
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)

of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 5, 2026

GRAIL, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-42045
(Commission
File Number)

86-3673636
(IRS Employer
Identification No.)

1525 O'Brien Drive Menlo Park, California 94025
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (833) 694-2553

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	GRAL	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of operations and financial condition.

On May 5, 2026, GRAIL, Inc. (the “Company” or “GRAIL”) issued a press release announcing its financial results for the first quarter ended March 31, 2026. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in Item 2.02 of this Current Report on Form 8-K and the exhibits attached hereto are intended to be “furnished” and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Except as shall be expressly set forth by specific reference in such filing, the information contained herein and in the accompanying exhibits shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of GRAIL, Inc. dated May 5, 2026 (GRAIL Reports First Quarter 2026 Financial Results)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GRAIL, INC.

Date: May 5, 2026

By: /s/ Aaron Freidin
Name: Aaron Freidin
Title: Chief Financial Officer

GRAIL Reports First Quarter 2026 Financial Results

Q1 Galleri® Revenue Grew 37% Year-Over-Year to \$39.8 Million, and Test Volume Increased 50% to More Than 56,000

Announced Plans to Integrate the Galleri Test Into Epic Electronic Health Record Platform to Expand Access Nationwide

New Data From the NHS-Galleri Trial and PATHFINDER 2 Study to be Presented at 2026 American Society of Clinical Oncology (ASCO) Annual Meeting

MENLO PARK, Calif. — May 5, 2026 — GRAIL, Inc. (Nasdaq: GRAL), a healthcare company whose mission is to detect cancer early when it can be cured, today reported business and financial results for the first quarter of 2026.

Total revenue in the first quarter grew 28% year over year to \$40.8 million, and Galleri revenue grew 37% year-over-year to \$39.8 million. Galleri test volume for the quarter grew 50% year-over-year to more than 56,000. Net loss for the quarter was \$93.2 million. Gross loss was \$14.3 million. Non-GAAP adjusted gross profit was \$19.7 million, and non-GAAP adjusted EBITDA was \$(79.9) million.¹

“GRAIL continues to execute commercially, with strong volume growth in Q1. We continue to build new partnerships to support demand and were pleased to announce our collaboration with Epic, which will expand access to Galleri for physicians and patients,” said Bob Ragusa, Chief Executive Officer at GRAIL. “We are looking forward to our upcoming presentations of detailed results from our 35,000 PATHFINDER 2 study and the 140,000 NHS-Galleri trial, which were accepted for presentation at the 2026 ASCO Annual Meeting in late May.”

For the three months ended March 31, 2026, as compared to the three months ended March 31, 2025, GRAIL reported:

- **Revenue:** Total revenue, comprised of screening and development services revenue, was \$40.8 million, an increase of \$8.9 million or 28%.
- **Net loss:** Net loss was \$93.2 million, an improvement of \$13.0 million or 12%.
- **Gross loss:** Gross loss was \$14.3 million, an improvement of \$5.6 million or 28%.
- **Adjusted gross profit¹:** Adjusted gross profit was \$19.7 million, an increase of \$5.4 million or 38%.
- **Adjusted EBITDA¹:** Adjusted EBITDA was \$(79.9) million, an improvement of \$18.8 million or 19%.

Cash position: Cash, cash equivalents, and short-term marketable securities totaled \$823.1 million as of March 31, 2026.

¹ See “Non-GAAP Disclosure” and the associated reconciliations for important information about our use of non-GAAP measures.

Recent business highlights include:

