GRAIL Reports First Quarter 2025 Financial Results

May 13, 2025

Q1 U.S. Galleri Revenue Grew 22% Year-Over-Year to $28.7 Million

GRAIL Announces Positive Top-Line Results From the Prevalent Screening Round of the NHS-Galleri Trial

Cash Position of $677.9 Million Provides Runway Into 2028

MENLO PARK, Calif., May 13, 2025 /PRNewswire/ -- 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 2025.

Total revenue in the first quarter was $31.8 million, representing 19% growth year over year, and Galleri revenue was $29.1 million, representing 24% growth year over year. U.S. Galleri revenue was $28.7 million, representing 22% growth year over year. Net loss for the quarter was $106.2 million, which includes amortization of Illumina acquisition-related intangible items of $34.6 million. Gross loss was $19.9 million. Adjusted gross profit was $14.3 million, and adjusted EBITDA was $(98.7) million.[1]

"We are pleased with the continued U.S. commercial growth of Galleri, with more than 37,000 Galleri tests completed in the first quarter of 2025, as well as recent steps to streamline the test ordering process and increase test access," said Bob Ragusa, Chief Executive Officer at GRAIL. "We remain focused on developing the market for population scale multi-cancer early detection, advancing Galleri to unlock broad access, and cost efficiency."

For the three months ended March 31, 2025, as compared to the three months ended March 31, 2024, GRAIL reported:

- **Revenue:** Total revenue, comprised of screening and development services revenue, was $31.8 million, an increase of $5.1 million or 19%.
- **Net loss:** Net loss was $106.2 million, an improvement of $112.7 million or 51%.
- **Gross loss:** Gross loss was $19.9 million, an improvement of $2.0 million or 9%.
- **Adjusted gross profit[1]:** Adjusted gross profit was $14.3 million, an increase of $2.3 million or 19%.
- **Adjusted EBITDA[1]:** Adjusted EBITDA was $(98.7) million, an improvement of $53.2 million or 35%.

Cash position: Cash, cash equivalents, restricted cash and short-term marketable securities totaled $677.9 million as of March 31, 2025.

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

NHS-Galleri Trial Update

GRAIL recently completed a review of Galleri test performance results in the intervention arm from the prevalent screening round of the registrational NHS-Galleri trial. The prevalent screening round is the first round of blood draws (of the three total blood draw rounds in the trial) with one year of follow up.

Data from the prevalent screening round showed a substantially higher positive predictive value (PPV) than that observed in the PATHFINDER study, which was previously published in *The Lancet*. Cancer signal of origin (CSO) accuracy and specificity were consistent with that observed in the PATHFINDER study. In PATHFINDER, Galleri demonstrated a PPV of 43%, CSO accuracy of 88%, and specificity of 99.5%. There were no serious safety concerns in the NHS-Galleri prevalent screening round, also consistent with the PATHFINDER study.

"We are very pleased with these initial results from the NHS-Galleri trial, which is the largest randomized controlled trial of any MCED test," added Ragusa. "We plan to share registrational data from the PATHFINDER 2 study later this year and final results from the NHS-Galleri trial in mid-2026."

The NHS-Galleri trial was designed with three consecutive years of screening in order to achieve the primary endpoint, which is the absolute reduction in the number of late stage (stages 3 and 4) cancer diagnoses. Final clinical utility results from all three years of the trial are expected in mid-2026. GRAIL plans to submit data from the prevalent screening round of the NHS-Galleri trial as part of our premarket approval application in the first half of

2026.

