or ~50% reduction in insulin dose.

- **Procedure safety**: our KOL checks suggest <5% perforation / hospitalization rate post-procedure would be acceptable.

Follow-on obesity program aims to provide 'off-ramp' for GLP1 therapy

Beyond insulin-dependent T2D, Fractyl plans to evaluate Revita DMR for maintenance of weight loss for obese patients who have achieved initial weight loss with a GLP1 drug and want to maintain the weight loss even without continuing with their GLP1 regimen. In terms of timing, Fractyl plans to submit an IDE (investigational device exemption) and IDE-equivalent to the FDA and ex-US regulators in 1Q24, followed by initiation of a new clinical trial in obesity in 2H24. The trial would consist of two parts in sequential order:

1. **Reveal-1**: an open-label, lead-in cohort which is to serve as a 'test run' for utilizing the Revita DMR procedure in patients with obesity in up to 100 patients, prior to initiation of the randomized portion of the trial, Remain-1. Fractyl plans to initiate the Reveal-1 cohort and begin reporting updates in 2H24.

2. **Remain-1**: a randomized, double-blind, sham-controlled cohort that is expected to enroll ~300 patients who have lost at least 10% total body weight on a GLP-1 class of drug (semaglutide or tirzepatide) and wish to discontinue their GLP1 therapy. The trial enrollees are expected to randomize 2:1 into Revita DMR (n~200) and sham control (n~100). The primary endpoint of the Remain-1 would be to assess the efficacy of Revita DMR on weight maintenance at 24 weeks after GLP1 discontinuation. We expect a 24-week duration to be sufficiently long for capturing a maintenance of weight loss benefit, given in a separate GLP1 withdrawal trial (STEP-1 extension study), patients regained around one-third to half of their weight

loss 6 months after discontinuing semaglutide. Fractyl's Remain-1 study is designed to be potentially registrational.

Revita DMR led to weight loss in T2D, though efficacy untested in obesity

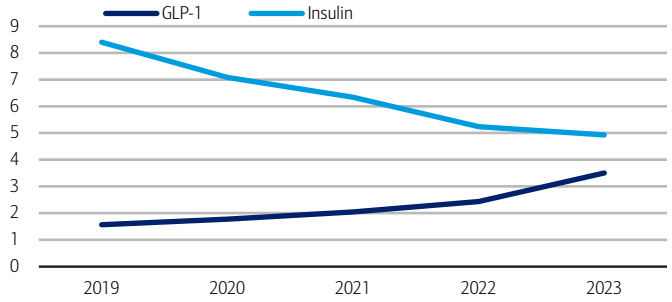
In a pooled (post-hoc) analysis of Fractyl's previously conducted studies in T2D, DMR led to 3.4% (n=100) in total body weight loss at 4 weeks in T2D on multiple anti-diabetic agents and sustained mean body weight loss of 4.0% (n=94) at 48 weeks. While the analysis point to positive impact Revita may have on weight loss, we note the data were post-hoc and not derived from a randomized, sham-controlled study. On the flip side, magnitude of weight loss via treatment intervention may be higher in obese patients than in T2D, based on clinical trial results of GLP1 drugs in both indications. For instance, high-dose semaglutide in T2D (6-10% nominal) vs in obesity (mid-teens % nominal). We look to Remain-1 results for validation of the effectiveness of Revita DMR in maintenance of weight loss in obesity.

Revita commercial: diabetes >$1bn + obesity large, heavily risk-adj peak

Lead diabetes indication remains large, despite drop in insulin use

Our KOL checks suggest the primary unmet need for Revita DMR would be in T2D patients who remain insulin dependent despite having tried multiple anti-diabetic drugs. As GLP1 class of anti-diabetic drugs become more broadly used in earlier lines of therapy, use of insulin has declined in the US from over 8m patients in 2019 to below 5m patients in 2023, by our estimates based on reported net drug sales (Exhibit 7). While declining insulin use could compress the market opportunity for Revita, we note downward trend of insulin use seems to be moderating in 2023 based on reported US net sales (Exhibit 7) and script data (Exhibit 8) of insulin. We estimate insulin use would decline to ~3.5m US patients in out years at steady state.

