Fractyl Health Reports Third Quarter 2026 Financial Results and Business Updates

Nov 12, 2026

REMAIN-1 Pivotal Cohort met its six-month co-primary endpoint with high statistical significance (p=0.0023); Revita® participants retained approximately 80% of GLP-1-induced weight loss versus 67% for sham

Planned FDA De Novo submission in late Q4 2026; topline 12-month data from the REMAIN-1 Pivotal Cohort anticipated in Q1 2027

Sharpened focus on Revita, with a workforce reduction of approximately 45% and discontinuation of internal Rejuva development

Cash runway into Q2 2027, through planned De Novo submission and anticipated 12-month pivotal data; quarterly operating cash spending expected to be reduced by approximately 50%, to approximately $8 million, by the end of Q2 2027

Conference call today at 4:30 p.m. ET

BURLINGTON, Mass., Nov. 12, 2026 (GLOBE NEWSWIRE) -- Fractyl Health, Inc. (Nasdaq: GUTS) (the Company or Fractyl), a clinical-stage metabolic therapeutics company focused on pioneering novel approaches to treat obesity and type 2 diabetes (T2D), today announced third quarter 2026 financial results and provided business updates. The Company also reiterated its anticipated Revita® milestones, including a planned U.S. Food and Drug Administration (FDA) De Novo marketing application submission in late Q4 2026 and topline 12-month data from the REMAIN-1 Pivotal Cohort in Q1 2027, and its cash runway guidance into Q2 2027.

“There are approximately 1 million Americans discontinuing GLP-1s each month, and these individuals are at high risk of weight and metabolic rebound. In this context, we believe the positive pivotal results from REMAIN-1 represent a defining moment for Fractyl. In the most rigorous stress test we could conceive, a single Revita procedure met its six-month co-primary endpoint with high statistical significance,” said Harith Rajagopalan, M.D., Ph.D., Co-Founder, President and Chief Executive Officer of Fractyl. “Armed with positive data, we have focused the Company around Revita’s post-GLP-1 weight maintenance opportunity. We expect the capital we have today to be sufficient to fund our planned De Novo submission and upcoming 12-month pivotal data and. Our goal is for Revita to potentially establish an entirely new therapeutic category of post-GLP-1 weight maintenance by aiming to reverse years of diet-induced damage to the gut.”

Select Recent Revita Clinical Highlights

Fractyl is studying Revita in the REMAIN-1 weight maintenance program, which is designed to evaluate Revita’s potential to maintain weight loss following GLP-1 based therapy discontinuation. The REMAIN-1 program includes three distinct participant cohorts that are conducted under a single IDE: the REVEAL-1 Cohort, the REMAIN-1 Midpoint Cohort and the REMAIN-1 Pivotal Cohort.

- In October 2026, Fractyl reported positive topline six-month results from the REMAIN-1 Pivotal Cohort, a 308-participant, multicenter, randomized, double-blind, sham-controlled study of Revita for weight maintenance in adults with obesity following discontinuation of GLP-1 therapy. REMAIN-1 met its pre-specified six-month co-primary endpoint of weight loss retention, as patients treated with a single Revita procedure demonstrated a highly statistically significant reduction in weight regain compared to sham (p=0.0023).
    - **Six-month co-primary endpoint met:** In the modified intention-to-treat (mITT) population (N=308), Revita participants maintained approximately 80% of their GLP-1-induced weight loss after a single treatment at six months with high statistical significance versus sham (p=0.0023). 32% of Revita participants were either weight stable or had further weight loss at six months post GLP-1 discontinuation (<2% regain or incremental loss) versus 18% for sham (post hoc; nominal p=0.020).
    - **Dose-dependent effect observed:** In a post hoc analysis by ablation length, participants who received 12 to 18 cm of duodenal ablation had 43% less regain than sham (observed mean weight regain of 4.7% versus 8.2%; n=107 versus 74). Participants who received 20 cm or more had 53% less regain than sham (mean regain of 3.8%; n=47).
    - **Treatment effect grew over time:** The difference in weight regain between Revita and sham widened at each assessment, nearly doubling from Month 3 to Month 6.

    - **Favorable interim safety data:** There have been no device- or procedure-related serious adverse events, no deaths, and no unanticipated adverse device effects observed as of the September 24, 2026, data cut-off date. Related adverse events were predominantly mild and peri-procedural, with 94% occurring within seven days of the procedure.
- The second co-primary endpoint, the proportion of Revita participants maintaining at least 5% total body weight loss relative to their pre-tirzepatide weight at one year, will be assessed against an FDA-mandated pre-specified performance goal of greater than 50%.

