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): August 12, 2025

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 August 12, 2025, GRAIL, Inc. (the "Company" or "GRAIL") issued a press release announcing its financial results for the second quarter ended June 30, 2025. 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

Exhibit No.	Description
99.1	Press Release of GRAIL, Inc. dated August 12, 2025 (GRAIL Reports Second Quarter 2025 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: August 12, 2025

By: /s/ Aaron Freidin

Name: Aaron Freidin

Title: Chief Financial Officer

GRAIL

NEWS RELEASE **Exhibit 99.1**

GRAIL Reports Second Quarter 2025 Financial Results

Q2 U.S. Galleri Revenue Grew 21% Year-Over-Year to $34.2 Million

Q2 Galleri Tests Sold Grew 29% Year-Over-Year to More Than 45,000

Detailed Results From First 25,000 Enrolled in PATHFINDER 2 to be Submitted for Presentation at ESMO 2025 in October

MENLO PARK, Calif. — August 12, 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 second quarter 2025.

Total revenue in the second quarter grew 11% year-over-year to $35.5 million, and Galleri revenue grew 22% year-over-year to $34.4 million. U.S. Galleri revenue was $34.2 million, representing 21% growth year-over-year. Net loss for the quarter was $114.0 million, which includes impairment of Illumina acquisition-related intangible assets of $28.0 million. Gross loss was $17.8 million. Non-GAAP adjusted gross profit was $16.1 million and non-GAAP adjusted EBITDA was $(78.3) million.[1]

“We are pleased with Galleri’s growing uptake in the U.S., with more than 45,000 Galleri tests sold in the second quarter, as we continue to drive provider and patient awareness of the MCED opportunity and Galleri’s ability to detect cancer earlier, when it is more amenable to treatment,” said Bob Ragusa, Chief Executive Officer at GRAIL. “Our registrational trials in large, intended use populations in the U.S. and U.K. are beginning to read out, and following very promising top-line performance and safety results from the PATHFINDER 2 study in the U.S., we plan to submit detailed results for presentation at the European Society for Medical Oncology Congress 2025 in October.”

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

- **Revenue:** Total revenue, comprised of screening and development services revenue, was $35.5 million, an increase of $3.6 million or 11%.
- **Net loss:** Net loss was $114.0 million, an improvement of $1.5 billion or 93%. Net loss in the second quarter includes impairment of Illumina acquisition-related intangible assets of $28.0 million. In the second quarter of 2024, net loss included Illumina acquisition-related goodwill and intangible impairments of $1.42 billion.
- **Gross loss:** Gross loss was $17.8 million, an improvement of $0.1 million or 1%.
- **Adjusted gross profit[1]:** Adjusted gross profit was $16.1 million, an increase of $0.1 million or 1%.
- **Adjusted EBITDA[1]:** Adjusted EBITDA was $(78.3) million, an improvement of $61.1 million or 44%.
- **Cash position:** Cash, cash equivalents, restricted cash and short-term marketable securities totaled $606.1 million as of June 30, 2025.

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

Recent business highlights include:

- Positive top-line performance and safety results from the pre-specified analysis of the first 25,578 participants in the registrational PATHFINDER 2 study were announced in June:
  - Adding Galleri to standard of care screening demonstrated substantially greater additional cancer detection than that observed in the first PATHFINDER study. The first PATHFINDER study showed a more than doubling of the overall number of cancers detected when added to standard of care.
  - Positive predictive value (PPV) was substantially higher than the 43% PPV observed in the first PATHFINDER study.
  - Specificity and cancer signal origin (CSO) accuracy were consistent with the 99.5% and 88%, respectively, observed in the first PATHFINDER study. There were no serious safety concerns reported in PATHFINDER 2.
  - These data follow positive top-line results from the prevalent screening round of the registrational NHS-Galleri trial, which showed a substantially higher PPV than that observed in the PATHFINDER study. CSO accuracy and specificity were consistent with those observed in the PATHFINDER study.
- Entered a new collaboration with Everlywell, a digital health company pioneering the next generation of biomarker intelligence, to expand access to the Galleri test. Galleri is now available for request directly on everlywell.com via prescription.
- In July, Rush University System for Health, one of the largest health systems in the U.S., announced it is the first health system in the Chicago-area market to offer the Galleri test.
- Data presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in May included a 5-year follow up analysis of the Circulating Cell-free Genome Atlas (CCGA) study, which demonstrated Galleri's preferential detection of aggressive, clinically meaningful cancers. (https://assets.grail.com/wp-content/uploads/2025/05/Swanton.ASCO-2025.CCGA-5-Year-Outcomes.Oral-Presentation_FINAL-1.pdf.) Findings are consistent with earlier analyses assessing the prognostic significance of Galleri's cfDNA-based methylation approach.