Exhibit 7: Estimated US patients (m) on T2D therapies
Insulin use compressed to below est. 5m patients as GLP1 use increases



Source: company filings

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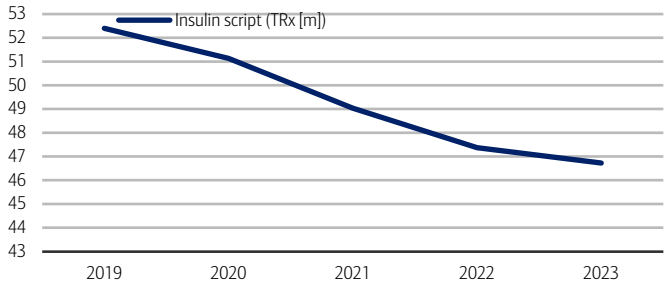
Exhibit 8: Insulin US script volume in recent years
Insulin scripts trended down over the years, though downward trend seems to be moderating



Source: IQVIA NPA 2019-2023

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Large market can accommodate multiple players

On competition, besides pharmaceutical agents such as GLP1 and SGLT2, there are other device competitors evaluating DMR procedures in T2D in clinical trials. Endogenex is evaluating an electric field ablation technology in 200+ patients in a sham-controlled trial, with data expected in 2026. Aqua Medical is conducting a small pilot open-label

trial evaluating a steam ablation technology in 30 patients in T2D, with expected 2H24E. We believe Revita DMR is well positioned to be first to market with meaningful lead time based on current timeline, and competitor programs help support DMR as a mechanism with therapeutic potential in T2D.

US insurance payer mix skews CMS in T2D

According to prior Lilly's disclosure (2020), the payer mix of the company's T2D business in the US consists of roughly 40% commercial, 20% Medicare Part D, 10% Medicaid, 15% other government / hospital, and remainder 15% in other segments including Medicare Part B, uninsured/cash pay. Conversely, reimbursement pathways for GLP1 drugs in obesity is in its early days, but Medicare currently does not cover obesity drugs and less than 20 States cover obesity drugs through Medicaid.

Revita involves a paradigm shift in how diabetes pts are managed

Our KOL checks suggest Revita could fit into current treatment algorithm if it can reduce/eliminate insulin usage in T2D or help obese patients maintain weight loss after discontinuation of a GLP1 therapy. While peak sales opportunities are sizable for Revita's lead indications, KOLs framed a few unknowns that may lead to a more gradual launch curve / ramp of Revita as physicians become accustomed to prescribing and performing Revita procedure to eligible patients.

- **Advanced endoscopists in large US academic centers may be early adopter**: endocrinologists specialize in managing and treating insulin-dependent T2D patients and would be the primary prescriber base for referring T2D patients to gastroenterologists / endoscopists for the Revita procedure. The multi-disciplinary nature of US centers enables seamless in-network referral from an endocrinologist to a gastroenterologist. Further, our KOL checks suggest advanced endoscopists would likely be early adopter of the DMR procedure. Fractyl estimates Revita can be a simple add-on procedure to 4.7 million endoscopies performed by ~10k gastroenterologists in the US, and that it would take less than 5 procedures for an endoscopist to become proficient at performing DMR with Revita. However, some endoscopist KOLs we spoke are more cautious on ramp in DMR learning curve.

- **Private practice buy-in TBD without defined / favorable reimbursement coding structure**: given Revita has not been approved by the FDA nor commercialized in US market, there is no reimbursement code for us to gauge patient access and likelihood of adoption by physician networks. Without favorable billing code that helps cover overhead cost (e.g. cost of device, facility fee, etc), financial incentive may sway private practice to other procedures that have more favorable reimbursement revenue stream. By comparison, physicians in US centers are not exposed to differential financial incentive between different procedures. We estimate a procedure with a strong, data-driven value proposition could help establish favorable reimbursement coding within 6 months of FDA approval if not earlier around the time of launch. Under the proposed TCET (Transitional Coverage for Emerging Technologies) rule for device with Breakthrough Device Designation (BDD), the CMS aims at finalizing national coverage determination (NCD) within 6 months of approval. Without TCET consideration, it generally takes 6-12 months for a new procedure to secure reimbursement post approval and potentially faster for device with BDD (eg Revita).

Obesity TAM is substantial + chronic GLP1 suboptimal; Revita profile TBD

Demand for GLP1 drugs in obesity is high given their effectiveness at helping patients lose weights. In clinical trials, semaglutide or tirzepatide led to 15-20%+ nominal weight loss (or 10-20% placebo adjusted) in over a year (68-72 weeks). Nonetheless, patients may choose to discontinue their GLP1 therapy, e.g. unable to tolerate drug-related adverse events (eg nausea, diarrhea), desire to stop taking a drug chronically, or reimbursement/cost issues. KOLs we spoke with see value in Revita DMR if the procedure can help patients maintain weight loss after GLP1 discontinuation.

