

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 15, 2025

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 January 15, 2025, GRAIL, Inc. (the “Company”) plans to present a corporate update and preliminary financial information for the quarter and year ended December 31, 2024 at the 2025 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

[Presentation of GRAIL, Inc. dated January 15, 2025.](#)

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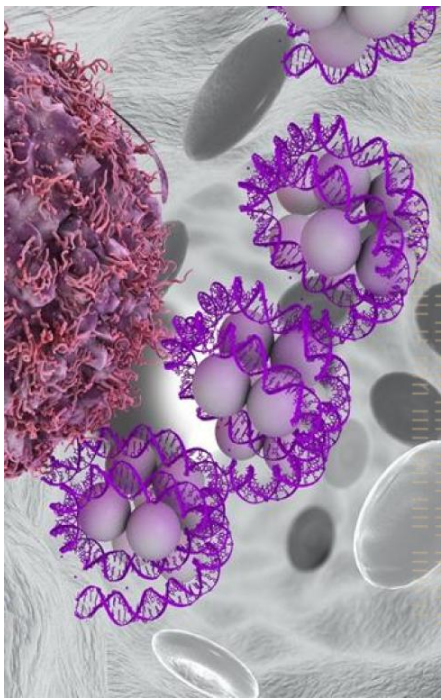
**SIGNATURES**

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 15, 2025

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



GRAIL

# 43rd Annual J.P. Morgan Healthcare Conference

Bob Ragusa, CEO

January 2025

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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, regulatory compliance, potential market opportunity, anticipated growth strategies, restructuring costs, sufficiency of cash on hand to finance our business, cost savings, budgets and strategies, restructuring and stock-based compensation costs, impact of the restructuring on our operations 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 section entitled "Risk Factors" in our Quarterly Report on Form 10-Q for the period ended September 30, 2024 (the "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 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 also contains preliminary select financial results which are unaudited and subject to change. We will report our final and complete fourth quarter and full-year 2024 financial results in February 2025. The Company has not completed its financial closing procedures for the quarter or year ended December 31, 2024, and its actual results could be materially different from these preliminary financial results.

# GRAIL highlights

## Focused on detecting cancer early, when it can be cured<sup>1</sup>

- Current recommended screening is limited, and most asymptomatic deadly cancers are found too late
- Multi-cancer early detection (MCED) is the solution for effective population screening

## Uniquely suited to address one of the most meaningful opportunities in healthcare

- Galleri® was designed for population scale screening
- Expansive evidence program setting the standard for MCED development
- Targeting completion of modular PMA submission in 1H 2026

## Leader in expansive global market

- >290,000 commercial Galleri tests sold through year end 2024
- Galleri is routinely detecting asymptomatic deadly cancers in clinical practice today
- Expanding commercial Galleri adoption in US, with large global opportunity
- Prepared for commercial scale with recent launch of new Galleri version

## Cancers are often found too late

**~70%**

Of cancer deaths result from cancers without recommended screening<sup>1</sup>

**86%**

Of cancers are not found through recommended screening<sup>2</sup>

**~4x**

Survival rate when diagnosed **EARLY**<sup>3</sup>

<sup>1</sup> Among individuals 50-79 years old. Assumes screening is available for all prostate, breast, cervical, and colorectal cancer cases and 43% of lung cancer cases (based on estimated proportion of lung cancers that occur in screen-eligible individuals older than 40 years). Estimated deaths per year in 2021 from American Cancer Society Cancer Facts and Figures 2021. Available at: <http://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2021/cancer-facts-and-figures-2021.pdf>. Data on file GA-2021-0065. <sup>2</sup> NORC at the University of Chicago. Based on five-year survival rate. <sup>3</sup> Data on file from Surveillance, Epidemiology, and End Results (SEER) 18 Regs Research Data, Nov 2023 Submission. Includes persons aged 50-79. Estimated deaths per year in 2020 from American Cancer Society Cancer Facts and Figures 2020. Available at: [www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2020/cancer-facts-and-figures-2020.pdf](http://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2020/cancer-facts-and-figures-2020.pdf).

# Galleri®: Clinically-validated, commercially-available MCED test<sup>1</sup>

-  Simple blood test
-  Very low false positive rate
-  Predicts cancer signal origin
-  Identifies aggressive cancers



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<sup>1</sup> We believe that the results of our large CCGA clinical study provides clinical validation for Galleri. Klein, et al, Clinical Validation of a targeted methylation-based multi-cancer early detection test using an independent validation set, *Annals of Oncology* 2021. Galleri was further tested in our PATHFINDER implementation study. Schrag, et al. Blood-based tests for multicancer early detection (PATHFINDER): a prospective cohort study, *The Lancet* 2023.

