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): November 4, 2026

GRAIL, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-42045**	**86-3673636**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

250 S. Mathilda Avenue, Suite 100, Sunnyvale, California 94086
(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 November 4, 2026, GRAIL, Inc. (the "Company" or "GRAIL") issued a press release announcing its financial results for the third quarter ended September 30, 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

Exhibit No.	Description
99.1	Press Release of GRAIL, Inc. dated November 4, 2026 (GRAIL Reports Third 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: November 4, 2026

By: /s/ Aaron Freidin

Name: Aaron Freidin

Title: Chief Financial Officer

GRAIL

NEWS RELEASE **Exhibit 99.1**

GRAIL Reports Third Quarter 2026 Financial Results

FDA Advisory Committee Voted in Favor of Approval of GRAIL's Galleri Multi-Cancer Early Detection Test

Q3 Galleri® Test Volume Increased ~24% to More Than 56,000 Year-Over-Year, Year-to-Date Test Volume Increased ~36% to More Than 174,000

Q3 Galleri Revenue Grew 14% Year-Over-Year to $37.3 Million

SUNNYVALE, Calif. — Nov. 4, 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 third quarter of 2026.

Galleri test revenue for the third quarter grew 14% year-over-year to $37.3 million, and total revenue grew 4% year-over-year to $37.5 million. Galleri test volume for the third quarter grew approximately 24% year-over-year to more than 56,000 tests. Total Galleri test volume and revenue for the nine months ended September 30, 2026 grew 36% year-over-year to more than 174,000 tests and 24% to $119.7 million, respectively. Net loss for the third quarter was $103.6 million. Gross loss was $18.1 million. Non-GAAP adjusted gross profit was $15.9 million, and non-GAAP adjusted EBITDA was $(92.6) million.[1]

"GRAIL achieved significant milestones this quarter including a favorable vote for approval of Galleri at the FDA Advisory Committee," said Josh Ofman, MD, MSHS, Chief Executive Officer of GRAIL. "This achievement strengthens the foundation for Galleri as we continue on our path towards potential regulatory approval, broader access and reimbursement. We are seeing continued commercial momentum as a number of positive advancements, consistent market education, and promotional pricing initiatives gain traction."

For the three months ended September 30, 2026, as compared to the three months ended September 30, 2025, GRAIL reported:

- **Revenue:** Total revenue, comprised of screening and development services revenue, was $37.5 million, an increase of $1.3 million or 4%.
- **Net loss:** Net loss was $103.6 million, an increase of $14.6 million or 16%.
- **Gross loss:** Gross loss was $18.1 million, an increase of $4.4 million or 32%.
- **Adjusted gross profit[1]:** Adjusted gross profit was $15.9 million, a decrease of $4.1 million or 20%.
- **Adjusted EBITDA[1]:** Adjusted EBITDA was $(92.6) million, an increase in adjusted EBITDA loss of $20.9 million or 29%.
- **Cash position:** Cash, cash equivalents, and short-term marketable securities totaled $788.7 million as of September 30, 2026.

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

Recent business highlights include:

- Announced a favorable vote for approval of the Galleri test from the FDA's Molecular and Clinical Genetics Panel of the Medical Device Advisory Committee (the “Advisory Committee”) in September. The company anticipates an FDA decision by early Q1 2027.

- Published results from the NHS-Galleri trial in The New England Journal of Medicine and Nature Medicine, and final results from the PATHFINDER 2 study in Nature Medicine. The publications report clinical utility, test performance, and safety results from approximately 175,000 participants enrolled in the UK and North America. The results across the studies demonstrated:
    - Substantially increased cancer detection (4-6.5x more cancers detected) with robust performance, a favorable safety profile and consistent clinical performance across the two large trials.
    - Additionally, the NHS-Galleri trial demonstrated a substantial reduction of >20% in Stage IV diagnoses of 12 prespecified aggressive cancers and a 25% reduction in cancers diagnosed after emergency presentation in the Galleri arm compared to the control arm.
    - In the NHS-Galleri trial, Galleri added to standard-of-care screening detected more Stage I-II cancers than the UK national screening program found all cancers across all stages.

These data support the potential of multi-cancer early detection screening at population scale to identify cancers before symptoms appear — when they can be treated more easily and are potentially curable.

Conference Call and Webcast
A webcast and conference call will be held today, Nov. 4, 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 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 Sunnyvale, Calif. 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
The GRAIL 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 Food and Drug Administration. The GRAIL 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, Adjusted Gross Margin 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 and Adjusted Gross Margin are key performance measures that our management uses to assess our operational performance, as they represent the results of revenues and direct costs, which are key components of our operations. We believe that these non-GAAP financial measures are useful to investors and other interested parties in analyzing our financial performance because they reflect the gross profitability of our operations, and exclude 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. We calculate Adjusted Gross Margin as Adjusted Gross Profit divided by total revenue.

- 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, intangible and other assets impairment, 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 statements related to the potential benefits, uses and impacts of the Galleri test, comparability of clinical study results to a real world setting, benefits of population screening with existing or future versions of Galleri, commercial and expansion plans, growth trends and reimbursement, potential regulatory decision timeline and outcome, and impacts of our commercial strategies, among others.