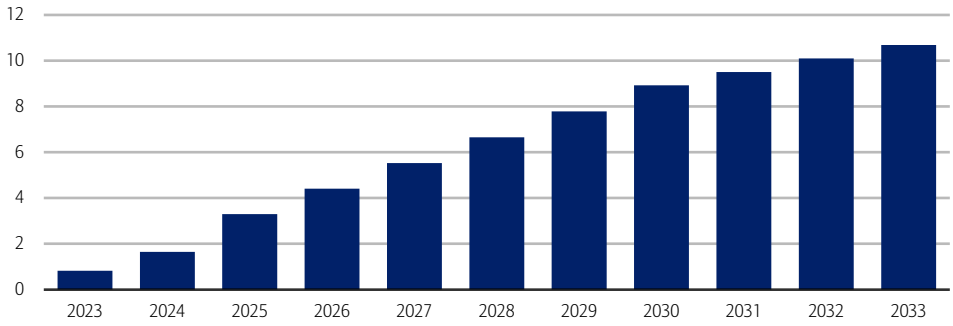
Obesity is a large market; estimated ~100m US adult are obese

The CDC (centers for disease control and prevention) estimates ~42% of the adult population or ~110m adults are obese in the US. GLP1 drugs approved for obesity (Wegovy and Zepbound) are annualizing at ~$5.7bn in US net sale which would imply a penetration rate of 1% (or ~1m patients). That said, the demand for GLP1 in obesity is likely understated, considering T2D-indicated GLP1 drugs are prescribed off-label for obesity and broader GLP1 class of drugs are in supply constraints. We estimate a peak GLP1 penetration of ~10% which would imply a ~11m theoretical addressable market population for Revita DMR in maintenance of weight loss in a post-GLP1 setting.

Segmentation of addressable market may evolve over time

According to patient-claims data in T2D and obesity, studies have reported around half to two-third of patients discontinuing their GLP1 therapy after one year (for any reason). Reasons for discontinuations were not documented in these studies. Per our KOL checks, those published results could have likely overstated the patients' desire to discontinue their GLP1 therapy citing supply constraints. Nonetheless, the KOLs framed unmet need in ~20% of patients who cannot tolerate GLP1 therapy (2-2.5m US patients). Importantly, the KOLs sees value in Revita DMR in obesity if the procedure can help patients maintain weight loss after GLP1 discontinuation.

Exhibit 9: Our estimates of obese adults on a GLP1 therapy (m)
We est. GLP1 penetration could exceed 10m patients per year, offering Revita a large addressable market in maintenance of weight loss



Source: BofA Global Research estimates

BofA GLOBAL RESEARCH

Market models: focus on T2D and obesity indications

Revita for insulin-dependent T2D

We forecast $1.2bn in nominal peak US sales and assume 55% likelihood of success (POS) for Revita's lead indication in insulin-dependent T2D. Key assumptions:

- **3-4m of insulin-dependent T2D patients**: due to compression in insulin usage as discussed above, we expect the number of US patients on insulin to decline from est. ~5m currently to ~4m during initial launch phase of Revita in 2026E+ before

moderating to ~3.5m at steady state around 2030. Of those, we assume 75% of patients (or 2.5-3m total) will be eligible for Revita based on enrollment criteria for Revitalize-1.

- **20% cumulative penetration rate at peak**: we model a gradual uptake of Revita DMR from low single digit in penetration at early launch to 5% a year at peak by 2034. Our assumption on ramp curve is directionally based on KOL feedbacks which suggest the multi-disciplinary nature of physician involvement and complexity of DMR procedure may limit initial adoption to advanced endoscopists within large US academic centers. Durability of DMR procedure has not been established clinically, but we tentatively assume one-time treatment for majority of patients and 30% will be re-treated in 5 years. Collectively, our assumptions imply ~20% of the 2.5-3m eligible insulin-dependent patients will be exposed to Revita DMR at least once in their lifetime by 2037.

- **$10k cost per procedure**: we assume $10k per DMR procedure which would put DMR toward the low end of $10-30k cost range for bariatric surgery and similar to net cost of two-year worth of GLP1 medications. We model $90k cost for each Revita device, though we expect vast majority of revenue stream (>95%) to be coming from the procedure (consumable) as opposed to the device.

