
**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): February 20, 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 February 20, 2025, GRAIL, Inc. (the “Company” or “GRAIL”) issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2024. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of GRAIL, Inc. dated February 20, 2025 (GRAIL Reports Fourth Quarter and Full Year 2024 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: February 20, 2025

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

GRAIL Reports Fourth Quarter and Full Year 2024 Financial Results

Sold More Than 137,000 Galleri® Tests in 2024, Growing U.S. Galleri Revenue 45% Year-Over-Year to \$108.6 Million

Completed Study Visits For Two Registrational Studies in July to Support Modular PMA Submission For Galleri On Track for Continued Commercial Growth in 2025 With TRICARE Coverage and Recent Announcement of Quest Integration

Moderated Cash Burn, Ending 2024 with a Cash Position of \$767M, Extending Runway into 2028

MENLO PARK, Calif. — Feb. 20, 2025 — 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 fourth quarter and full year 2024 and provided business updates.

Fourth quarter revenue grew 26% year-over-year to \$38.3 million, and Galleri revenue grew 39% year over year to \$31.6 million. Net loss for the quarter was \$97.1 million, which includes amortization of Illumina acquisition-related intangible items of \$34.6 million. Gross loss was \$16.0 million. Non-GAAP adjusted gross profit was \$17.9 million and non-GAAP adjusted EBITDA was \$(84.0) million.¹

For the full year, total revenue grew 35% year over year to \$125.6 million, and Galleri revenue grew 45% year over year to \$108.6 million. Net loss for the year was \$2.0 billion, which includes goodwill and intangible assets impairment of \$1.4 billion and amortization of Illumina acquisition-related intangible items of \$138.3 million. Gross loss was \$78.0 million. Non-GAAP adjusted gross profit was \$57.8 million and non-GAAP adjusted EBITDA was \$(483.5) million.¹

Additionally, TRICARE Health Insurance recently added GRAIL's Galleri multi-cancer early detection test as a covered benefit. The Galleri test will be covered for patients who are 50 years or older with an elevated risk for cancer. TRICARE is one of the largest health plans in the U.S. and serves active duty service members, National Guard and Reserve members, retirees and their families.

“2024 was a transformational year for GRAIL as we completed the separation from Illumina in June 2024, and completed study visits for our two registrational studies in July,” said Bob Ragusa, Chief Executive Officer at GRAIL. “We executed a restructuring in the third and fourth quarters, and continue to focus on business efficiencies while also growing commercially. We plan to read out our registrational studies in 2025 and 2026 and complete our modular PMA submission in the first half of 2026.”

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

For the three months ended December 31, 2024, as compared to the three months ended December 31, 2023, GRAIL reported:

- **Revenue:** Total revenue, comprised of screening and development services revenue, was \$38.3 million, an increase of \$7.9 million or 26%.
- **Net loss:** Net loss was \$97.1 million, an improvement of \$90.5 million or 48%.
- **Gross loss:** Gross loss was \$16.0 million, an improvement of \$2.7 million or 14%.
- **Adjusted gross profit¹:** Adjusted gross profit was \$17.9 million, an increase of \$2.6 million or 17%.
- **Adjusted EBITDA¹:** Adjusted EBITDA was \$(84.0) million, an improvement of \$39.4 million or 32%.

For the twelve months ended December 31, 2024, as compared to the twelve months ended December 31, 2023, GRAIL reported:

- **Revenue:** Total revenue, comprised of screening and development services revenue, was \$125.6 million, an increase of \$32.5 million or 35%.
- **Net loss:** Net loss was \$2.0 billion, an increase of \$561.3 million or 38%, primarily driven by goodwill and intangible asset impairment.
- **Gross loss:** Gross loss was \$78.0 million, an improvement of \$17.6 million or 18%.
- **Adjusted gross profit¹:** Adjusted gross profit was \$57.8 million, an increase of \$17.6 million or 44%.
- **Adjusted EBITDA¹:** Adjusted EBITDA was \$(483.5) million, an improvement of \$40.3 million or 8%.