Commercial Readiness and Market Access

- In September 2026, Fractyl hosted a Commercial Investor Day outlining the potential path to commercializing Revita in post-GLP-1 weight maintenance. The Company's launch plan focuses on the top 100 to 200 of approximately 1,000 accredited bariatric centers in the United States, beginning with 30 to 50 centers in the first year.
- In October 2026, the American Medical Association published Category III CPT code 1122T, a dedicated code for the Revita procedure, which takes effect January 1, 2027, well ahead of a potential U.S. launch in early 2028.
- The Centers for Medicare & Medicaid Services (CMS) has proposed RAPID, a pathway that could align Medicare coverage with FDA authorization for breakthrough devices. More than 160 comments were filed during the comment period, nearly all supporting an on-ramp for devices with pivotal trials already underway, including comments from ASGE and ASMBS that cited Revita. Fractyl expects to learn whether CMS adopts such an on-ramp in early January 2027.
- In October 2026, Fractyl announced findings from company-sponsored market research highlighting strong patient interest in a one-time procedural approach to weight maintenance following GLP-1 therapy. Among nearly 300 current or recent GLP-1 users surveyed, 33% preferred stopping GLP-1 therapy and receiving a hypothetical endoscopic procedure.
- In October 2026, Fractyl announced additions to its U.S. patent portfolio for Revita. The U.S. Patent and Trademark Office issued U.S. Patent No. 12,740,821, covering features of the Revita single-use catheter, with a term extending to November 28, 2042, and issued a Notice of Allowance for a patent application directed to Revita's thermal dosing method. Fractyl's intellectual property portfolio includes 39 granted U.S. patents, approximately 40 pending U.S. applications and more than 50 issued patents outside the United States.

Sharpened Focus on Revita

On October 21, 2026, Fractyl adopted a plan to sharpen its strategic focus on its Revita program in connection with a strategic reprioritization, concentrating its financial and operational resources on advancing Revita toward potential FDA marketing authorization and commercialization in post-GLP-1 weight maintenance.

- **Workforce Reduction:** The Company is reducing its workforce by approximately 45%, with the reduction expected to be completed during the fourth quarter of 2026. The Company estimates that it will incur charges of approximately $2 million for severance and other employee termination-related costs, with the majority of such costs to be incurred in the fourth quarter of 2026.
- **Reduced Quarterly Operating Cash Spending:** As cost reductions take effect and REMAIN-1 Pivotal Cohort expenditures decline, the Company expects quarterly operating cash spending to be reduced by approximately 50%, to approximately $8 million, by the end of Q2 2027.
- **Rejuva Strategic Alternatives:** The Company is discontinuing internal development of its Rejuva gene therapy program and is seeking strategic alternatives to maximize the value of the program. There can be no assurance that the Company's review of strategic alternatives for Rejuva will result in any transaction, and the Company does not intend to disclose further developments unless and until it determines that disclosure is appropriate or required.

Appointment of Michael Wartell as Independent Director

- On November 6, 2026, the Company announced that effective November 2, 2026, the Board of Directors (the "Board") increased the size of the Board from nine to ten and appointed Michael Wartell as a Class III director, with a term expiring at the Company's 2027 annual meeting of stockholders and until his successor is duly elected and qualified or until his earlier resignation or removal. Mr. Wartell is the President of Bluerose Associates LLC and has extensive experience serving as an independent director for both public and private corporations, specializing in guiding companies through complex situations.

Fractyl Forward: Advancing Revita Toward a New Therapeutic Category in Obesity Care

The Company continues to anticipate the following milestones:

- **Late Q4 2026:** Planned FDA De Novo submission for Revita in post-GLP-1 weight maintenance.
- **January 1, 2027:** Category III CPT code 1122T for the Revita procedure takes effect.
- **Q1 2027:** Anticipated topline 12-month data from the REMAIN-1 Pivotal Cohort, including the second co-primary endpoint.
- **Late 2027:** Potential FDA marketing authorization.
- **Early 2028:** Potential U.S. commercial launch.

As in all applications, the FDA indicated that final pathway determinations will be made following review of the complete safety dataset, which the Company intends to include in its potential De Novo submission.