- **55% POS risk-adjustment**: our POS assumption falls on the lower end of 50-70% POS we typically assign for a pivotal-stage asset, as we factor in imperfect Ph2 data given the lack of a sham control and confounding factor with background medication.

Revita for maintenance of weight loss in obesity

We forecast $2bn in nominal peak US sales and assume 20% POS for Revita in obesity. We model 110m obese adult population in the US based on CDC estimates and assume 10% penetration rate for GLP1 at peak in obesity, which translate into 10-11m addressable obese patients for Revita in maintenance of weight loss setting. Of those patients, we conservatively assume 1% penetration per year for Revita at peak, pending clarity of Revita's effectiveness at maintaining weight loss post-GLP1 discontinuation based on results from the Remain-1 trial. Given large addressable patient population, 1% penetration per year still translates into $1-2bn in nominal sales in the out years. We assume same procedure cost for both T2D and obesity settings.

Rejuva: one-time GLP1 gene therapy for remission of T2D/obesity

Rejuva is a preclinical-stage, GLP1-based gene therapy program aimed at helping patients achieve remission of T2D or obesity as a one-time therapy. Fractyl expects to complete IND (investigational new drug)-enabling or equivalent studies for its lead candidate RJVA-001 in 2H24, followed by initiation of a first-in-human clinical study ex-US in 1H25. Development risks are consistent with early-stage gene therapies and we believe initial 2025-26 human safety data plus demonstration of improvement GLP1-related efficacy measures (HbA1c and weight) will be highly informative of go/no-go decision making. Until we see human data, we heavily risk-adjust Rejuva and model a 5% POS supported by preclinical work to offer initial validation for the approach.

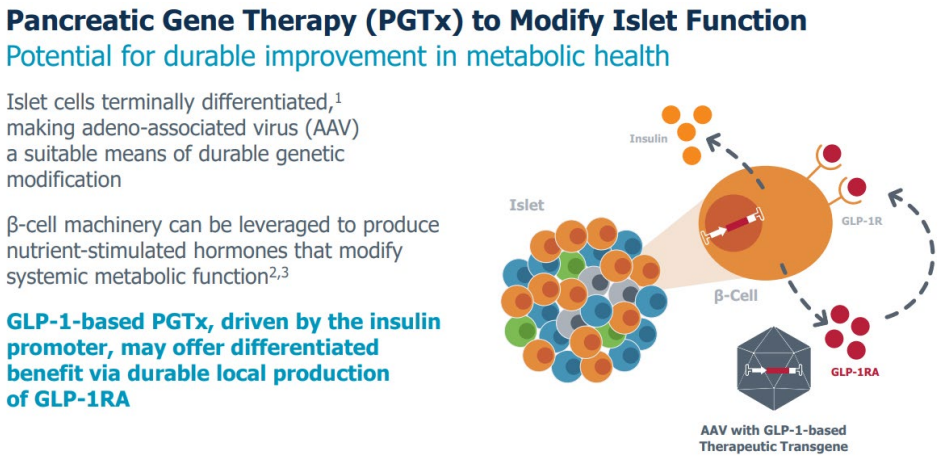
Local delivery to pancreas to rejuvenate endocrine system

Rejuva gene therapy is to be injected locally the patient's pancreas under guidance of the Revita-based endoscope. The first Rejuva candidate RJVA-001 contains an AAV9 (adeno-associated viral) vector carrying a full-length human GLP-1 gene under the control of the insulin promoter. Pancreas houses a cluster of hormone-producing islet cells that play an important role in endocrine function and glucose metabolism. In

obesity or prediabetic patients, metabolic dysfunction can lead to progressive islet (beta) cell dysfunction, impaired insulin production and secretion, and subsequent development of T2D. The GLP1 gene therapy is intended to restore islet beta-cell health and rejuvenate the body's natural ability to produce insulin. Fractyl believes Rejuva may have advantages over current GLP1-based therapy:

- **One-time therapy**: Rejuva is designed to be a one-and-done approach to help patients achieve remission of T2D/obesity without being on a GLP1 drug life-long.
- **Improved tolerability**: local administration of GLP1 to the site of action (pancreas) could limit systemic exposure of GLP1 and in turn may reduce GI (gastro)-related adverse events which are primary drivers for patients' intolerance to current systemic GLP1 drugs on market.