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# PATHFINDER results: Galleri *more than doubled* the number of cancers identified when added to standard of care screening

## Impact with Galleri

**>2x**

Cancers identified

**~1 of 2**

Galleri-detected new cancers were early stage<sup>1</sup>

**~7 of 10**

Galleri-detected cancers have no routine screening

No serious adverse events



## Galleri performance

**43%**

Positive predictive value (PPV)

PPVs for: FIT 1.2%, LDCT 3.8%, mammography 4.4%<sup>2,3,4</sup>

**88%**

Localization accuracy

Galleri performance data: Schrag, et al. PATHFINDER: A prospective study of a multi-cancer early detection blood test. ESMO 2022.

Localization: cancer signal of origin prediction accuracy of first or second predicted classifications in true positive population.

<sup>1</sup> Proportion of MCEd-detected new cancers without USPSTF-recommended (standard of care) cancer screening identified in stage 1 or 2. <sup>2</sup> Pickhardt, P.J. Emerging stool-based and blood-based non-invasive DNA tests for colorectal cancer screening: the importance of cancer prevention in addition to cancer detection. *Abdom Radiol* 41, 1441–1444 (2016). <sup>3</sup> *N Engl J Med*. 2013 May 23;368(21): 1980–1991. <sup>4</sup> USPSTF. 2016. Lehman, et al. *Radiology*. 2017;283(1):49-58.

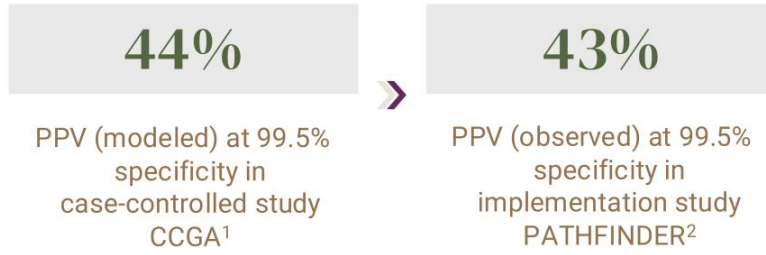
FIT: fecal immunochemical test. LDCT: low dose computed tomography.

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# Galleri performance has replicated across studies



**New version  
enables  
scalability  
along with CSO  
enhancements**

*Launched  
December 2024*



<sup>1</sup> Klein, et al. Clinical Validation of a targeted methylation-based multi-cancer early detection test using an independent validation set. *Annals of Oncology* 2021. CCGA study. Galleri was further tested in our PATHFINDER implementation study. <sup>2</sup> Schrag, et al. Blood-based tests for multicancer early detection (PATHFINDER): a prospective cohort study. *The Lancet* 2023. CSO: cancer signal of origin.

## The global addressable market is significant



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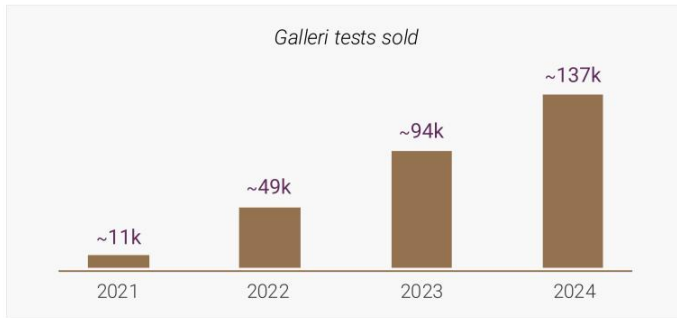
<sup>1</sup> WHO, All Cancers Fact Sheet 2020. <sup>2</sup> ACS, Cancer Statistics 2022, <https://doi.org/10.3322/caac.21708>. <sup>3</sup> JAMA Oncol. 2023;9(4):465-472. doi:10.1001/jamaoncol.2022.7826. Estimated screening populations represent adult population between 50-79 years of age. US Census and international government statistics. Includes certain developed countries worldwide.

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# Robust Galleri adoption and strong partnerships

- FY24 commercial tests sold: **137K**
- Ordering providers<sup>1</sup>: **>13k**
- Repeat orders<sup>2</sup>: **>20%**



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<sup>1</sup> As of December 31, 2024.

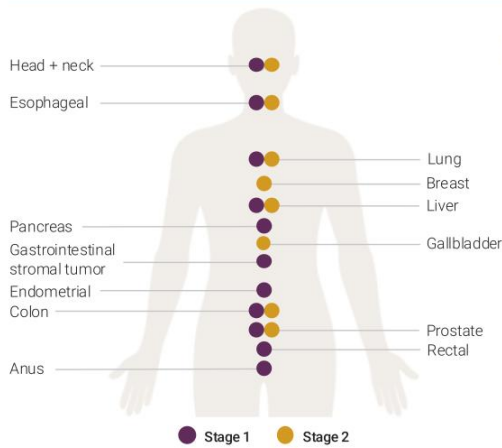
<sup>2</sup> As of December 31, 2024. Repeat volume as percentage of total Galleri volume since launch.

