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 13, 2024

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 13, 2024, GRAIL, Inc. (the "Company" or "GRAIL") issued a press release announcing its financial results for the second quarter ended June 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

Exhibit No.	Description
99.1	Press Release of GRAIL, Inc. dated August 13, 2024 (GRAIL Reports Second Quarter 2024 Financial Results and Provides a Strategic Update)

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 13, 2024

By: /s/ Aaron Freidin

Name: Aaron Freidin

Title: Chief Financial Officer

GRAIL

NEWS RELEASE **Exhibit 99.1**

GRAIL Reports Second Quarter 2024 Financial Results and Provides a Strategic Update

Second Quarter Revenue Grew 43% Year-Over-Year to $32.0 Million

Portfolio Prioritization and Corporate Restructure Extends Cash Runway into 2028

MENLO PARK, Calif. — Aug. 13, 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 second quarter 2024.

Revenue in the second quarter was $32.0 million, representing 43% growth year over year. Net loss for the quarter, which includes amortization and impairment of acquisition-related intangible items, was $(1.6) billion. Our gross loss was $(17.9) million. Non-GAAP adjusted gross profit was $16.0 million and Non-GAAP adjusted EBITDA was $(139.4) million.[1]

“GRAIL completed the separation from Illumina on June 24, 2024 and we are pleased to report our quarterly results for the first time as an independent public company. In the second quarter of 2024, GRAIL continued to deliver U.S. commercial growth, and as of June 30, we have sold more than 215,000 Galleri® tests. We are focused on detecting cancer early, when it can be cured, and are committed to serving Galleri patients, providing support for ordering physicians, advancing our commercial and research partnerships, and building our clinical and real-world evidence base,” said Bob Ragusa, Chief Executive Officer at GRAIL.

“We have an unprecedented opportunity to establish a new standard of care by adding Galleri to existing single-cancer screenings, and to establish and maintain the market leading position in multi-cancer detection.”

For the three months ended June 30, 2024, as compared to the three months ended July 2, 2023, GRAIL reported:

- **Revenue:** Total revenue, comprised of screening and development services revenue, was $32.0 million, an increase of $9.6 million or 43%.
- **Net loss:** Net loss was $1.59 billion, an increase of $1.39 billion or 721%. Net loss includes goodwill and intangible impairment of $1.42 billion.
- **Gross loss:** Gross loss was $(17.9) million, an improvement of $6.4 million or 26%.
- **Adjusted gross profit[1]:** Adjusted gross profit was $16.0 million, an increase of $6.4 million or 66%.
- **Adjusted EBITDA[1]:** Adjusted EBITDA was $(139.4) million, a decrease of $2.8 million or 2%.
- **Cash position:** Cash and cash equivalents totaled $958.8 million as of June 30, 2024.

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

Recent business highlights include:

- Commenced enrollment in the REACH study. The REACH study, also known as the Galleri-Medicare study, will enroll 50,000 individuals and allow for three annual screens to provide clinical validation and utility in the Medicare population, with a focus on health equity. Medicare beneficiaries are among those most at risk for cancer due to age and other risk factors, representing an important unmet need for early cancer detection.
- Completed enrollment of more than 35,000 participants in the registrational PATHFINDER 2 study. The PATHFINDER 2 study is a prospective, multi-center, interventional study evaluating the safety and performance of Galleri in a population of individuals aged 50 years and older who are eligible for guideline-recommended cancer screening in the United States.
- Completed final study visits for the registrational NHS-Galleri trial. The NHS-Galleri trial is a prospective, randomized controlled clinical utility trial of over 140,000 participants between the ages of 50-77 at the time of enrollment, each of whom provided three annual blood samples to evaluate the implementation of Galleri alongside existing NHS standard of care screenings.

Strategic update:

Following a portfolio review, we are reducing our overall spend and focusing our resources on our core multi-cancer early detection ("MCED") priorities, including progress toward completion of our registrational studies and our premarket approval application submission.

As part of this restructure, we are reducing existing headcount and planned hires for 2024 by approximately 30% and substantially decreasing investment in product programs beyond Galleri. We are also reducing the size of our commercial organization, focusing our field-based activities on the most productive provider territories and streamlining investments in our enterprise business, which includes the Company's employer and life insurance businesses. In addition, we are making reductions in general and administrative expense to reflect the focus on our MCED opportunity. We will continue to invest in our biopharmaceutical partnerships, and are committed to working with our partners to leverage GRAIL's proprietary methylation technology in precision oncology applications.

We expect these cost reductions to extend our existing cash runway from the second half of 2026 into 2028. As a result, we anticipate reducing our burn in 2025 to $325 million. In 2024, we expect $27 million in savings, net of anticipated severance and benefits costs.

Conference Call and Webcast
A webcast and conference call will be held today, **Aug. 13, 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.

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 Quarterly Report on Form 10-Q for the period ended June 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.