Cash position: Cash, cash equivalents, restricted cash and short-term marketable securities totaled \$766.8 million as of December 31, 2024.

Additional business highlights include:

- Patient Reported Outcomes for GRAIL's Galleri Multi-Cancer Early Detection Blood Test Published in *Lancet Oncology*. Analysis of patient reported outcomes from PATHFINDER indicate minimal patient distress associated with multi-cancer early detection (MCED) testing, and high overall satisfaction with the MCED test was reported across participant groups regardless of signal detection status and eventual diagnosis. Most participants reported they were "likely"/"very likely" to adhere to future guideline recommended screening tests as recommended by their healthcare provider.
- GRAIL and Quest Diagnostics Announced Availability of GRAIL's Galleri MCED Test Through the Quest Diagnostics Test Ordering System. The Quest Diagnostics connectivity system enables providers in the United States to order and receive reports of laboratory tests electronically through Quest's Quantum laboratory portal and more than 900 electronic health record systems. More than 500,000 providers used the Quest connectivity system last year. The integration will help streamline the process of ordering the Galleri test and increase availability by allowing patients access to the test at any of the approximately 7,400 patient access points nationwide. Patients can now go directly to Quest without needing to bring a Galleri test kit to the blood draw appointment.

Conference Call and Webcast

A webcast and conference call will be held today, February 20, 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 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.

* Sensitivity in 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 or income 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 section entitled “Risk Factors” in our Annual Report on Form 10-K for the period ended December 31, 2024 (the “Form 10-K”). 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 Contacts

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GRAIL
Condensed Consolidated Balance Sheets

(in thousands, except for per share data)

	December 31, 2024	December 31, 2023
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 214,234	\$ 97,287
Short-term marketable securities	549,236	—
Accounts receivables, net	20,312	16,942
Supplies	18,632	21,695
Prepaid expenses and other current assets	17,447	20,141
Total current assets	819,861	156,065
Property and equipment, net	69,061	84,995
Operating lease right-of-use assets	66,373	84,386
Restricted cash	3,349	4,225
Intangibles assets, net	2,016,890	2,687,223
Goodwill	—	888,936
Other non-current assets	7,773	7,984
Total assets	\$ 2,983,307	\$ 3,913,814
Liabilities and stockholders'/member's (deficit) equity		
Current liabilities:		
Accounts payable	\$ 4,844	\$ 19,673
Accrued liabilities	57,241	73,806
Incentive plan liabilities	—	54,513
Operating lease liabilities, current portion	13,260	14,809
Other current liabilities	1,580	809
Total current liabilities	76,925	163,610
Operating lease liabilities, net of current portion	54,881	69,598
Deferred tax liabilities, net	345,860	32,921
Other non-current liabilities	2,236	1,498
Total liabilities	479,902	267,627
Stockholders'/member's equity:		
Preferred stock, par value of \$0.001 per share; 50,000,000 shares authorized, no shares issued and outstanding as of December 31, 2024 and December 31, 2023	—	—
Common stock \$0.001 par value per share, 1,500,000,000 shares authorized, 33,893,409 shares issued and outstanding as of December 31, 2024, no shares authorized, issued and outstanding as of December 31, 2023	34	—
Additional paid-in capital	12,305,250	—
Member's equity	—	11,421,446
Accumulated other comprehensive income	1,451	1,066
Accumulated deficit	(9,803,330)	(7,776,325)
Total stockholders'/member's equity	2,503,405	3,646,187
Total liabilities and stockholders'/member's equity	2,983,307	3,913,814