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 year ended December 31, 2025 and our subsequent Quarterly Reports on Form 10-Q. 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, financial condition and success in our business strategies and operations 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.

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

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 28,976	$ 249,727
Short-term marketable securities	759,700	654,703
Accounts receivable, net	18,998	18,295
Supplies	18,475	16,017
Prepaid expenses and other current assets	16,649	15,107
Total current assets	842,798	953,849
Property and equipment, net	42,691	51,813
Operating lease right-of-use assets	84,073	52,070
Restricted cash	6,943	6,974
Intangible assets, net	1,746,806	1,850,556
Other non-current assets	7,251	6,753
Total assets	$ 2,730,562	$ 2,922,015
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 10,209	$ 2,083
Accrued liabilities	76,305	63,945
Operating lease liabilities, current portion	6,272	11,715
Other current liabilities	1,546	1,927
Total current liabilities	94,332	79,670
Operating lease liabilities, net of current portion	79,576	43,148
Deferred tax liability, net	99,742	218,583
Other non-current liabilities	3,393	2,752
Total liabilities	277,043	344,153
Preferred stock, par value of $0.001 per share; 50,000,000 shares authorized, no shares issued and outstanding as of September 30, 2026 and December 31, 2025	—	—
Common stock $0.001 par value per share, 1,500,000,000 shares authorized as of September 30, 2026 and December 31, 2025 and 44,753,179 and 40,331,360 shares issued and outstanding as of September 30, 2026 and December 31, 2025	45	40
Additional paid-in capital	12,970,363	12,786,848
Accumulated other comprehensive income	1,794	2,655
Accumulated deficit	(10,518,683)	(10,211,681)
Total stockholders' equity	2,453,519	2,577,862
Total liabilities and stockholders' equity	$ 2,730,562	$ 2,922,015

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

	Three Months Ended		Nine Months Ended	
	September 30, 2026	September 30, 2025	September 30, 2026	September 30, 2025
Revenue:				
Screening revenue	$ 37,269	$ 32,807	$ 119,743	$ 96,319
Development services revenue	266	3,387	3,264	7,256
Total revenue	37,535	36,194	123,007	103,575
Costs and operating expenses:				
Cost of screening revenue (exclusive of amortization of intangible assets)	22,032	15,910	66,623	52,379
Cost of development services revenue	141	544	951	2,216
Cost of revenue — amortization of intangible assets	33,473	33,473	100,417	100,417
Research and development	44,073	48,647	139,523	148,898
Sales and marketing	41,695	25,503	110,020	89,021
General and administrative	40,740	37,408	134,217	120,396
Intangible and other assets impairment	—	—	25,423	28,000
Total costs and operating expenses	182,154	161,485	577,174	541,327
Loss from operations	(144,619)	(125,291)	(454,167)	(437,752)
Other income:				
Interest income	7,843	6,107	23,059	20,695
Other income (expense), net	(545)	466	(444)	(929)
Total other income, net	7,298	6,573	22,615	19,766
Loss before income taxes	(137,321)	(118,718)	(431,552)	(417,986)
Benefit from income taxes	33,753	29,741	124,550	108,811
Net loss	$ (103,568)	$ (88,977)	$ (307,002)	$ (309,175)
Net loss per share — Basic and Diluted	$ (2.21)	$ (2.46)	$ (6.84)	$ (8.73)
Weighted-average shares of common stock used in computing net loss per share:	46,777,729	36,124,256	44,858,893	35,415,266

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

	Three Months Ended		Nine Months Ended	
	September 30, 2026	September 30, 2025	September 30, 2026	September 30, 2025
Gross loss [1]	$ (18,111)	$ (13,733)	$ (44,984)	$ (51,437)
Amortization of intangible assets	33,473	33,473	100,417	100,417
Stock-based compensation	552	271	1,734	1,450
Adjusted Gross Profit	$ 15,914	$ 20,011	$ 57,167	$ 50,430
Adjusted Gross Margin [2]	42%	55%	46%	49%

[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.
[2] Adjusted Gross Margin is calculated as adjusted gross profit divided by total revenue.

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

	Three Months Ended		Nine Months Ended	
	September 30, 2026	September 30, 2025	September 30, 2026	September 30, 2025
Net loss	$ (103,568)	$ (88,977)	$ (307,002)	$ (309,175)
Adjusted to exclude the following:				
Amortization of intangible assets [1]	34,583	34,583	103,750	103,750
Stock-based compensation	14,109	14,139	50,459	44,518
Intangible and other assets impairment [2]	—	—	25,423	28,000
Depreciation	3,892	4,399	12,207	13,686
Benefit from income taxes	(33,753)	(29,741)	(124,550)	(108,811)
Interest income	(7,843)	(6,107)	(23,059)	(20,695)
Restructuring	—	—	—	(34)
Adjusted EBITDA	$ (92,580)	$ (71,704)	$ (262,772)	$ (248,761)

[1] Represents amortization of intangible assets, including developed technology and trade names.
[2] Represents the impairment charge related to the deferred asset recognized in connection with the Samsung SPA in the second quarter of 2026 and the in-process research and development ("IPR&D") impairment charge in the prior period.