- The Premarket Approval (PMA) application for Galleri was submitted to the U.S. Food and Drug Administration (FDA) in January and accepted by FDA for review. The PMA submission is focused on test performance and safety results from 25,000 consented participants in the U.S.-based PATHFINDER 2 study with one year of follow up and from the prevalent screening round (first year) of the 140,000 participant NHS-Galleri trial, the largest, and only, randomized, controlled intended use trial of any multi-cancer early detection (MCED) test. The submission is also supported by a bridging analysis to compare performance of the version of Galleri used in clinical trials to the updated version that has been submitted to the FDA for premarket approval.
- Announced planned integration of the Galleri test into Epic's electronic health record (EHR) platform to expand access nationwide. Epic is a leading EHR platform used by many large and advanced health systems. Integration through Epic Aura will allow health systems and their healthcare providers to order the Galleri test directly at the point of care, receive structured results, and manage patient follow-up seamlessly within their existing native EHR and within their existing clinical workflows. Broad availability in Epic EHR platform is expected by the end of 2026.
- Data presentations at the American Association of Cancer Research (AACR) 2026 Annual Meeting in April:
 - An analysis of the association between emergency department involvement in the diagnosis of cancer and overall survival across different cancer types in the Medicare population. Emergency department involvement was associated with a significant fraction of overall mortality in patients with cancer. Emergency department involvement at diagnosis remained a strong independent predictor of mortality after adjusting for sociodemographics, comorbidities, and stage at diagnosis.
 - An analysis of adherence to mammography screening before and after MCED testing. showed that women who received a negative MCED result maintained high adherence to guideline-recommended mammography, with >80% undergoing screening in the 24 months after MCED testing, similar to rates in the 24 months before testing. These findings suggest that MCED testing does not negatively impact participation in guideline-recommended cancer screening.
- Announced new data from both the NHS-Galleri trial and the PATHFINDER 2 study will be presented at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, May 29 - June 2, 2026:
 - Detailed NHS-Galleri Trial results will be presented as a late-breaking abstract in an oral presentation during a clinical science symposium on Saturday, May 30.
 - Final PATHFINDER 2 study results will be presented as a late-breaking abstract in an oral presentation on Sunday, May 31.
 - More than 174,000 participants enrolled across both studies, demonstrating the scientific rigor of the Galleri clinical development program.

Conference Call and Webcast

A webcast and conference call will be held today, May 5, 2026, at 1:30 p.m. PT / 4:30 p.m. ET. Individuals interested in listening to the conference call may access it on the investor relations section of GRAIL's website at investors.grail.com.

A replay of the webcast will be available on GRAIL's website for 30 days.

About GRAIL

GRAIL, Inc. is a healthcare company whose mission is to detect cancer early, when it can be cured. GRAIL is focused on alleviating the global burden of cancer by using the power of next-generation sequencing, population-scale clinical studies, and state-of-the-art machine learning, software, and automation to detect and identify multiple deadly cancer types in earlier stages. GRAIL's targeted methylation-based platform can support the continuum of care for screening and precision oncology, including multi-cancer early detection in symptomatic patients, risk stratification, minimal residual disease detection, biomarker subtyping, treatment and recurrence monitoring. GRAIL is headquartered in Menlo Park, CA with locations in Washington, D.C., North Carolina, and the United Kingdom. GRAIL's common stock is listed under the ticker symbol "GRAL" on the Nasdaq Stock Exchange.

For more information, visit grail.com.

About Galleri®

The Galleri multi-cancer early detection test is a proactive tool to screen for cancer. With a simple blood draw, the Galleri test can identify DNA shed by cancer cells, which can act as a unique "fingerprint" of cancer, to help screen for some of the deadliest cancers that don't have recommended screening today, such as pancreatic, esophageal, ovarian, liver, and others. The Galleri test can be used to screen for cancer before a person becomes symptomatic, when cancer may be more easily treated and potentially curable. The Galleri test can indicate the origin of the cancer, giving healthcare providers a roadmap of where to explore further. The Galleri test requires a prescription from a licensed healthcare provider and should be used in addition to recommended cancer screenings such as mammography, colonoscopy, prostate-specific antigen (PSA) test, or cervical cancer screening. The Galleri test is recommended for adults with an elevated risk for cancer, such as those aged 50 or older.

For more information, visit galleri.com.

Laboratory/Test Information

GRAIL's clinical laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and accredited by the College of American Pathologists. The Galleri test was developed, and its performance characteristics were determined by GRAIL. The Galleri test has not been cleared or approved by the U.S. Food and Drug Administration. GRAIL's clinical laboratory is regulated under CLIA to perform high-complexity testing. The Galleri test is intended for clinical purposes.

Non-GAAP Disclosure

In addition to our financial results provided throughout this press release that are determined in accordance with U.S. generally accepted accounting principles ("GAAP"), this press release also includes financial measures that are not calculated in accordance with GAAP. Our non-GAAP financial disclosure includes Adjusted Gross Profit and Adjusted EBITDA. We encourage investors to carefully consider our results under GAAP in conjunction with our supplemental non-GAAP information and the reconciliation between these presentations.

- Adjusted Gross Profit is a key performance measure that our management uses to assess our operational performance, as it represents the results of revenues and direct costs, which are key components of our operations. We believe that this non-GAAP financial measure is useful to investors and other interested parties in analyzing our financial performance because it reflects the gross profitability of our operations, and excludes the costs associated with our sales and marketing, product development, general and administrative activities and the impact of our financing methods and income taxes.