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# Commercial use of Galleri is finding early cancers

## EXAMPLES OF CONFIRMED EARLY-STAGE CANCERS



I just want to encourage others to get tested even when you're feeling fine. That's the best time – the best time – to do something like this. ... **If I had waited another two to three months, when my throat started to hurt, the doctors have told me we'd be having a much different conversation.**

Tad Carper, SVP Dallas Cowboys & Galleri patient  
December 2024, WFAA-TV Dallas



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Data based on confirmed cancers through June 2023; Healthcare provider-defined end to the diagnostic evaluation, stage 1 or 2. Cases of early-stage Leukemia, Lymphoma and Myeloma were also confirmed.

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## Financial profile

### FY 2024 Revenue

- \$124 - 126M total revenue
- \$107 - 110M US Galleri revenue

### Cash balance

- \$767M as of December 31, 2024<sup>1</sup>
- Runway into 2028

2025 U.S. Galleri sales

**20-30% growth**

Projected cash burn 2025

**<\$320M**

# Significant investments provide market lead

## Scalable lab operations

~170,000 sf CAP-accredited, CLIA-certified lab facilities

Sufficient capacity to support multiple years of growth

## Leading clinical program

Technology developed through comprehensive head-to-head discovery study

Unprecedented clinical program includes ~385,000 participants

## Demonstrated execution

>600,000 clinical and commercial tests through our labs

>300 publications and presentations

## Our vision: Population-scale multi-cancer early detection



Laying the groundwork today  
**to intercept the opportunity**





# Focused on strategic priorities & cost management

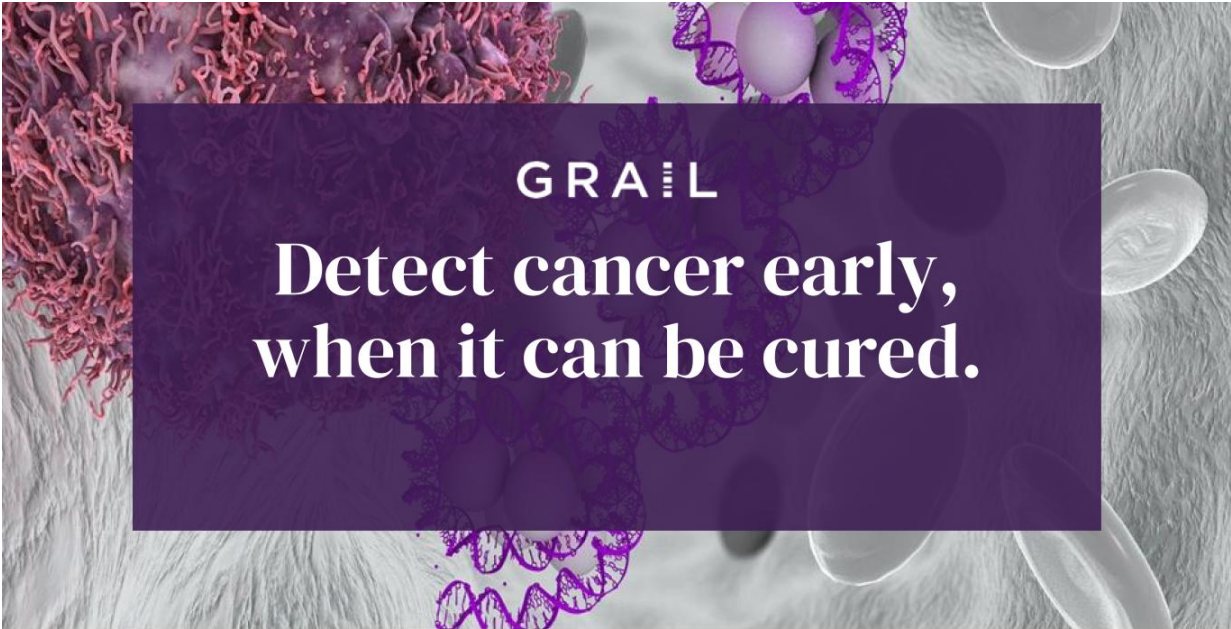


## Strategic priorities

- Seek FDA approval of Galleri
- Pursue CMS coverage and broad commercial reimbursement for Galleri

## Upcoming catalysts

- Registrational trial data (PATHFINDER 2 and NHS)
- Completion of modular PMA submission to FDA



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Detect cancer early,  
when it can be cured.

