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): January 12, 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.)**

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 January 12, 2026, GRAIL, Inc. (the "Company") plans to present a corporate update and preliminary financial information for the quarter and year ended December 31, 2025 at the 2026 J.P. Morgan Healthcare Conference. A copy of the presentation that will be used is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 2.02 of this Current Report on Form 8-K and the exhibit 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 exhibit 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.

99.1*	Results of operations and financial condition.

* Filed herewith

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: January 12, 2026

By: /s/ Aaron Freidin

Name: Aaron Freidin

Title: Chief Financial Officer

GRAIL

44th Annual J.P. Morgan Healthcare Conference

January 12, 2026

Bob Ragusa, Chief Executive Officer
Josh Ofman, President

This presentation 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, technology, clinical studies, including early or preliminary study results, regulatory compliance, potential market opportunity, anticipated growth strategies, sufficiency of cash on hand to finance our business and expected cash runway, strategies, budgets 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 section entitled “Risk Factors” in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2025, June 30, 2025 and September 30, 2025 and our Annual Report on Form 10-K for the period ended December 31, 2024. 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 presentation to conform our prior statements to actual results or revised expectations or to reflect new information or the occurrence of unanticipated events.

This presentation contains certain preliminary unaudited financial information. These amounts are preliminary, have not been subject to review by the Company's independent registered public accounting firm, and are subject to change pending completion of the Company's audited financial statements for the quarter and year ended December 31, 2025. Actual results could be materially different from the preliminary unaudited financial information. Additional information and disclosures would be required for a more complete understanding of the Company's financial position and results of operations as of and for the quarter and year ended December 31, 2025.

Agenda

Business Review	Bob Ragusa, Chief Executive Officer
Galleri Differentiation & Opportunity	Josh Ofman, President
Q&A	

GRAIL at a glance

>4 years
In market with Galleri MCED test

$147-148M
2025 revenue

>800k
Clinical and commercial tests completed to-date

1M+
Test capacity at RTP site

>475k
Commercial Galleri® tests sold to-date

$904M
Cash position[1] as of year end 2025

Galleri is the only MCED test with demonstrated performance in the intended use population

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MCED: multi-cancer early detection; PMA: Pre-market approval. [1] Unrestricted cash, cash equivalents, and short-term marketable securities. Preliminary unaudited financial information. These amounts are preliminary, have not been subject to review by the Company's independent registered public accounting firm, and are subject to change pending completion of the Company's audited financial statements for the quarter and year ended December 31, 2025. Additional information and disclosures would be required for a more complete understanding of the Company's financial position and results of operations as of and for the quarter and year ended December 31, 2025.

Upcoming

- Complete PMA submission
- Present full datasets from 140k randomized controlled NHS-Galleri trial and 35k PATHFINDER 2 study
- Continue to expand US commercial market
- Advance Galleri in international markets

Strengthened balance sheet

$435M raised in Q4, and $110M anticipated from Samsung upon close

$325M
Private placement

$110M
ATM sales

$110M
Samsung[1] strategic investment

Close anticipated in January

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[1] Samsung C&T and Samsung Electronics

Strong commercial momentum

Adoption trends

>185k total Galleri volume
35% growth over 2024

~17k prescribers[1]
>30% growth over 2024

>30% repeat orders[2]

Growth drivers

- Partnerships enable ordering and execution simplicity
  - Quest Diagnostics, athenahealth, RECURO HEALTH
- Health systems integrate Galleri into workflows
  - Intermountain Health, HCA Healthcare, RUSH, Mercy, Community Health Network
- Digital health partners expand access
  - Function, everlywell
- Distributor partners tap international markets
  - SAMSUNG, ONCOTEST, MEDCAN

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[1] Unique prescribers since launch, as of December 31, 2025.
[2] As of December 31, 2025. Repeat volume as percentage of total Galleri volume since launch.