Exhibit 10: Mechanistic illustration of Rejuva GLP1 gene therapy
Local delivery of Rejuva can lead to selectivity exposure in the pancreas



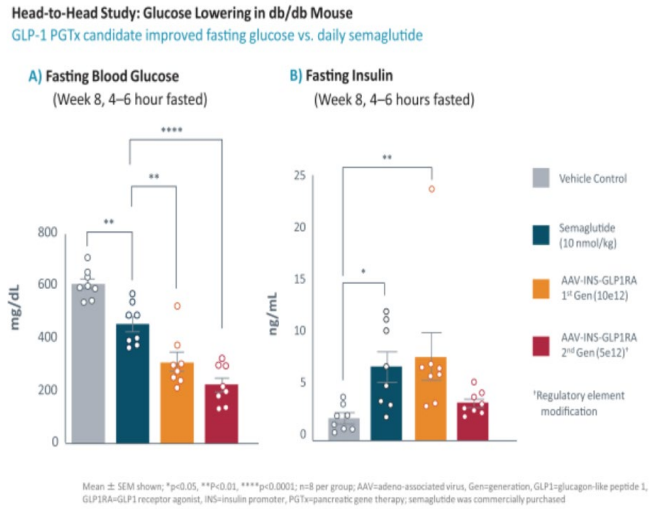
Source: World Congress on Insulin Resistance, Diabetes and Cardiovascular Disease (WCIRDC 2023)

BofA GLOBAL RESEARCH

Rejuva can reduce weight effectively in mouse models

In preclinical head-to-head studies using common animal models for T2D and obesity, a preclinical candidate of Rejuva showed weight loss and improvement in glucose control at similar or better magnitude vs semaglutide, the active pharmaceutical ingredient in FDA-approved GLP1 drugs. These studies have demonstrated the mechanistic feasibility of inducing weight loss and lowering blood glucose in animals with a GLP1-based gene therapy approach. Nonetheless, we view initial human data as key to de-risking the effectiveness and safety of RJVA-001, given construct differences between RJVA-001 (human GLP1) and preclinical candidates (mouse GLP1).

Exhibit 11: Head-to-head preclinical study comparing Rejuva candidates to semaglutide in glucose control
Rejuva candidates lowered blood glucose at least as good as semaglutide in a db/db mouse model



Source: company filing

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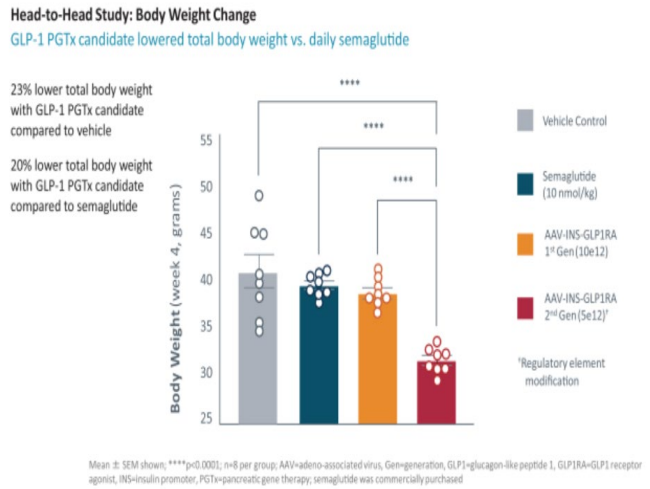
Exhibit 12: Head-to-head preclinical study comparing Rejuva candidates to semaglutide in weight loss
Rejuva candidates led to weight loss at similar or better potency than semaglutide in a db/db mouse model



Source: company filing

BofA GLOBAL RESEARCH

Rejuva passes safety tests in animal; safety in human key

Given Rejuva is designed to be a one-and-done gene therapy approach for the remission of T2D/obesity, we believe safety in human patients (in addition to efficacy) is crucial to its eventual commercial success. One safety risk is potential injury or inflammation to the pancreas (e.g. pancreatitis) following Rejuva injection. To minimize risk of complication, Rejuva is to be injected to the tail end of pancreas which minimizes risk of pancreatitis and severity of pancreatitis (if an event were to occur) due to anatomy of the pancreas; the tail of pancreas can be snipped off as a last resort in the worst case scenario. To date, Fractyl has injected Rejuva into over 50 animals with success and no safety red flags. Another tolerability risk is uncontrolled and prolonged gastrointestinal (GI) side effects that are commonly associated with approved GLP1 drugs. Given Rejuva is locally administered to the pancreas, Fractyl believes GLP1 modulation can be isolated to the organ, thereby driving therapeutic potential of GLP1 possibly without increasing GLP1 exposure in systemic circulation (thus minimizing GI side effects).