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

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, 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, 2024 and in our Quarterly Report on Form 10-Q for the period ended June 30, 2025 (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 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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GRAIL, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(amounts in thousands, except for share and per share data)

	June 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 127,427	$ 214,234
Short-term marketable securities	475,327	549,236
Accounts receivables, net	16,313	20,312
Supplies	19,739	18,632
Prepaid expenses and other current assets	13,038	17,447
Total current assets	651,844	819,861
Property and equipment, net	60,210	69,061
Operating lease right-of-use assets	60,033	66,373
Restricted cash	3,349	3,349
Intangible assets, net	1,919,723	2,016,890
Other non-current assets	7,392	7,773
Total assets	$ 2,702,551	$ 2,983,307
Liabilities and stockholders'/member's equity		
Current liabilities:		
Accounts payable	$ 6,283	$ 4,844
Accrued liabilities	48,870	57,241
Operating lease liabilities, current portion	13,689	13,260
Other current liabilities	1,797	1,580
Total current liabilities	70,639	76,925
Operating lease liabilities, net of current portion	48,475	54,881
Deferred tax liability, net	266,174	345,860
Other non-current liabilities	2,620	2,236
Total liabilities	387,908	479,902
Preferred stock, par value of $0.001 per share; 50,000,000 shares authorized, no shares issued and outstanding as of June 30, 2025 and December 31, 2024	—	—
Common stock $0.001 par value per share, 1,500,000,000 shares authorized, 36,047,799 shares issued and outstanding as of June 30, 2025, 33,893,409 shares issued and outstanding as of December 31, 2024	36	34
Additional paid-in capital	12,335,832	12,305,250
Accumulated other comprehensive income	2,303	1,451
Accumulated deficit	(10,023,528)	(9,803,330)
Total stockholders'/member's equity	2,314,643	2,503,405
Total liabilities and stockholders'/member's equity	2,702,551	2,983,307

GRAIL, Inc.
Condensed Consolidated Statements of Operations
(unaudited)
(amounts in thousands, except share and per share data)

	Three Months Ended		Six Months Ended	
	June 30, 2025	June 30, 2024	June 30, 2025	June 30, 2024
Revenue:				
Screening revenue	$ 34,379	$ 28,163	$ 63,512	$ 51,702
Development services revenue	1,165	3,807	3,869	6,989
Total revenue	35,544	31,970	67,381	58,691
Costs and operating expenses:				
Cost of screening revenue (exclusive of amortization of intangible assets)	19,346	15,789	36,469	29,511
Cost of development services revenue	501	621	1,672	2,057
Cost of revenue — amortization of intangible assets	33,472	33,472	66,944	66,944
Research and development	46,626	94,196	100,251	195,821
Sales and marketing	28,539	40,989	63,518	87,808
General and administrative	37,914	67,258	82,988	124,327
Goodwill and intangible assets impairment	28,000	1,420,936	28,000	1,420,936
Total costs and operating expenses	194,398	1,673,261	379,842	1,927,404
Loss from operations	(158,854)	(1,641,291)	(312,461)	(1,868,713)
Other income (expense):				
Interest income	6,809	2,805	14,588	5,706
Other income (expense), net	(811)	5	(1,395)	47
Total other income, net	5,998	2,810	13,193	5,753
Loss before income taxes	(152,856)	(1,638,481)	(299,268)	(1,862,960)
Benefit from income taxes	38,871	53,144	79,070	58,709
Net loss	$ (113,985)	$ (1,585,337)	$ (220,198)	$ (1,804,251)
Net loss per share — Basic and Diluted	$ (3.18)	$ (51.06)	$ (6.28)	$ (58.11)
Weighted-average shares of common stock used in computing net loss per share:	35,793,154	31,049,148	35,054,896	31,049,148

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

	Three Months Ended		Six Months Ended	
	June 30, 2025	June 30, 2024	June 30, 2025	June 30, 2024
Gross loss [1]	$ (17,775)	$ (17,912)	$ (37,704)	$ (39,821)
Amortization of intangible assets	33,472	33,472	66,944	66,944
Stock-based compensation	417	463	1,179	944
Adjusted Gross Profit	$ 16,114	$ 16,023	$ 30,419	$ 28,067

[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		Six Months Ended	
	June 30, 2025	June 30, 2024	June 30, 2025	June 30, 2024
Net loss	$ (113,985)	$ (1,585,337)	$ (220,198)	$ (1,804,251)
Adjusted to exclude the following:				
Interest income	(6,809)	(2,805)	(14,588)	(5,706)
Benefit from income tax expense	(38,871)	(53,144)	(79,070)	(58,709)
Amortization of intangible assets [1]	34,583	34,583	69,167	69,167
Depreciation	4,592	4,805	9,287	10,218
Goodwill and intangible impairment [2]	28,000	1,420,936	28,000	1,420,936
Illumina/GRAIL merger & divestiture legal and professional services costs [3]	—	15,624	—	21,932
Stock-based compensation [4]	14,168	25,947	30,379	55,053
Restructuring[5]	—	—	(34)	—
Adjusted EBITDA	$ (78,322)	$ (139,391)	$ (177,057)	$ (291,360)

(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 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.