GRAIL Reports Third Quarter 2025 Financial Results

November 12, 2025

Q3 U.S. Galleri Revenue Grew 28% Year-Over-Year to $32.6 Million

Q3 Galleri Tests Sold Grew 39% Year-Over-Year to More Than 45,000

Galleri PMA Submission to FDA Now Anticipated in Q126

Cash Position of More Than $850 Million Includes Recently Completed Private Placement

MENLO PARK, Calif., Nov. 12, 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 third quarter of 2025.

Total revenue in the third quarter grew 26% year-over-year to $36.2 million, and Galleri revenue grew 29% year-over-year to $32.8 million. U.S. Galleri revenue was $32.6 million, representing 28% growth year-over-year. Net loss for the quarter was $89.0 million. Gross loss was $13.7 million. Non-GAAP adjusted gross profit was $20.0 million, and non-GAAP adjusted EBITDA was $(71.7) million.[1]

"We remain very pleased by Galleri's commercial uptake with 39% growth in Galleri test volume in the third quarter. Our teams continue to build awareness of Galleri among providers and patients, and recent data from our registrational PATHFINDER 2 study adds to the evidence base," said Bob Ragusa, Chief Executive Officer at GRAIL. "We have also made key recent strides in opportunities beyond the U.S., led by our strategic collaboration with Samsung to bring Galleri to key Asian markets, as well as Galleri's commercial introduction in Canada. Looking ahead, we anticipate completing our PMA submission for Galleri to the FDA in the first quarter of 2026."

For the three months ended September 30, 2025, as compared to the three months ended September 30, 2024, GRAIL reported:

- **Revenue:** Total revenue, comprised of screening and development services revenue, was $36.2 million, an increase of $7.5 million or 26%.
- **Net loss:** Net loss was $89.0 million, an improvement of $36.7 million or 29%.
- **Gross loss:** Gross loss was $13.7 million, an improvement of $8.5 million or 38%.
- **Adjusted gross profit[1]:** Adjusted gross profit was $20.0 million, an increase of $8.2 million or 69%.
- **Adjusted EBITDA[1]:** Adjusted EBITDA was $(71.7) million, an improvement of $36.5 million or 34%.
- **Cash position:** Cash, cash equivalents, restricted cash and short-term marketable securities totaled $547.1 million as of September 30, 2025.

Recent business highlights include:

- Positive results from PATHFINDER 2 and SYMPLIFY studies add to the evidence base for the effectiveness of multi-cancer early detection.
- Positive detailed performance and safety results from the pre-specified analysis of the first approximately 25,000 participants in the registrational PATHFINDER 2 study were presented at the European Society of Medical Oncology ("ESMO") Congress 2025 in October:
  - Adding Galleri to recommended screenings for breast, cervical, colorectal, and lung cancers (USPSTF A and B recommendations) led to a more than seven-fold increase in the number of cancers found within a year
  - Galleri detected approximately three times as many cancers when added to standard-