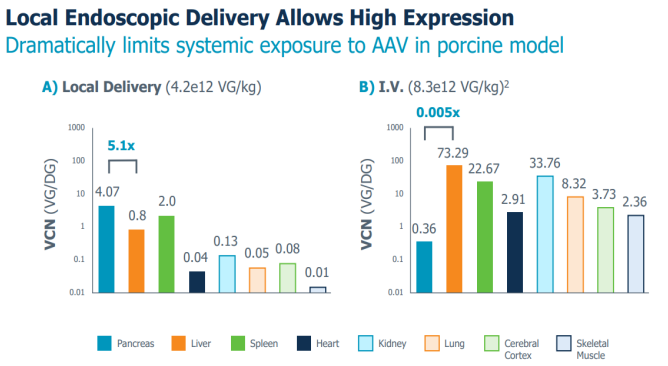
While Rejuva is in early stage of development (preclinical), we are encouraged with the animal data generated so far. Below, we highlight key preclinical safety datasets:

- **Minimizing systemic exposure of gene therapy is feasible in animal model**: in an animal model, local delivery of Rejuva to the pancreas can limit the AAV-based gene therapy to the pancreas at ~5x of higher selectivity vs other organs and ~1000x selectivity compared to IV (systemic) delivery. There is no good animal model for assessing GI tolerability issues associated with GLP1 class of drugs.

- **Rejuva injection appears safe to the pancreas and liver in animal model:** In lab tests, levels for liver enzyme (ALT) and pancreas enzyme (lipase) stay within normal range following a single Rejuva injection.

Exhibit 13: Vector copy number (VCN) of Rejuva after injection to a pig model

Local delivery of Rejuva can lead to selectivity exposure in the pancreas



Source: World Congress on Insulin Resistance, Diabetes and Cardiovascular Disease (WCIRDC 2023)

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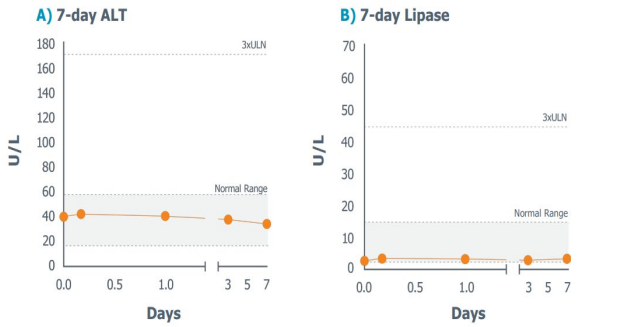
Exhibit 14: Liver and pancreas enzyme tests following Rejuva injection in animal

Rejuva injection appears safe without causing injury to liver or pancreas



Source: World Congress on Insulin Resistance, Diabetes and Cardiovascular Disease (WCIRDC 2023)

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Price objective basis & risk

Fractyl Health (GUTS)

Our PO of $26 is based on a risk-adjusted, SOTP DCF. We assume: (1) a discount rate of 11% for a clinical stage biopharma with lead asset in late-stage development, (2) likelihood of success (POS) of 55%/20% for Revita in insulin-dependent T2D / maintenance of weight loss post-GLP1, (3) POS of 5% for Rejuva for remission of T2D, and (4) DCF analysis through 2038E and -20% in terminal growth rate.

Downside risks: 1) clinical trial failure or data coming in below expectation, 2) market competition or slower than expected commercial uptake, 3) dilutive capital raise

Analyst Certification

I, Jason M. Gerberry, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or view expressed in this research report.

