



Fractyl Health Reports First Quarter 2026 Financial Results and Business Updates

May 12, 2026

Next anticipated Revita® clinical data readouts are 1-year data from the REVEAL-1 Cohort in Q2 2026 and 1-year randomized data from the REMAIN-1 Midpoint Cohort in Q3 2026

Early Q4 2026 timing for topline 6-month randomized data from the REMAIN-1 Pivotal Cohort and late Q4 2026 timing for potential FDA De Novo marketing application submission in post-GLP-1 weight maintenance reaffirmed

Clinical Trial Application authorization of RJVA-001 first-in-human study in the Netherlands for T2D; first-in-human dosing anticipated in second half of 2026 reiterated

Cash runway guidance into early 2027, beyond anticipated Pivotal data readout reiterated

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

BURLINGTON, Mass., May 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 first quarter 2026 financial results and provided business updates. The Company also reiterated all previously disclosed 2026 Revita® clinical and regulatory milestones, including topline 6-month randomized data from the REMAIN-1 Pivotal Cohort expected in early Q4 2026, and its cash runway guidance into early 2027.

"We believe Revita has the potential to offer a transformational new approach to durable weight maintenance and a clinically needed off ramp from GLP-1 therapy. Our first quarter results reflect continued execution across every dimension of our business toward that goal," said Harith Rajagopalan, M.D., Ph.D., Co-Founder and Chief Executive Officer of Fractyl. "Topline 6-month randomized data from the REMAIN-1 Pivotal Cohort remains on track for early Q4 2026. This registrational study is prospectively designed and statistically powered to demonstrate Revita's potential effect across the full cohort, with enrichment in participants with higher run-in weight loss and longer ablation length. Ahead of that readout, we expect to report 1-year REVEAL-1 Cohort data in Q2 2026 and 1-year REMAIN-1 Midpoint Cohort randomized data in Q3 2026. Fractyl stands alone in developing the first potential procedural option for post-GLP-1 weight maintenance, and with cash runway into early 2027, we are funded beyond the anticipated pivotal data readout."

Select Recent Revita Clinical Highlights

The Company 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 January 2026](#), Fractyl announced compelling 6-month randomized REMAIN-1 Midpoint Cohort data showing durable weight maintenance with Revita after GLP-1 discontinuation. Participants with above median GLP-1-associated weight loss experienced approximately 70% less post-GLP-1 weight regain with Revita versus sham at 6 months. These pilot study results support the pivotal study design and further substantiate Revita's potential to be the first durable procedural therapy for post-GLP-1 weight maintenance.
- [In February 2026](#), Fractyl completed participant randomization in the REMAIN-1 Pivotal Cohort.
- [In March 2026](#), Fractyl reported post-hoc analyses from the REMAIN-1 Midpoint Cohort showing a statistically significant ablation length (i.e., dose)-dependent treatment effect on post-GLP-1 weight maintenance at 6 months. In participants with above median GLP-1-induced weight loss who received greater than 14 cm duodenal ablation, Revita participants retained 88% of GLP-1-induced weight loss at six months compared to only 60% in sham participants.
- [In March 2026](#), Fractyl also reported that it had received pre-submission feedback from the U.S. Food and Drug Administration (FDA) acknowledging that the safety profile of the Revita DMR System, based on clinical data from over 300 procedures, is consistent with a Class II device classification.

Fractyl Forward: Reiterating Anticipated 2026 Revita Milestones

With randomization of the REMAIN-1 Pivotal Cohort complete, Fractyl is advancing toward multiple anticipated clinical and regulatory milestones toward pivotal readout and potential U.S. regulatory submission. The Company reiterates its previously announced cash runway into early 2027, beyond the anticipated pivotal data readout.