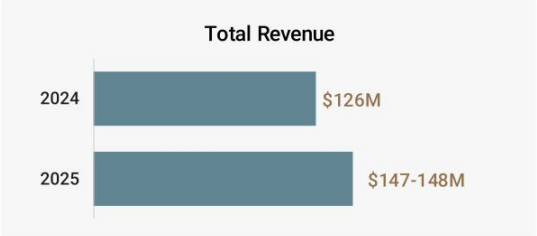
Financial profile

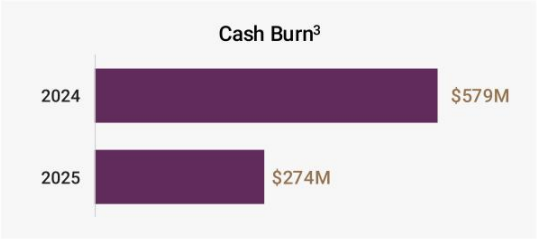
Revenue

	US Galleri Revenue	Total Revenue
4Q 2025 *Year over year*	$41-42M *+30-33%*	$43-44M *+13-15%*
FY 2025 *Year over year*	$136-137M[1] *+25-26%*	$147-148M *+17-18%*

Cash position

- **$904M** as of December 31, 2025[2]





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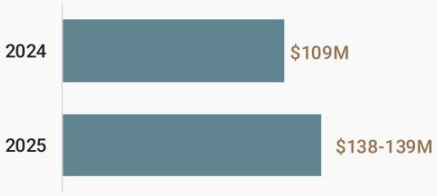
[1] Total global Galleri revenue in FY2025 was $138-139M. [2] Unrestricted cash, cash equivalents, and short-term marketable securities.
[3] Cash burn is calculated as the change in cash, cash equivalents, marketable securities, and restricted cash, excluding net proceeds from the PIPE and ATM offerings and including cash received from employee ESPP contributions.
All 2025 financial information represents preliminary unaudited financial information. These amounts are preliminary, have not been subject to review by the Company's independent registered public accounting firm, and are subject to change pending completion of the Company's audited financial statements for the quarter and year ended December 31, 2025. Additional information and disclosures would be required for a more complete understanding of the Company's financial position and results of operations as of and for the quarter and year ended December 31, 2025.

2026 guidance

Total Galleri revenue



2026 guidance: 22–32% growth

Cash burn[1]

2026 guidance: <$300M

Runway[2] into 2030

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[1] Cash burn is calculated as the change in cash, cash equivalents, marketable securities, and restricted cash, excluding net proceeds from the PIPE and ATM offerings and including cash received from employee ESPP contributions. All 2025 financial information represents preliminary, unaudited financial information. These amounts are preliminary, have not been subject to review by the Company's independent registered public accounting firm, and are subject to change pending completion of the Company's audited financial statements for the quarter and year ended December 31, 2025. Additional information and disclosures would be required for a more complete understanding of the Company's financial position and results of operations as of and for the quarter and year ended December 31, 2025.

Population-scale MCED screening could reduce cancer burden

Only 14% of cancers
are found with standard of care screening[1]

>70% of cancer deaths
are from cancers without screening[2]

Galleri®
Multi-cancer early detection

Adding Galleri to standard of care single-cancer screenings could enable screen detection of ~60% of cancers[3]

Future of MCED

Broadly Accessible | Large Public Health Benefit | Strong Value Proposition

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[1] NORC at the University of Chicago. Based on five-year survival rate.
[2] US National Center for Health Statistics, with eligibility for and adherence to guideline based low-dose computed tomography screening for lung cancer.
[3] Nabavizadeh et al, *Safety and Performance of a Multi-Cancer Early Detection (MCED) Test in an Intended Use Population: Initial Results from the Registrational PATHFINDER 2 Study*, European Society of Medical Oncology Congress 2025.

Defining the field: Galleri is highly differentiated

Simple blood test for individuals at elevated risk of cancer

Intended to complement current single-cancer screening tests

✔ High PPV (62%) ✔ Low false positive rate (0.4%) ✔ High CSO accuracy (>90%)

✔ Only MCED validated in screening population

Technology	Delivery	Clinical evidence & conviction
Methylation patterns reveal a shared cancer signal	State of the art, highly- automated CAP/CLIA laboratory	Pursuing FDA approval with breakthrough designation
High specificity and PPV and accurate signal origin prediction	1M+ test capacity per year, can expand substantially without additional footprint	Extensive validation in screening populations, consistent results
Minimizes overdiagnosis	Substantial fixed cost leverage will enable price reductions over time	RCT clinical utility, largest Medicare study
Data flywheel enables test improvements		>4 years in market as an LDT; >475k commercial tests performed

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PPV: positive predictive value. CSO: cancer signal of origin. CAP/CLIA: College of American Pathologists / Clinical Laboratory Improvement Amendments certified. RCT: Randomized control trial. LDT: Lab developed test.
Nabavizadeh et al, *Safety and Performance of a Multi-Cancer Early Detection (MCED) Test in an Intended Use Population: Initial Results from the Registrational PATHFINDER 2 Study*, European Society of Medical Oncology Congress 2025