of-care screening for breast, cervical, colorectal, lung, and prostate cancers (USPSTF A, B, and C recommendations)
    - Approximately three-quarters of the cancers detected by Galleri do not have standard of care screening options
    - More than half of the new cancers detected by Galleri were stage 1 or 2 and more than two-thirds were detected at stages 1-3
    - Galleri positive predictive value ("PPV"), or the likelihood of receiving a cancer diagnosis following a positive test result, was 61.6%
    - Specificity was 99.6%, translating to a false positive rate of 0.4%
    - Cancer signal of origin accuracy was 92%, leading to efficient diagnostic workups
    - Diagnostic resolution took a median of 46 days, and only 0.6% of all participants had an invasive procedure and invasive procedures were two times more common in participants with cancer than in those without
    - No serious, study-related adverse events were reported
- Positive long-term results from an extended registry follow-up of the SYMPLIFY study with the University of Oxford were presented at the Early Detection of Cancer Conference ("EDCC") in October. A previous primary analysis, published in *The Lancet Oncology*, followed participants until diagnostic resolution or up to nine months and demonstrated Galleri's PPV was 75.5%. Patients reported to have a false positive Galleri result were followed for 24 months in national cancer registries for England and Wales.
    - The updated analysis presented at EDCC showed that approximately one-third of participants initially believed to have a false positive result were later diagnosed with cancer during the subsequent follow up period
    - This reduction in false positives resulted in an increase of Galleri's PPV in this symptomatic population to 84.2%
- Announced a collaboration with Medcan, a global leader in proactive health and wellness services, to provide access to the Galleri test at Medcan's clinics. Additionally, Manulife Canada announced it now offers access to Galleri, in partnership with Medcan, to eligible life insurance customers through its innovative Manulife Vitality program.
- Announced a strategic collaboration with Samsung in October to bring the Galleri test to key Asian markets. Subject to execution of definitive agreements, the parties will work as exclusive partners to commercialize Galleri in Korea, and possibly other key Asian markets, including Japan and Singapore. In addition, the parties intend to explore potential additional strategic and operational collaborations. Samsung has also agreed to make an equity investment of $110 million in GRAIL, subject to closing conditions.
- Completed a private placement of equity in October resulting in gross proceeds of approximately $325 million, before deducting placement agents' fees and other expenses. Including proceeds from this transaction, GRAIL's cash position of more than $850 million provides runway into 2030.

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

Conference Call and Webcast
A webcast and conference call will be held today, Nov. 12, 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.

GRAIL Analyst Day 2025 Tomorrow
GRAIL will host its Analyst Day 2025 tomorrow, Nov. 13, 2025, at the Company's central laboratories in Research Triangle Park, North Carolina beginning at 8:00 a.m. PT / 11:00 a.m. ET.

The live webcast and recorded replay will be available at the investor relations section of GRAIL's website at investors.grail.com and at https://grail-analyst-day-2025.open-exchange.net/registration.

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 (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 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.

We calculate Adjusted EBITDA as net income (loss) adjusted to exclude interest (income) expense, income tax expense (benefit), depreciation, impairment of goodwill and intangible assets, and amortization of intangible assets, which represent intangible assets resulting from pushdown accounting, legal and professional services fees related to Illumina's acquisition of the Company in August 2021 ("the Acquisition") and corresponding antitrust litigation, including compliance with the hold separate arrangements imposed by the European Commission, and our divestment from Illumina, restructuring charges, and stock-based compensation. We believe that the items subject to these further adjustments are not indicative of our ongoing operations due to their nature, especially considering the impact of certain items as a result of the Acquisition.

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, patient awareness of our products, technology, clinical studies, 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 and negotiation of definitive agreements in the Samsung collaboration, 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, 2024 and in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2025, June 30, 2025 and September 30, 2025. 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, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(amounts in thousands, except share and per share data)

	September 30, 2025	December 31, 2024
Assets		

Current assets:		
Cash and cash equivalents	$ 126,892	$ 214,234
Short-term marketable securities	413,238	549,236
Accounts receivable, net	16,282	20,312
Supplies	18,390	18,632
Prepaid expenses and other current assets	14,579	17,447
Total current assets	589,381	819,861
Property and equipment, net	56,180	69,061
Operating lease right-of-use assets	56,061	66,373
Restricted cash	6,974	3,349
Intangible assets, net	1,885,140	2,016,890
Other non-current assets	7,295	7,773
Total assets	$ 2,601,031	$ 2,983,307
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,407	$ 4,844
Accrued liabilities	58,076	57,241
Operating lease liabilities, current portion	14,022	13,260
Other current liabilities	1,928	1,580
Total current liabilities	77,433	76,925
Operating lease liabilities, net of current portion	44,568	54,881
Deferred tax liability, net	236,265	345,860
Other non-current liabilities	2,802	2,236
Total liabilities	361,068	479,902
Preferred stock, par value of $0.001 per share; 50,000,000 shares authorized, no shares issued and outstanding as of September 30, 2025 and December 31, 2024	—	—
Common stock $0.001 par value per share, 1,500,000,000 shares authorized, 36,160,998 shares issued and outstanding as of September 30, 2025, 33,893,409 shares issued and outstanding as of December 31, 2024	36	34
Additional paid-in capital	12,349,976	12,305,250
Accumulated other comprehensive income	2,456	1,451
Accumulated deficit	(10,112,505)	(9,803,330)
Total stockholders' equity	2,239,963	2,503,405
Total liabilities and stockholders' equity	$ 2,601,031	$ 2,983,307