- **Q2 2026:** 1-year REVEAL-1 Cohort data.
- **Q3 2026:** 1-year REMAIN-1 Midpoint Cohort randomized data.
- **Early Q4 2026:** Topline 6-month randomized data from REMAIN-1 Pivotal Cohort.
- **Late Q4 2026:** Potential FDA De Novo marketing application submission in post-GLP-1 weight maintenance.

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 marketing application submission.

Rejuva® Development Progress and Anticipated 2026 Rejuva Milestones

Rejuva is Fractyl's gene therapy platform designed to enable long-term remission of T2D and obesity by durably reprogramming pancreatic islet cells to endogenously produce metabolic hormones. The lead product candidate, RJVA-001, is being advanced for patients with inadequately controlled T2D. The second candidate, RJVA-002, is a preclinical-stage dual GIP/GLP-1 gene therapy designed to treat obesity.

In April 2026, we received CTA authorization in the Netherlands for RJVA-001, enabling initiation of the anticipated Phase 1/2 first-in-human study evaluating RJVA-001 in adults with inadequately controlled T2D. Subject to site activation, we expect to dose the first patient with RJVA-001 and report preliminary data in the second half of 2026. We also plan to conduct the study at sites in Australia, where a CTA has been submitted and regulatory feedback is expected in the third quarter of 2026.

- **H2 2026:** First-in-human dosing of RJVA-001, subject to site activation, and expected reporting of preliminary data.

First Quarter 2026 Financial Results

- **Research and Development Expenses:** R&D expenses were \$15.6 million for the quarter ended March 31, 2026, compared to \$19.4 million for the same period in 2025. The decrease was primarily related to reduced spending on our Revita and Rejuva programs, as well as lower personnel-related expenses.
- **Selling, General and Administrative Expenses:** SG&A expenses were \$5.2 million for the quarter ended March 31, 2026, consistent with \$5.3 million for the same period in 2025.
- **Net Income (Loss):** For the quarter ended March 31, 2026, Fractyl reported a net income of \$9.2 million, compared to net loss of \$23.7 million for the same period in 2025. The shift was primarily driven by a \$30.1 million non-cash accounting change in fair value related to our warrant liabilities and does not reflect a change in our underlying operating performance. Operating expenses for the quarter ended March 31, 2026 were \$3.9 million lower compared to the same period in 2025.
- **Adjusted EBITDA:** Adjusted EBITDA was negative \$18.0 million for the quarter ended March 31, 2026, compared to negative \$23.0 million for the same period in 2025. The decrease in the non-GAAP adjusted loss was primarily due to the decrease in operating expenses.
- **Cash Position:** As of March 31, 2026, Fractyl had approximately \$63.2 million in cash and cash equivalents. Based on current business plans, the Company believes its cash position will fund operations into early 2027.

Webcast and Conference Call Information

Fractyl will host a conference call to discuss its first quarter financial results and provide business updates on Tuesday, May 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.

About Fractyl Health

Fractyl Health is a clinical-stage metabolic therapeutics company advancing two differentiated candidates designed to target the root causes of obesity and T2D: Revita, a procedural therapy in pivotal development for post-GLP-1 weight maintenance, and Rejuva, an AAV-based gene therapy platform with its lead candidate RJVA-001 entering first-in-human clinical studies. Fractyl's goal is to advance metabolic disease treatment from chronic management toward prevention and reversal of disease. Fractyl is headquartered in Burlington, Massachusetts.

About Revita

Revita is Fractyl Health's lead product candidate, designed to remodel the duodenal lining via a one-time, minimally invasive endoscopic procedure intended to restore healthy nutrient sensing and signaling disrupted by chronic metabolic disease. 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.

About Rejuva

Fractyl Health's Rejuva platform is developing next-generation AAV-based, locally delivered gene therapies for the treatment of obesity and T2D. Rejuva leverages advanced delivery systems and proprietary screening methods to identify and develop metabolically active gene therapy candidates targeting the pancreas, with the goal of offering novel, disease-modifying therapies that address the underlying root causes of disease.