We calculate Adjusted Gross Profit as gross profit (loss) (as defined below) adjusted to exclude amortization of intangible assets and stock-based compensation allocated to cost of revenue. Adjusted Gross Profit should be viewed as a measure of operating performance that is a supplement to, and not a substitute for, operating income or loss from operations, net earnings or loss and other GAAP measures of income (loss) or profitability. Gross profit (loss) (as defined below) is the most directly comparable financial measure calculated in accordance with GAAP.

- Adjusted EBITDA is a key performance measure that our management uses to assess our financial performance and is also used for internal planning and forecasting purposes. We believe that this non-GAAP financial measure is useful to investors and other interested parties in analyzing our financial performance because it provides a comparable overview of our operations across historical periods. In addition, we believe that providing Adjusted EBITDA, together with a reconciliation of net loss to Adjusted EBITDA, helps investors make comparisons between our company and other companies that may have different capital structures, different tax rates, different operational and ownership histories, and/or different forms of employee compensation.

Adjusted EBITDA is used by our management team as an additional measure of our performance for purposes of business decision-making, including managing expenditures. Period-to-period comparisons of Adjusted EBITDA help our management identify additional trends in our financial results that may not be shown solely by period-to-period comparisons of net income (loss) or income (loss) from operations. Our management recognizes that Adjusted EBITDA has inherent limitations because of the excluded items, and may not be directly comparable to similarly titled metrics used by other companies.

The Company defines Adjusted EBITDA as net loss adjusted for amortization of intangible assets, stock-based compensation, depreciation, benefit from income taxes, interest income and restructuring expenses. These adjustments include non-cash items, significant non-recurring charges and/or other non-operating expenses that we do not believe are indicative of ongoing or future business operations.

Adjusted EBITDA should be viewed as a measure of operating performance that is a supplement to, and not a substitute for, operating income or loss from operations, net earnings or loss and other U.S. GAAP measures of income (loss). Additionally, it is not intended to be a measure of free cash flow for management's discretionary use, as it does not consider certain cash requirements such as interest and tax payments. Further, our definition of Adjusted EBITDA may differ from similarly titled measures used by other companies and therefore may not be comparable among companies. Net loss is the most directly comparable financial measure calculated in accordance with GAAP.

Full reconciliation of these non-GAAP measures to the most comparable GAAP measures is set forth in tabular form following the Condensed Consolidated Balance Sheets and Condensed Consolidated Statements of Operations.

Forward-Looking Statements

This press release contains forward-looking statements. In some cases, you can identify these statements by forward-looking words such as “aim,” “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “should,” “would,” or “will,” the negative of these terms, and other comparable terminology. These forward-looking statements, which are subject to risks, uncertainties, and assumptions about us, may include expectations and projections of our future financial performance, future tests or products, patient awareness of our products, technology, clinical studies, planned presentations at upcoming conferences, safety results, regulatory compliance, potential market opportunity, anticipated growth strategies, restructuring costs, sufficiency of cash on hand to finance our business, cost savings, budgets and strategies, satisfaction of closing conditions in the Samsung collaboration, planned integration with EHR systems, and growth and anticipated trends in our business.

These statements are only predictions based on our current expectations and projections about future events and trends. There are important factors that could cause our actual results, level of activity, performance, or achievements to differ materially and adversely from those expressed or implied by the forward-looking statements, including those factors and numerous associated risks discussed under the sections entitled “Risk Factors” in our Annual Report on Form 10-K for the period ended December 31, 2025 and in the Quarterly Report on Form 10-Q that we plan to file for the period ended March 31, 2026. Moreover, we operate in a dynamic and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results, level of activity, performance, or achievements to differ materially and adversely from those contained in any forward-looking statements we may make.

Forward-looking statements relate to the future and, accordingly, are subject to inherent uncertainties, risks, and changes in circumstances that are difficult to predict and many of which are outside of our control. Although we believe the expectations and projections expressed or implied by the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance, or achievements. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Except to the extent required by law, we undertake no obligation to update any of these forward-looking statements after the date of this press release to conform our prior statements to actual results or revised expectations or to reflect new information or the occurrence of unanticipated events.