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GRAIL
Condensed Consolidated Balance Sheets

(in thousands, except for per share data)	June 30, 2024	December 31, 2023
Assets	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 958,845	$ 97,287
Accounts receivables, net	13,406	16,942
Supplies	25,506	21,695
Prepaid expenses and other current assets	20,925	20,141
Total current assets	1,018,682	156,065
Property and equipment, net	78,005	84,995
Operating lease right-of-use assets	74,503	84,386
Restricted cash	3,918	4,225
Intangibles assets, net	2,086,056	2,687,223
Goodwill	—	888,936
Other non-current assets	8,476	7,984
Total assets	$ 3,269,640	$ 3,913,814
Liabilities and stockholders'/member's (deficit) equity		
Current liabilities:		
Accounts payable	$ 16,247	$ 19,673
Accrued liabilities	56,573	73,806
Incentive plan liabilities	—	54,513
Operating lease liabilities, current portion	13,945	14,809
Other current liabilities	1,413	809
Total current liabilities	88,178	163,610
Operating lease liabilities, net of current portion	62,165	69,598
Deferred tax liabilities, net	422,163	32,921
Other non-current liabilities	2,007	1,498
Total liabilities	574,513	267,627
Preferred stock, par value of $0.001 per share; 50,000,000 shares authorized, no shares issued and outstanding as of June 30, 2024 and December 31, 2023	—	—
Common stock $0.001 par value per share, 1,500,000,000 shares authorized, 31,049,148 shares issued and outstanding as of June 30, 2024, no shares authorized, issued and outstanding as of December 31, 2023	31	—
Additional paid-in capital	12,274,286	—
Member's equity	—	11,421,446
Accumulated other comprehensive income	1,386	1,066
Accumulated deficit	(9,580,576)	(7,776,325)
Total stockholders'/member's equity	2,695,127	3,646,187
Total liabilities and stockholders'/member's equity	3,269,640	3,913,814

GRAIL
Condensed Consolidated Statements of Operations
(Unaudited)

(in thousands except for per share data)	Three Months Ended		Six months ended	
	June 30, 2024	July 2, 2023	June 30, 2024	July 2, 2023
Revenue:				
Screening revenue	$ 28,163	$ 20,027	$ 51,702	$ 35,599
Development services revenue	3,807	2,387	6,989	6,458
Total revenue	31,970	22,414	58,691	42,057
Costs and operating expenses:				
Cost of screening revenue (exclusive of amortization of intangible assets)	15,789	11,125	29,511	21,550
Cost of development services revenue	621	2,095	2,057	3,455
Cost of revenue — amortization of intangible assets	33,472	33,472	66,944	66,944
Research and development	94,196	88,710	195,821	174,583
Sales and marketing	40,989	40,737	87,808	86,572
General and administrative	67,258	50,642	124,327	97,351
Goodwill and intangible impairment	1,420,936	—	1,420,936	—
Total costs and operating expenses	1,673,261	226,781	1,927,404	450,455
Loss from operations	(1,641,291)	(204,367)	(1,868,713)	(408,398)
Other income (expense):				
Interest income	2,805	1,847	5,706	4,074
Other income (expense), net	5	(320)	47	(225)
Total other income (expense), net	2,810	1,527	5,753	3,849
Loss before income taxes	(1,638,481)	(202,840)	(1,862,960)	(404,549)
Benefit from income taxes	53,144	9,796	58,709	17,839
Net loss	$ (1,585,337)	$ (193,044)	$ (1,804,251)	$ (386,710)
Net loss per share — Basic and Diluted	$ (51.06)	$ (6.22)	$ (58.11)	$ (12.45)
Weighted average shares of common stock—basic and diluted	31,049	31,049	31,049	31,049

GRAIL
Condensed Consolidated Statements of Cash Flows
(Unaudited)

(in thousands)	Six Months Ended June 30, 2024	Six Months Ended July 2, 2023
Net cash used by operating activities	$ (379,085)	$ (309,391)
Net cash used by investing activities	(3,934)	(5,923)
Net cash provided by financing activities	1,244,300	303,775
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(30)	257
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 861,251	$ (11,282)
Cash, cash equivalents and restricted cash — beginning of period	$ 101,512	$ 246,128
Cash, cash equivalents and restricted cash — end of period	$ 962,763	$ 234,846

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

(in thousands)	Three Months Ended		Six Months Ended	
	June 30, 2024	July 2, 2023	June 30, 2024	July 2, 2023
Gross loss (1)	$ (17,912)	$ (24,278)	$ (39,821)	$ (49,892)
Amortization of intangible assets	33,472	33,472	66,944	66,944
Stock-based compensation	463	450	944	823
Adjusted Gross Profit	$ 16,023	$ 9,644	$ 28,067	$ 17,875

(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		Six Months Ended	
	June 30, 2024	July 2, 2023	June 30, 2024	July 2, 2023
Net loss	$ (1,585,337)	$ (193,044)	$ (1,804,251)	$ (386,710)
Adjusted to exclude the following:				
Interest income	(2,805)	(1,847)	(5,706)	(4,074)
Benefit from income tax expense	(53,144)	(9,796)	(58,709)	(17,839)
Amortization of intangible assets (1)	34,583	34,583	69,167	69,167
Depreciation	4,805	4,545	10,218	9,802
Goodwill and intangible impairment(2)	1,420,936	—	1,420,936	—
Illumina/GRAIL merger & divestiture legal and professional services costs (3)	15,624	3,466	21,932	8,254
Stock-based compensation (4)	25,947	25,548	55,053	47,064
Adjusted EBITDA	$ (139,391)	$ (136,545)	$ (291,360)	$ (274,336)

(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.