Strong performance data & robust PMA package

PATHFINDER 2

7x increase in cancer detection rate when added to A/B rated single cancer screenings[1]

>50% cancers detected were stage 1 & 2

~62% positive predictive value

74% episode sensitivity for 12 deadly cancers responsible for 2/3 deaths

>90% CSO accuracy

No serious, study-related adverse events

PMA package

First 25,000 PATHFINDER 2 participants
1 year follow up

+

NHS-Galleri prevalent screening round data for 140,000 participants
1 year follow up

+

Bridging data[2]

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[1] Results from PATHFINDER 2 demonstrated a 3x increase in cancer detection rate when Galleri was added to single cancer screenings with USPSTF A, B, and C ratings. [2] Analyses bridging clinical trial version to PMA version of Galleri test. Nabavizadeh et al, *Safety and Performance of a Multi-Cancer Early Detection (MCED) Test in an Intended Use Population: Initial Results from the Registrational PATHFINDER 2 Study*, European Society of Medical Oncology Congress 2025.

Evidence base expanding with full study readouts and clinical utility data

2026

Full PATHFINDER 2 readout

35,000 PATHFINDER 2 participants

1 year follow up

Full NHS-Galleri readout

140,000 individual randomized, controlled longitudinal clinical study

3 annual Galleri tests or standard of care

1 year follow-up

Enrolling

REACH (Galleri-Medicare) study

50,000 individual, single-arm study with synthetic matched control

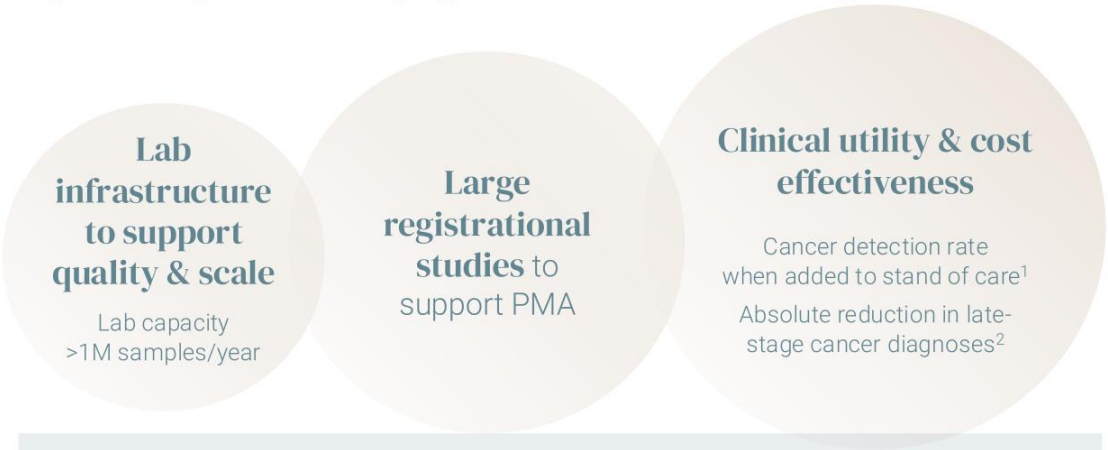
3 annual Galleri tests

1 year follow up

Near-term growth drivers prior to broad reimbursement

- **Expanding awareness** of MCED
- **Significant differentiation** for Galleri
- **Increasing patient, provider & employer conviction** with data and potential regulatory approval
- **Further integration into health systems** including electronic ordering
- **Growth of digital health market**

Progressing towards population scale testing



Widely-supported & stakeholder-driven MCED legislation could enable Medicare coverage for Galleri after FDA approval

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[1] PATHFINDER 2 and Galleri-Medicare (REACH) endpoint. [2] NHS-Galleri and Galleri-Medicare (REACH) endpoint.

Advancing towards our vision of population-scale multi-cancer early detection

Near term milestones

- Complete modular PMA submission in Q1 2026
- Present full data from longitudinal randomized, controlled NHS-Galleri trial in mid-2026 (clinical utility and performance)
- Present full results from PATHFINDER 2 study (35k participants) in mid-2026

Q&A

Advancing towards our vision of population-scale multi-cancer early detection