GRAIL Contacts

Corporate Communications

Kristen Davis

Trish Rowland

pr@grail.com

Investor Relations

Alex Dobbin

Alexis Tosti

ir@grail.com

GRAIL, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(amounts in thousands, except share and per share data)

	March 31, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	\$ 69,344	\$ 249,727
Short-term marketable securities	753,761	654,703
Accounts receivables, net	20,345	18,295
Supplies	17,194	16,017
Prepaid expenses and other current assets	16,703	15,107
Total current assets	877,347	953,849
Property and equipment, net	47,853	51,813
Operating lease right-of-use assets	48,055	52,070
Restricted cash	6,974	6,974
Intangible assets, net	1,815,972	1,850,556
Other non-current assets	7,273	6,753
Total assets	\$ 2,803,474	\$ 2,922,015
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,668	\$ 2,083
Accrued liabilities	58,267	63,945
Operating lease liabilities, current portion	9,939	11,715
Other current liabilities	1,835	1,927
Total current liabilities	74,709	79,670
Operating lease liabilities, net of current portion	41,091	43,148
Deferred tax liability, net	184,035	218,583
Other non-current liabilities	2,953	2,752
Total liabilities	302,788	344,153
Preferred stock, par value of \$0.001 per share; 50,000,000 shares authorized, no shares issued and outstanding as of March 31, 2026 and December 31, 2025	—	—
Common stock \$0.001 par value per share, 1,500,000,000 shares authorized as of March 31, 2026 and December 31, 2025 and 41,134,219 and 40,331,360 shares issued and outstanding as of March 31, 2026 and December 31, 2025	41	40
Additional paid-in capital	12,803,640	12,786,848
Accumulated other comprehensive income	1,873	2,655
Accumulated deficit	(10,304,868)	(10,211,681)
Total stockholders' equity	2,500,686	2,577,862
Total liabilities and stockholders' equity	\$ 2,803,474	\$ 2,922,015

GRAIL, Inc.
Condensed Consolidated Statements of Operations
(unaudited)
(amounts in thousands, except share and per share data)

	Three Months Ended	
	March 31, 2026	March 31, 2025
Revenue:		
Screening revenue	\$ 39,832	\$ 29,133
Development services revenue	953	2,704
Total revenue	40,785	31,837
Costs and operating expenses:		
Cost of screening revenue (exclusive of amortization of intangible assets)	21,244	17,123
Cost of development services revenue	376	1,171
Cost of revenue — amortization of intangible assets	33,472	33,472
Research and development	48,021	53,625
Sales and marketing	30,668	34,979
General and administrative	42,769	45,074
Total costs and operating expenses	176,550	185,444
Loss from operations	(135,765)	(153,607)
Other income:		
Interest income	7,986	7,779
Other income (expense), net	256	(584)
Total other income, net	8,242	7,195
Loss before income taxes	(127,523)	(146,412)
Benefit from income taxes	34,336	40,199
Net loss	\$ (93,187)	\$ (106,213)
Net loss per share — Basic and Diluted	\$ (2.29)	\$ (3.10)
Weighted-average shares of common stock used in computing net loss per share:	40,640,879	34,308,435

GRAIL, Inc.
Reconciliation of GAAP to Non-GAAP Financial Measures
(unaudited)
(amounts in thousands)

	Three Months Ended	
	March 31, 2026	March 31, 2025
Gross loss ⁽¹⁾	\$ (14,307)	\$ (19,929)
Amortization of intangible assets	33,472	33,472
Stock-based compensation	533	762
Adjusted Gross Profit	<u>\$ 19,698</u>	<u>\$ 14,305</u>

⁽¹⁾ Gross loss is calculated as total revenue less cost of screening revenue (exclusive of amortization of intangible assets), cost of development services revenue and cost of revenue—amortization of intangible assets.

GRAIL, Inc.
Reconciliation of GAAP to Non-GAAP Financial Measures
(unaudited)
(amounts in thousands)

	Three Months Ended	
	March 31, 2026	March 31, 2025
Net loss	\$ (93,187)	\$ (106,213)
Adjusted to exclude the following:		
Amortization of intangible assets ⁽¹⁾	34,584	34,584
Stock-based compensation	16,793	16,211
Depreciation	4,210	4,695
Benefit from income tax expense	(34,336)	(40,199)
Interest income	(7,986)	(7,779)
Restructuring	—	(34)
Adjusted EBITDA	\$ (79,922)	\$ (98,735)

⁽¹⁾ Represents amortization of intangible assets, including developed technology and trade names.