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	Arrowhead Pharmaceuticals	ARWR	ARWR US	Jason M. Gerberry
	bluebird bio	BLUE	BLUE US	Jason M. Gerberry
	Exelixis	EXEL	EXEL US	Jason M. Gerberry
	Fractyl Health	GUTS	GUTS US	Jason M. Gerberry
	Immunovant, Inc.	IMVT	IMVT US	Jason M. Gerberry
	Intra-Cellular Therapies	ITCI	ITCI US	Jason M. Gerberry
	Ionis	IONS	IONS US	Jason M. Gerberry
	Jazz Pharmaceuticals	JAZZ	JAZZ US	Jason M. Gerberry
	Lyra Therapeutics	LYRA	LYRA US	Jason M. Gerberry
	Oculis Holding AG	OCS	OCS US	Jason M. Gerberry
	Relay Therapeutics	RLAY	RLAY US	Jason M. Gerberry
	Tarsus Pharmaceuticals	TARS	TARS US	Jason M. Gerberry
	Teva Pharmaceuticals	TEVA	TEVA US	Jason M. Gerberry
	Vaxcyte Inc	PCVX	PCVX US	Jason M. Gerberry
	Xenon Pharmaceuticals	XENE	XENE US	Jason M. Gerberry
NEUTRAL				
	Alkermes	ALKS	ALKS US	Jason M. Gerberry
	Amphastar Pharmaceuticals	AMPH	AMPH US	Jason M. Gerberry
	Axsome Therapeutics	AXSM	AXSM US	Jason M. Gerberry
	Galapagos	GLPG	GLPG US	Jason M. Gerberry
	ProKidney Corp	PROK	PROK US	Jason M. Gerberry
	Roivant	ROIV	ROIV US	Chi M. Fong
UNDERPERFORM				
	Bausch Health Cos Inc	BHC	BHC US	Jason M. Gerberry
	FibroGen Inc.	FGEN	FGEN US	Jason M. Gerberry
	Harmony Biosciences	HRMY	HRMY US	Jason M. Gerberry
	Organon	OGN	OGN US	Jason M. Gerberry
	Viatris Inc.	VTRS	VTRS US	Jason M. Gerberry

iQmethod℠ Measures Definitions

Business Performance	Numerator	Denominator
Return On Capital Employed	NOPAT = (EBIT + Interest Income) × (1 – Tax Rate) + Goodwill Amortization	Total Assets – Current Liabilities + ST Debt + Accumulated Goodwill Amortization
Return On Equity	Net Income	Shareholders' Equity
Operating Margin	Operating Profit	Sales
Earnings Growth	Expected 5 Year CAGR From Latest Actual	N/A
Free Cash Flow	Cash Flow From Operations – Total Capex	N/A

Quality of Earnings	Numerator	Denominator
Cash Realization Ratio	Cash Flow From Operations	Net Income
Asset Replacement Ratio	Capex	Depreciation
Tax Rate	Tax Charge	Pre-Tax Income
Net Debt-To-Equity Ratio	Net Debt = Total Debt – Cash & Equivalents	Total Equity
Interest Cover	EBIT	Interest Expense

Valuation Toolkit	Numerator	Denominator
Price / Earnings Ratio	Current Share Price	Diluted Earnings Per Share (Basis As Specified)
Price / Book Value	Current Share Price	Shareholders' Equity / Current Basic Shares
Dividend Yield	Annualised Declared Cash Dividend	Current Share Price
Free Cash Flow Yield	Cash Flow From Operations – Total Capex	Market Cap = Current Share Price × Current Basic Shares
Enterprise Value / Sales	EV = Current Share Price × Current Shares + Minority Equity + Net Debt + Other LT Liabilities	Sales
EV / EBITDA	Enterprise Value	Basic EBIT + Depreciation + Amortization

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Important Disclosures

Equity Investment Rating Distribution: Health Care Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships [R1]	Count	Percent
Buy	234	60.94%	Buy	115	49.15%
Hold	80	20.83%	Hold	36	45.00%
Sell	70	18.23%	Sell	29	41.43%

Equity Investment Rating Distribution: Global Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships [R1]	Count	Percent
Buy	1895	53.62%	Buy	1083	57.15%
Hold	832	23.54%	Hold	454	54.57%
Sell	807	22.84%	Sell	383	47.46%

[R1] Issuers that were investment banking clients of BofA Securities or one of its affiliates within the past 12 months. For purposes of this Investment Rating Distribution, the coverage universe includes only stocks. A stock rated Neutral is included as a Hold, and a stock rated Underperform is included as a Sell.

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Investment rating	Total return expectation (within 12-month period of date of initial rating)	Ratings dispersion guidelines for coverage cluster[R2]
Buy	≥ 10%	≤ 70%
Neutral	≥ 0%	≤ 30%
Underperform	N/A	≥ 20%

[R2]Ratings dispersions may vary from time to time where BofA Global Research believes it better reflects the investment prospects of stocks in a Coverage Cluster.

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