The platform's lead candidate, RJVA-001, has received Clinical Trial Authorization in the Netherlands to initiate a Phase 1/2 first-in-human clinical trial in T2D, the first clinical-stage program from the Rejuva platform. Fractyl expects to dose the first patient with RJVA-001 and report preliminary data in the second half of 2026, subject to site activation. Additional Rejuva candidates, including RJVA-002 (a dual GIP/GLP-1 gene therapy candidate designed to treat obesity), remain in preclinical development. In the United States, Rejuva is in preclinical development. No Investigational New Drug (IND) application has been filed with the U.S. Food and Drug Administration (the FDA), and Rejuva has not been approved or authorized by the FDA for use in humans.

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 income (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 Income (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 expected initiation, timing, design, endpoints, site activation, and conduct of the RJVA-001 first-in-human clinical trial; the timing and results of first-in-human dosing and reporting of preliminary data; our regulatory strategy, including submissions to and communications with regulators in the European Union, Australia, and other jurisdictions; the promise, potential impact, and mechanism of action of RJVA-001 and our Rejuva platform; our anticipated financial performance, including cash and cash equivalents, for any period of time, our strategic reprioritization and related workforce reduction, including its implementation and the expected costs and benefits, if any; our expected cash runway; the promise and potential impact of our preclinical or 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 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 our product candidates or products, the REMAIN-1 Midpoint Cohort and the REMAIN-1 Pivotal Cohort; the potential treatment population or benefits for any of our product candidates or products; our regulatory strategy, including 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); our 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 our 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 our filings with the Securities and Exchange Commission (the SEC) including the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 24, 2026, and other documents we subsequently file with or furnish to the SEC, including our Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, filed with the SEC on May 12, 2026. These forward-looking statements are based on management's

current estimates and expectations. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

Contact

Brian Luque, Head of Investor Relations and Corporate Development
IR@fractyl.com, 951.206.1200

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

	<u>March 31,</u> <u>2026</u>	<u>December 31,</u> <u>2025</u>
Cash and cash equivalents	\$ 63,168	\$ 81,540
Restricted cash	4,255	4,255
Working capital ⁽¹⁾	50,512	69,247
Total assets	99,385	121,402
Notes payable, long-term	30,136	30,586
Total liabilities	78,008	111,944
Total stockholders' equity	21,377	9,458

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

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

	<u>Three Months Ended</u> <u>March 31,</u>	
	<u>2026</u>	<u>2025</u>
Operating expenses:		
Research and development	\$ 15,598	\$ 19,435
Selling, general and administrative	5,222	5,324
Total operating expenses	<u>20,820</u>	<u>24,759</u>
Loss from operations	<u>(20,820)</u>	<u>(24,759)</u>
Other income (expense), net:		
Interest income, net	593	503
Change in fair value of notes payable	(610)	(283)
Change in fair value of warrant liabilities	30,055	825
Other expense, net	<u>—</u>	<u>(21)</u>
Total other income, net	<u>30,038</u>	<u>1,024</u>
Net income (loss) and comprehensive income (loss)	<u>\$ 9,218</u>	<u>\$ (23,735)</u>
Net income (loss) per share, basic and diluted	<u>\$ 0.06</u>	<u>\$ (0.49)</u>
Weighted-average number of common shares outstanding, basic and diluted	<u>158,492,158</u>	<u>48,865,468</u>

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

Three Months Ended
March 31,

	<u>2026</u>	<u>2025</u>
Net income (loss)	\$ 9,218	\$ (23,735)
Interest income, net	(593)	(503)
Depreciation	281	290
EBITDA	<u>8,906</u>	<u>(23,948)</u>
Stock-based compensation expense	2,531	1,406
Change in fair value of notes payable	610	283
Change in fair value of warrant liabilities	(30,055)	(825)
Adjusted EBITDA	<u>\$ (18,008)</u>	<u>\$ (23,084)</u>