

**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): November 12, 2024

**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 November 12, 2024, GRAIL, Inc. (the “Company” or “GRAIL”) issued a press release announcing its financial results for the third quarter ended September 30, 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 November 12, 2024 (GRAIL Reports Third Quarter 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: November 12, 2024

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

## GRAIL Reports Third Quarter 2024 Financial Results

*Galleri Revenue Grew 52% Year-Over-Year to \$25.4 Million*

*Commercial Galleri Sales Surpassed 250,000 Tests Since Launch*

*Cash Balance of \$853.6 Million Provides Runway Into 2028*

MENLO PARK, Calif. — Nov. 12, 2024 — 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 2024.

Revenue in the third quarter was \$28.7 million, representing 38% growth year over year, and revenue for Galleri was \$25.4 million, representing 52% growth year over year. Net loss for the quarter was \$(125.7) million, which includes amortization of Illumina acquisition-related intangible items of \$34.6 million and a restructuring charge of \$19.0 million. Gross loss was \$(22.2) million. Non-GAAP adjusted gross profit was \$11.8 million and non-GAAP adjusted EBITDA was \$(108.2) million.<sup>1</sup>

“In our first operating quarter as a public company, GRAIL continued to deliver U.S. commercial growth, with more than 250,000 Galleri® tests sold as of September 30. Over the quarter, we reduced our expense base and continued to advance our mission,” said Bob Ragusa, Chief Executive Officer at GRAIL. “We will continue to focus on cost management as we work towards completing our registrational studies to support our U.S. FDA PMA submission and pursuing broad reimbursement.”

For the three months ended September 30, 2024, as compared to the three months ended October 1, 2023, GRAIL reported:

- **Revenue:** Total revenue, comprised of screening and development services revenue, was \$28.7 million, an increase of \$7.9 million or 38%.
- **Net loss:** Net loss was \$125.7 million, an improvement of \$765.8 million or 86%.
- **Gross loss:** Gross loss was \$(22.2) million, an improvement of \$4.8 million or 18%.
- **Adjusted gross profit<sup>1</sup>:** Adjusted gross profit was \$11.8 million, an increase of \$4.8 million or 68%.
- **Adjusted EBITDA<sup>1</sup>:** Adjusted EBITDA was \$(108.2) million, an improvement of \$17.9 million or 14%.
- **Cash position:** Cash and cash equivalents totaled \$853.6 million as of September 30, 2024.

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

Recent business highlights include:

- Published results of GRAIL's Galleri Multi-Cancer Early Detection Blood Test in prostate cancer in JCO Precision Oncology. The analysis of the study demonstrated that when Galleri detected prostate cancer, most were high-grade and clinically significant, and usually indicated an aggressive disease where additional diagnostic evaluation is necessary. These data, previously shared at AACR in March, build on earlier findings regarding Galleri's preferential detection of aggressive, deadly cancers.
- Presented early results from REFLECTION real-world experience study of Galleri at the Early Detection of Cancer Conference in October. This initial analysis included data from seven US Department of Veterans Affairs (VA) sites with 180 days of post-test follow-up. The signal detection rate for the veteran cohort was 1.3% and the positive predictive value (PPV) of the test was 42.9%. More than half of the cases were identified at early stages (I-III).

### **Conference Call and Webcast**

A webcast and conference call will be held today, November 12, 2024, 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](https://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](https://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](https://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 Quarterly Report on Form 10-Q for the period ended September 30, 2024 (the “Form 10-Q”). Moreover, we operate in a dynamic and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results, level of activity, performance, or achievements to differ materially and adversely from those contained in any forward-looking statements we may make.

Forward-looking statements relate to the future and, accordingly, are subject to inherent uncertainties, risks, and changes in circumstances that are difficult to predict and many of which are outside of our control. Although we believe the expectations and projections expressed or implied by the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance, or achievements. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Except to the extent required by law, we undertake no obligation to update any of these forward-looking statements after the date of this 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**

Corporate Communications

Kristen Davis

Trish Rowland

[pr@grail.com](mailto:pr@grail.com)

Investor Relations

Alex Dobbin

Alexis Tosti

[ir@grail.com](mailto:ir@grail.com)



**GRAIL**  
**Condensed Consolidated Balance Sheets**

(in thousands, except for per share data)