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, 2025	**September 30, 2024**	**September 30, 2025**	**September 30, 2024**
Revenue:				
Screening revenue	$ 32,807	$ 25,374	$ 96,319	$ 77,076
Development services revenue	3,387	3,278	7,256	10,267
Total revenue	36,194	28,652	103,575	87,343
Costs and operating expenses:				
Cost of screening revenue (exclusive of amortization of intangible assets)	15,910	15,970	52,379	45,481
Cost of development services revenue	544	1,442	2,216	3,499
Cost of revenue — amortization of intangible assets	33,473	33,473	100,417	100,417
Research and development	48,647	78,231	148,898	274,052
Sales and marketing	25,503	35,625	89,021	123,433
General and administrative	37,408	47,418	120,396	171,745
Goodwill and intangible assets impairment	—	—	28,000	1,420,936
Total costs and operating expenses	161,485	212,159	541,327	2,139,563
Loss from operations	(125,291)	(183,507)	(437,752)	(2,052,220)
Other income:				
Interest income	6,107	11,661	20,695	17,367

Other income (expense), net	466	(561)	(929)	(514)
Total other income, net	6,573	11,100	19,766	16,853
Loss before income taxes	(118,718)	(172,407)	(417,986)	(2,035,367)
Benefit from income taxes	29,741	46,719	108,811	105,428
Net loss	$ (88,977)	$ (125,688)	$ (309,175)	$ (1,929,939)
Net loss per share — Basic and Diluted	$ (2.46)	$ (3.94)	$ (8.73)	$ (61.61)
Weighted-average shares of common stock used in computing net loss per share:	36,124,256	31,880,054	35,415,266	31,326,117

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

	Three Months Ended		Nine Months Ended	
	September 30, 2025	September 30, 2024	September 30, 2025	September 30, 2024
Gross loss [1]	$ (13,733)	$ (22,233)	$ (51,437)	$ (62,054)
Amortization of intangible assets	33,473	33,473	100,417	100,417
Stock-based compensation	271	578	1,450	1,522
Adjusted Gross Profit	$ 20,011	$ 11,818	$ 50,430	$ 39,885

(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		Nine Months Ended	
	September 30, 2025	September 30, 2024	September 30, 2025	September 30, 2024
Net loss	$ (88,977)	$ (125,688)	$ (309,175)	$ (1,929,939)
Adjusted to exclude the following:				
Interest income	(6,107)	(11,661)	(20,695)	(17,367)
Benefit from income tax expense	(29,741)	(46,719)	(108,811)	(105,428)
Amortization of intangible assets [1]	34,583	34,583	103,750	103,750
Depreciation	4,399	4,647	13,686	14,865
Goodwill and intangible impairment [2]	—	—	28,000	1,420,936
Illumina/GRAIL merger & divestiture legal and professional services costs [3]	—	226	—	22,158
Stock-based compensation [4]	14,139	17,449	44,518	72,502
Restructuring [5]	—	19,007	(34)	19,007
Adjusted EBITDA	$ (71,704)	$ (108,156)	$ (248,761)	$ (399,516)

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

(2) Reflects impairment of goodwill and intangible assets recognized as a result of the Acquisition.

(3) 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.

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

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

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