Third Quarter 2026 Financial Results

- **Research and Development Expenses:** R&D expenses were $12.5 million for the quarter ended September 30, 2026, compared to $17.5 million for the same period in 2025. The decrease of $5.0 million was primarily related to reduced spending on Fractyl's Revita and Rejuva programs, as well as lower personnel-related expenses.
- **Selling, General and Administrative Expenses:** SG&A expenses were $6.2 million for the quarter ended September 30, 2026, compared to $5.2 million for the same period in 2025. The increase of $1.0 million was primarily driven by higher personnel-related expenses and stock compensation expenses, partially offset by decreased professional service fees.
- **Net Loss:** For the quarter ended September 30, 2026, Fractyl reported a net loss of $14.2 million, compared to a net loss of $45.6 million for the same period in 2025. The decrease in net loss of $31.5 million was driven by a $4.0 million reduction in operating expenses, a $25.7 million favorable non-cash change in the fair value of warrant liabilities, $1.6 million lower non-cash loss from change in fair value of debt, and $0.1 million higher interest income.
- **Adjusted EBITDA:** Adjusted EBITDA was negative $16.0 million for the quarter ended September 30, 2026, compared to negative $20.8 million for the same period in 2025. The decrease in the non-GAAP adjusted loss of $4.8 million was primarily due to reduced operating expenses excluding stock compensation expenses.
- **Cash Position:** As of September 30, 2026, Fractyl had approximately $31.5 million in cash and cash equivalents. Based on current business plans, the Company believes its cash position will fund operations into the second quarter of 2027, through the planned De Novo submission and anticipated 12-month REMAIN-1 Pivotal Cohort data, subject to compliance with the minimum liquidity covenant under the Company's credit agreement, as discussed further in the "Liquidity and Capital Resources" section of our Quarterly Report on Form 10-Q.

Webcast and Conference Call Information

Fractyl will host a conference call to discuss its third quarter financial results and provide business updates on Thursday, November 12, 2026, at 4:30 p.m. ET. A live webcast of the conference call can be accessed in the "Events" section of Fractyl's website at ir.fractyl.com. The webcast will be archived and available for replay for at least 30 days after the event.

Ahead of the call, Fractyl invited all shareholders to submit and vote on questions for management through Say by Robinhood by visiting: https://app.saytechnologies.com/fractyl-health-2026-q3. Management will address a selection of the most-voted shareholder questions during the call.

About Fractyl Health

Fractyl is a clinical-stage metabolic therapeutics company focused on pioneering novel approaches to treat obesity and type 2 diabetes. The Company's lead product candidate, Revita, is an endoscopic procedural therapy in pivotal development for post-GLP-1 weight maintenance. Fractyl's goal is to change the course of metabolic disease, advancing treatment from chronic management toward prevention and reversal of disease. Fractyl is headquartered in Burlington, Massachusetts.

About Revita

The Revita® DMR System is Fractyl's lead product candidate, designed to remodel the duodenal lining via a single, minimally invasive endoscopic procedure intended to restore healthy nutrient sensing and signaling disrupted by chronic metabolic disease. By targeting duodenal dysfunction, Revita is designed to address an underlying driver of obesity and enable durable weight maintenance following GLP-1 discontinuation. Revita has received FDA Breakthrough Device Designation for weight maintenance in people with obesity who discontinue GLP-1 therapies. Revita is for investigational use only in the United States and is CE marked in the European Union and United Kingdom.

Non-GAAP Financial Measures

This press release contains certain financial information that is not presented in conformity with U.S. generally accepted accounting principles (GAAP), including Adjusted EBITDA, which is a non-GAAP financial measure as defined in Regulation G promulgated under the Securities Exchange Act of 1934. This non-GAAP financial measure is provided as supplemental information to Fractyl's financial measures presented in this press release in accordance with GAAP.

The Company defines Adjusted EBITDA as net loss adjusted to exclude (i) interest income, net, (ii) depreciation expense, (iii)

stock-based compensation expense, (iv) change in fair value of notes payable and (v) change in fair value of warrant liabilities.

Management believes Adjusted EBITDA provides useful supplemental information to investors regarding the Company's core operating performance and facilitates period-to-period comparisons by excluding items that are non-cash or non-operational in nature and may vary in magnitude. Adjusted EBITDA is also used by management in evaluating the Company's operating performance and in planning and forecasting activities.