Additional recent business highlights include:

- Data presented at American Association for Cancer Research (AACR) 2025 in April include:
  - Real-world data in 100,000 patients demonstrating the Galleri test's ability to simultaneously screen for multiple cancers, as well as its high accuracy of cancer signal of origin prediction to support efficient diagnostic evaluation. Test performance in this real world analysis was consistent with that observed in prior clinical studies. (https://assets.grail.com/wp-content/uploads/2025/04/7202.Matrana.AACR-2025-RWE-100K_Poster_Final.pdf)
  - A modeling analysis highlighting that individuals receiving a negative MCED test have a reduced risk of cancer diagnosis for one year post-blood draw. The risk increases as the screening interval extends beyond one year, highlighting the importance of an annual MCED screening. (https://assets.grail.com/wp-content/uploads/2025/04/7132.Westgate.AACR-2025-Post-Test-Analysis_Poster_FINAL.pdf)
- Partnership with athenahealth to integrate ordering of the Galleri test into AthenaCoordinator Core, a leading cloud-based electronic health record (EHR) platform, helping to streamline the test ordering process and delivery of test results for more than 160,000 U.S. providers, and increase patient access.
- Partnership with award-winning actress Kate Walsh to launch Generation Possible, an educational initiative to raise awareness of MCED testing. More information about Generation Possible is available at genpossible.com, including Walsh's personal connection to cancer, details about MCED testing and access to important resources.

Conference Call and Webcast
A webcast and conference call will be held today, May 13, 2025, 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 do not 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.

* Sensitivity in CCGA study participants with – Pancreas cancer: 83.7% overall (61.9% stage I, 60.0% stage II, 85.7% stage III, 95.9% stage IV). Esophagus cancer 85.0% overall (12.5% stage I, 64.7% stage II, 94.7% stage III, 100% stage IV). Ovary cancer: 83.1% overall (50.0% stage I, 80.0% stage II, 87.1% stage III, 94.7% stage IV). Liver/bile duct cancer: 93.5% overall (100% stage I, 70.0% stage II, 100% stage III, 100% stage IV).

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, this press release also includes financial measures that are not calculated in accordance with U.S. generally accepted accounting principles ("GAAP"). Our non-GAAP financial disclosure includes Adjusted Gross Profit (Loss) 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 (Loss) 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 indirect costs associated with our sales and marketing, product development, general and administrative activities, and depreciation and amortization, and the impact of our financing methods and income taxes.

  We calculate Adjusted Gross Profit (Loss) 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 (Loss) 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. The following table presents a reconciliation of gross loss, the most directly comparable financial measure calculated in accordance with GAAP, to Adjusted Gross Profit.

- 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 income (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.

  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. The following table presents a reconciliation of net loss, the most directly comparable financial measure calculated in accordance with U.S. GAAP, to Adjusted EBITDA on a consolidated basis.

Full reconciliation of these non-GAAP measures to the most comparable GAAP measures is set forth in tabular form below.

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, 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 sections entitled "Risk Factors" in our Annual Report on Form 10-K for the period ended December 31, 2025 and our Quarterly Report on Form 10-Q for the period ended March 31, 2025. For example, results from our ongoing or future studies, including the final results from our NHS-Galleri trial may be inconsistent with certain results obtained from our completed studies or from interim results initially reported on those studies, including the results reported from the prevalent screening round or our NHS-Galleri Trial. The NHS-Galleri trial was designed as three annual blood draws, plus 12 months follow up, in order to evaluate Galleri's ability to move forward the stage of cancer diagnosis relative to standard of care (primary endpoint). Cancer screening trials designed to show clinical utility, like the NHS-Galleri trial, are commonly conducted over three years with an annual screening interval, because results can be influenced by the fact that the first screening round detects many prevalent late-stage asymptomatic cancers that have not yet been diagnosed. This and other factors could cause final results of the three year trial to differ from a review of the first round results. 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.

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Condensed Consolidated Balance Sheets

(Unaudited)

(in thousands, except for per share data)