	<b>September 30, 2024</b>	<b>December 31, 2023</b>
	(unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 853,551	\$ 97,287
Accounts receivables, net	15,211	16,942
Supplies	21,213	21,695
Prepaid expenses and other current assets	19,721	20,141
<b>Total current assets</b>	<b>909,696</b>	<b>156,065</b>
Property and equipment, net	73,886	84,995
Operating lease right-of-use assets	70,625	84,386
Restricted cash	3,918	4,225
Intangibles assets, net	2,051,473	2,687,223
Goodwill	—	888,936
Other non-current assets	8,356	7,984
<b>Total assets</b>	<b>\$ 3,117,954</b>	<b>\$ 3,913,814</b>
<b>Liabilities and stockholders'/member's (deficit) equity</b>		
Current liabilities:		
Accounts payable	\$ 7,321	\$ 19,673
Accrued liabilities	71,830	73,806
Incentive plan liabilities	—	54,513
Operating lease liabilities, current portion	13,524	14,809
Other current liabilities	1,593	809
<b>Total current liabilities</b>	<b>94,268</b>	<b>163,610</b>
Operating lease liabilities, net of current portion	58,667	69,598
Deferred tax liabilities, net	375,122	32,921
Other non-current liabilities	2,261	1,498
<b>Total liabilities</b>	<b>530,318</b>	<b>267,627</b>
Preferred stock, par value of \$0.001 per share; 50,000,000 shares authorized, no shares issued and outstanding as of September 30, 2024 and December 31, 2023	—	—
Common stock \$0.001 par value per share, 1,500,000,000 shares authorized, 33,203,744 shares issued and outstanding as of September 30, 2024, no shares authorized, issued and outstanding as of December 31, 2023	33	—
Additional paid-in capital	12,291,681	—
Member's equity	—	11,421,446
Accumulated other comprehensive income	2,186	1,066
Accumulated deficit	(9,706,264)	(7,776,325)
<b>Total stockholders'/member's equity</b>	<b>2,587,636</b>	<b>3,646,187</b>
<b>Total liabilities and stockholders'/member's equity</b>	<b>3,117,954</b>	<b>3,913,814</b>

**GRAIL**  
**Condensed Consolidated Statements of Operations**  
(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2024	October 1, 2023	September 30, 2024	October 1, 2023
(in thousands except for per share data)				
<b>Revenue:</b>				
Screening revenue	\$ 25,374	\$ 16,745	\$ 77,076	\$ 52,344
Development services revenue	3,278	3,977	10,267	10,435
Total revenue	28,652	20,722	87,343	62,779
<b>Costs and operating expenses:</b>				
Cost of screening revenue (exclusive of amortization of intangible assets)	15,970	12,829	45,481	34,379
Cost of development services revenue	1,442	1,489	3,499	4,944
Cost of revenue — amortization of intangible assets	33,473	33,473	100,417	100,417
Research and development	78,231	80,076	274,052	254,659
Sales and marketing	35,625	36,597	123,433	123,169
General and administrative	47,418	50,183	171,745	147,534
Goodwill and intangible impairment	—	718,466	1,420,936	718,466
Total costs and operating expenses	212,159	933,113	2,139,563	1,383,568
Loss from operations	(183,507)	(912,391)	(2,052,220)	(1,320,789)
<b>Other income (expense):</b>				
Interest income	11,661	2,529	17,367	6,603
Other expense, net	561	196	514	421
Total other income, net	11,100	2,333	16,853	6,182
Loss before income taxes	(172,407)	(910,058)	(2,035,367)	(1,314,607)
Benefit from income taxes	46,719	18,610	105,428	36,449
<b>Net loss</b>	<b>\$ (125,688)</b>	<b>\$ (891,448)</b>	<b>\$ (1,929,939)</b>	<b>\$ (1,278,158)</b>
Net loss per share — Basic and Diluted	\$ (3.94)	\$ (28.71)	\$ (61.61)	\$ (41.17)
Weighted average shares of common stock—basic and diluted	31,880,054	31,049,148	31,326,117	31,049,148

**GRAIL**  
**Condensed Consolidated Statements of Cash Flows**  
(Unaudited)

(in thousands)	Nine Months Ended	
	September 30, 2024	October 1, 2023
Net cash used by operating activities	\$ (483,666)	\$ (466,902)
Net cash used by investing activities	(4,905)	(8,992)
Net cash provided by financing activities	1,244,300	377,780
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	228	49
Net increase (decrease) in cash, cash equivalents, and restricted cash	\$ 755,957	\$ (98,065)
Cash, cash equivalents and restricted cash — beginning of period	\$ 101,512	\$ 246,128
Cash, cash equivalents and restricted cash — end of period	\$ 857,469	\$ 148,063

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

(in thousands)	Three Months Ended		Nine Months Ended	
	September 30, 2024	October 1, 2023	September 30, 2024	October 1, 2023
<b>Gross loss (1)</b>	\$ (22,233)	\$ (27,069)	\$ (62,054)	\$ (76,961)
Amortization of intangible assets	33,473	33,473	100,417	100,417
Stock-based compensation	578	625	1,522	1,448
<b>Adjusted Gross Profit</b>	\$ 11,818	\$ 7,029	\$ 39,885	\$ 24,904

<sup>(1)</sup> 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		Nine Months Ended	
	September 30, 2024	October 1, 2023	September 30, 2024	October 1, 2023
<b>Net loss</b>	\$ (125,688)	\$ (891,448)	\$ (1,929,939)	\$ (1,278,158)
Adjusted to exclude the following:				
Interest income	(11,661)	(2,529)	(17,367)	(6,603)
Benefit from income tax expense	(46,719)	(18,610)	(105,428)	(36,449)
Amortization of intangible assets (1)	34,583	34,583	103,750	103,750
Depreciation	4,647	5,216	14,865	15,018
Goodwill and intangible impairment(2)	—	718,466	1,420,936	718,466
Illumina/GRAIL merger & divestiture legal and professional services costs (3)	226	2,944	22,158	11,198
Stock-based compensation (4)	17,449	25,319	72,502	72,383
Restructuring(5)	19,007	—	19,007	—
<b>Adjusted EBITDA</b>	<b>\$ (108,156)</b>	<b>\$ (126,059)</b>	<b>\$ (399,516)</b>	<b>\$ (400,395)</b>

- (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 Restructuring Plan.