GRAIL
Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended		Year Ended	
	December 31, 2024	December 31, 2023	December 31, 2024	December 31, 2023
(in thousands except for per share data)				
Revenue:				
Screening revenue	\$ 31,551	\$ 22,655	\$ 108,627	\$ 74,999
Development services revenue	6,701	7,671	16,968	18,106
Total revenue	38,252	30,326	125,595	93,105
Costs and operating expenses:				
Cost of screening revenue (exclusive of amortization of intangible assets)	17,803	13,587	63,284	47,966
Cost of development services revenue	2,945	1,917	6,444	6,861
Cost of revenue — amortization of intangible assets	33,472	33,472	133,889	133,889
Research and development	48,328	84,086	322,380	338,745
Sales and marketing	30,525	39,123	153,958	162,292
General and administrative	42,117	52,734	213,862	200,268
Goodwill and intangible assets impairment	—	—	1,420,936	718,466
Total costs and operating expenses	175,190	224,919	2,314,753	1,608,487
Loss from operations	(136,938)	(194,593)	(2,189,158)	(1,515,382)
Other income (expense):				
Interest income	9,366	1,351	26,733	7,954
Other expense (income), net	578	213	64	(208)
Total other income, net	9,944	1,564	26,797	7,746
Loss before income taxes	(126,994)	(193,029)	(2,162,361)	(1,507,636)
Benefit from income taxes	29,928	5,502	135,356	41,951
Net loss	\$ (97,066)	\$ (187,527)	\$ (2,027,005)	\$ (1,465,685)
Net loss per share — Basic and Diluted	\$ (2.89)	\$ (6.04)	\$ (63.54)	\$ (47.21)
Weighted average shares of common stock—basic and diluted	33,612,372	31,049,148	31,901,259	31,049,148

GRAIL
Condensed Consolidated Statements of Cash Flows
(Unaudited)

(in thousands)	Year Ended	
	December 31, 2024	December 31, 2023
Net cash used by operating activities	\$ (577,156)	\$ (595,800)
Net cash used by investing activities	(551,011)	(12,887)
Net cash provided by financing activities	1,244,300	463,766
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(62)	305
Net increase (decrease) in cash, cash equivalents, and restricted cash	\$ 116,071	\$ (144,616)
Cash, cash equivalents and restricted cash — beginning of period	\$ 101,512	\$ 246,128
Cash, cash equivalents and restricted cash — end of period	\$ 217,583	\$ 101,512

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

(in thousands)	Three Months Ended		Year Ended	
	December 31, 2024	December 31, 2023	December 31, 2024	December 31, 2023
Gross loss ⁽¹⁾	\$ (15,968)	\$ (18,650)	\$ (78,022)	\$ (95,611)
Amortization of intangible assets	33,472	33,472	133,889	133,889
Stock-based compensation	432	522	1,954	1,970
Adjusted Gross Profit	\$ 17,936	\$ 15,344	\$ 57,821	\$ 40,248

⁽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)

(in thousands)	Three Months Ended		Year Ended	
	December 31, 2024	December 31, 2023	December 31, 2024	December 31, 2023
Net loss	\$ (97,066)	\$ (187,527)	\$ (2,027,005)	\$ (1,465,685)
Adjusted to exclude the following:				
Interest income	(9,366)	(1,351)	(26,733)	(7,954)
Benefit from income tax expense	(29,928)	(5,502)	(135,356)	(41,951)
Amortization of intangible assets ⁽¹⁾	34,583	34,583	138,333	138,333
Depreciation	4,858	5,346	19,723	20,364
Goodwill and intangible assets impairment ⁽²⁾	—	—	1,420,936	718,466
Illumina/GRAIL merger & divestiture legal and professional services costs ⁽³⁾	—	6,122	22,158	17,320
Stock-based compensation ⁽⁴⁾	13,582	24,852	86,084	97,235
Restructuring ⁽⁵⁾	(694)	—	18,313	—
Adjusted EBITDA	\$ (84,031)	\$ (123,477)	\$ (483,547)	\$ (523,872)

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

⁽²⁾ Reflects impairment of the goodwill and intangible assets recognized as a result of Illumina's acquisition of the Company in August 2021 ("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 Company's restructuring plan approved in August 2024.