	March 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 133,895	$ 214,234
Short-term marketable securities	540,688	549,236
Accounts receivables, net	19,309	20,312
Supplies	18,716	18,632
Prepaid expenses and other current assets	15,047	17,447
Total current assets	727,655	819,861
Property and equipment, net	64,615	69,061
Operating lease right-of-use assets	62,328	66,373
Restricted cash	3,349	3,349
Intangible assets, net	1,982,306	2,016,890
Other non-current assets	7,352	7,773
Total assets	$ 2,847,605	$ 2,983,307
Liabilities and stockholders'/member's equity		
Current liabilities:		
Accounts payable	$ 5,769	$ 4,844
Accrued liabilities	53,724	57,241
Operating lease liabilities, current portion	12,973	13,260
Other current liabilities	2,511	1,580
Total current liabilities	74,977	76,925
Operating lease liabilities, net of current portion	51,344	54,881
Deferred tax liability, net	305,192	345,860
Other non-current liabilities	2,424	2,236
Total liabilities	433,937	479,902
Preferred stock, par value of $0.001 per share; 50,000,000 shares authorized, no shares issued and outstanding as of March 31, 2025 and December 31, 2024	—	—
Common stock $0.001 par value per share, 1,500,000,000 shares authorized, 35,296,858 shares issued and outstanding as of March 31, 2025, 33,893,409 shares issued and outstanding as of December 31, 2024	35	34
Additional paid-in capital	12,321,510	12,305,250
Accumulated other comprehensive income	1,666	1,451
Accumulated deficit	(9,909,543)	(9,803,330)
Total stockholders'/member's equity	2,413,668	2,503,405

Total liabilities and stockholders'/member's equity	2,847,605	2,983,307

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Condensed Consolidated Statements of Operations
(Unaudited)
(amounts in thousands, except share and per share data)

	Three Months Ended	
	March 31, 2025	**March 31, 2024**
Revenue:		
Screening revenue	$ 29,133	$ 23,539
Development services revenue	2,704	3,182
Total revenue	31,837	26,721
Costs and operating expenses:		
Cost of screening revenue (exclusive of amortization of intangible assets)	17,123	13,722
Cost of development services revenue	1,171	1,436
Cost of revenue — amortization of intangible assets	33,472	33,472
Research and development	53,625	101,625
Sales and marketing	34,979	46,819
General and administrative	45,074	57,069
Total costs and operating expenses	185,444	254,143
Loss from operations	(153,607)	(227,422)
Other income (expense):		
Interest income	7,779	2,901
Other income (expense), net	(584)	42
Total other income, net	7,195	2,943
Loss before income taxes	(146,412)	(224,479)
Benefit from income taxes	40,199	5,565
Net loss	$ (106,213)	$ (218,914)
Net loss per share — Basic and Diluted	$ (3.10)	$ (7.05)
Weighted-average shares of common stock used in computing net loss per share:	34,308,435	31,049,148

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Reconciliation of GAAP to Non-GAAP Financial Measures
(Unaudited)
(amounts in thousands)

	Three Months Ended	
	March 31, 2025	**March 31, 2024**
Gross loss [(1)]	$ (19,929)	$ (21,909)
Amortization of intangible assets	33,472	33,472
Stock-based compensation	762	481
Adjusted Gross Profit	$ 14,305	$ 12,044

(1) Gross profit (loss) is calculated as total revenue less cost of revenue (exclusive of amortization of intangible assets), cost of revenue—related parties, and cost of revenue—amortization of intangible assets.

GRAIL
Reconciliation of GAAP to Non-GAAP Financial Measures
(Unaudited)
(amounts in thousands)

	Three Months Ended	
	March 31, 2025	**March 31, 2024**
Net loss	$ (106,213)	$ (218,914)
Adjusted to exclude the following:		

Interest income	(7,779)	(2,901)
Benefit from income tax expense	(40,199)	(5,565)
Amortization of intangible assets [1]	34,584	34,584
Depreciation	4,695	5,413
Illumina/GRAIL merger & divestiture legal and professional services costs[2]	—	6,308
Stock-based compensation [3]	16,211	29,106
Restructuring[4]	(34)	—
Adjusted EBITDA	$ (98,735)	$ (151,969)

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

(2) Represents legal and professional services costs associated with the Acquisition and corresponding antitrust litigation, including compliance with the hold separate arrangements imposed by the European Commission, and legal and professional services costs associated with the divestiture.

(3) Represents all stock-based compensation recognized on our standalone financial statements for the periods presented.

(4) Represents employee severance, benefits, payroll taxes, and other costs associated with the Restructuring Plan.

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