The non-GAAP financial measures used by Fractyl may not be the same or calculated in the same manner as those used and calculated by other companies. Non-GAAP financial measures have limitations as analytical tools and should not be considered in isolation or as a substitute for Fractyl's financial results prepared and reported in accordance with GAAP. This non-GAAP measure should not be construed as an inference that the Company's future results will be unaffected by unusual or non-recurring items. A reconciliation of Adjusted EBITDA reported in this press release to the most comparable GAAP measure for the respective periods appears in the table captioned "Reconciliation of GAAP Net Loss to Adjusted EBITDA" later in this press release.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release 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 press release include, without limitation, statements regarding: the potential benefits of Fractyl's sharpened strategic focus and reprioritization, including the workforce reduction and its anticipated impact on Fractyl's expenditures and financial runway; Fractyl's anticipated financial performance, including cash and cash equivalents, for any period of time; Fractyl's expected quarterly operating cash spending and cash runway, including the period over which its existing cash and cash equivalents will be sufficient to satisfy the minimum liquidity covenant under its credit agreement; Fractyl's ability to continue as a going concern; the promise and potential impact of Fractyl's clinical trial data and product candidates, including Revita's potential for maintaining weight loss after GLP-1 based therapy discontinuation; the design, initiation, timing and results of clinical studies or readouts, including readouts from the REMAIN-1 Pivotal Cohort, including anticipated 12-month data from the REMAIN-1 Pivotal Cohort and the second co-primary endpoint; the potential launch or commercialization of any of Fractyl's product candidates or products; Fractyl's commercial readiness activities and launch plans; coding, coverage and payment for Revita, including the effectiveness and use of Category III CPT code 1122T, the timing and outcome of any CMS rulemaking, including RAPID, and eligibility for or timing of Medicare transitional pass-through payment or other coverage, which are subject to AMA and CMS review and are not assured; Fractyl's regulatory strategy, including the timing of any potential De Novo marketing application submission and the potential use and benefits of the De Novo pathway (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, or as to the timing of any such authorization); the potential treatment population or benefits for any of Fractyl's product candidates or products; Fractyl's exploration of strategic alternatives for Rejuva and the potential benefits thereof; Fractyl's strategic and product development objectives and goals; and the timing of any of the foregoing. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause Fractyl's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the risks that are discussed more fully in Fractyl's filings with the Securities and Exchange Commission (the SEC) including the "Risk Factors" section of Fractyl's Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 24, 2026, and other documents Fractyl subsequently files with or furnishes to the SEC, including Fractyl's Quarterly Report on Form 10-Q for the quarter ended September 30, 2026, filed with the SEC on November 12, 2026. These forward-looking statements are based on management's current estimates and expectations. While Fractyl may elect to update such forward-looking statements at some point in the future, Fractyl disclaims any obligation to do so, even if subsequent events cause Fractyl's views to change.

Contact

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Fractyl Health, Inc.
Selected Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	September 30, 2026	December 31, 2025
Cash and cash equivalents	$ 31,515	$ 81,540
Restricted cash	4,255	4,255
Working capital [(1)]	16,989	69,247
Total assets	65,925	121,402
Notes payable, long-term	29,234	30,586
Total liabilities	79,141	111,944

Total stockholders' equity (deficit)	(13,216)	9,458

(1) Working capital is defined as total current assets less total current liabilities.

Fractyl Health, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except for share and per share information)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 12,454	$ 17,457	$ 41,864	$ 58,043
Selling, general and administrative	6,195	5,237	16,701	15,489
Total operating expenses	18,649	22,694	58,565	73,532
Loss from operations	(18,649)	(22,694)	(58,565)	(73,532)
Other income (expense), net:				
Interest income, net	297	166	1,321	895
Change in fair value of notes payable	(284)	(1,868)	(2,276)	(3,824)
Change in fair value of warrant liabilities	4,499	(21,201)	29,070	(20,724)
Other expense, net	(13)	(6)	(20)	(42)
Total other income (expense), net	4,499	(22,909)	28,095	(23,695)
Net loss and comprehensive loss	$ (14,150)	$ (45,603)	$ (30,470)	$ (97,227)
Net loss per share, basic and diluted [(2)]	$ (1.07)	$ (8.46)	$ (2.30)	$ (21.51)
Weighted-average number of common shares outstanding, basic and diluted [(2)]	13,250,080	5,387,747	13,226,323	4,520,293

(2) All share and per share information has been retroactively adjusted to reflect the 1-for-12 reverse stock split effected on October 2, 2026. Refer to Quarterly Report on Form 10-Q for details.

Fractyl Health, Inc.
Reconciliation of GAAP Net Loss to Adjusted EBITDA
(in thousands)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Net loss	$ (14,150)	$ (45,603)	$ (30,470)	$ (97,227)
Interest income, net	(297)	(166)	(1,321)	(895)
Depreciation	276	290	835	850
EBITDA	(14,171)	(45,479)	(30,956)	(97,272)
Stock-based compensation expense	2,386	1,638	7,413	4,829
Change in fair value of notes payable	284	1,868	2,276	3,824
Change in fair value of warrant liabilities	(4,499)	21,201	(29,070)	20,724
Adjusted EBITDA	$ (16,000)	$ (20,772)	$ (50,337)	$ (67,895)