UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 001-42045

GRAIL, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**86-3673636**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1525 O'Brien Drive **Menlo Park, California**	**94025**
(Address of Principal Executive Offices)	(Zip Code)

(833) 694-2553

Registrant's telephone number, including area code

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 Stock Market LLC**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes ☐ No ☒

As of May 12, 2025, the registrant had 35,973,494 shares of common stock, par value $0.001 per share, outstanding.

TABLE OF CONTENTS

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q (this "Form 10-Q") 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 landscape, compliance and strategy, potential market opportunity, anticipated growth strategies, 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 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 discussed under the sections entitled "Risk Factors" in this Form 10-Q and in our Annual Report on Form 10-K (filed on March 5, 2025) for the year ended December 31, 2024 (the "2024 Form 10-K). You should specifically consider the numerous risks described under these sections. 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 Form 10-Q to conform our prior statements to actual results or revised expectations or to reflect new information or the occurrence of unanticipated events.

Part I - Financial Information

Item 1. Financial Statements

GRAIL, Inc.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(amounts in thousands, except share and per share data)

	March 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 133,895	$ 214,234
Short-term marketable securities	540,688	549,236
Accounts receivable, net[1]	19,309	20,312
Supplies[2]	18,716	18,632
Prepaid expenses and other current assets[3]	15,047	17,447
Total current assets	727,655	819,861
Property and equipment, net[4]	64,615	69,061
Operating lease right-of-use assets	62,328	66,373
Restricted cash	3,349	3,349
Intangible assets, net	1,982,306	2,016,890
Other non-current assets	7,352	7,773
Total assets	$ 2,847,605	$ 2,983,307
Liabilities and stockholders'/member's equity		
Current liabilities:		
Accounts payable[5]	$ 5,769	$ 4,844
Accrued liabilities[6]	53,724	57,241
Operating lease liabilities, current portion	12,973	13,260
Other current liabilities	2,511	1,580
Total current liabilities	74,977	76,925
Operating lease liabilities, net of current portion	51,344	54,881
Deferred tax liability, net	305,192	345,860
Other non-current liabilities	2,424	2,236
Total liabilities	433,937	479,902
Preferred stock, par value of $0.001 per share; 50,000,000 shares authorized, no shares issued and outstanding as of March 31, 2025 and December 31, 2024	—	—
Common stock $0.001 par value per share, 1,500,000,000 shares authorized, 35,296,858 shares issued and outstanding as of March 31, 2025, 33,893,409 shares issued and outstanding as of December 31, 2024	35	34
Additional paid-in capital	12,321,510	12,305,250
Accumulated other comprehensive income	1,666	1,451
Accumulated deficit	(9,909,543)	(9,803,330)
Total stockholders'/member's equity	2,413,668	2,503,405
Total liabilities and stockholders'/member's equity	$ 2,847,605	$ 2,983,307

[1] Includes related party accounts receivable, net of $59 and $65, respectively.
[2] Includes related party supplies of $742 and $3,130, respectively.
[3] Includes related party prepaid expenses and other current assets of $70 and $77, respectively.
[4] Includes related party property and equipment, net of $1,978 and $2,227, respectively.
[5] Includes related party accounts payable of $5 and $— , respectively.
[6] Includes related party accrued liabilities of $75 and $104, respectively.

See accompanying notes to condensed consolidated financial statements.

GRAIL, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(amounts in thousands, except share and per share data)

	Three Months Ended	
	March 31, 2025	March 31, 2024
Revenue:		
Screening revenue[1]	$ 29,133	$ 23,539
Development services revenue	2,704	3,182
Total revenue	31,837	26,721
Costs and operating expenses:		
Cost of screening revenue (exclusive of amortization of intangible assets)[2]	17,123	13,722
Cost of development services revenue[3]	1,171	1,436
Cost of revenue — amortization of intangible assets	33,472	33,472
Research and development[4]	53,625	101,625
Sales and marketing	34,979	46,819
General and administrative[5]	45,074	57,069
Total costs and operating expenses	185,444	254,143
Loss from operations	(153,607)	(227,422)
Other income:		
Interest income	7,779	2,901
Other income (expense), net	(584)	42
Total other income, net	7,195	2,943
Loss before income taxes	(146,412)	(224,479)
Benefit from income taxes	40,199	5,565
Net loss	$ (106,213)	$ (218,914)
Net loss per share — Basic and Diluted	$ (3.10)	$ (7.05)
Weighted-average shares of common stock used in computing net loss per share:	34,308,435	31,049,148

[1] Includes related party screening revenue of $77 and $129, respectively.
[2] Includes related party cost of screening revenue of $1,511 and $2,669, respectively.
[3] Includes related party cost of development services revenue of $163 and $45, respectively.
[4] Includes related party research and development expenses of $1,396 and $4,802, respectively.
[5] Includes related party general and administrative expenses of $— and $51, respectively.

See accompanying notes to condensed consolidated financial statements.

GRAIL, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(unaudited)
(amounts in thousands)

	Three Months Ended	
	March 31, 2025	**March 31, 2024**
Net loss	$ (106,213)	$ (218,914)
Other comprehensive income (loss):		
Change in net unrealized gain on marketable securities	(250)	—
Foreign currency translation adjustment	465	(52)
Comprehensive loss	$ (105,998)	$ (218,966)

See accompanying notes to condensed consolidated financial statements.

GRAIL, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS'/ MEMBER'S EQUITY
(unaudited)
(amounts in thousands, except share data)

	Common Stock					
	Shares	Amount	Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balance as of December 31, 2024	33,893,409	$ 34	$ 12,305,250	$ 1,451	$ (9,803,330)	$ 2,503,405
Net loss	—	—	—	—	(106,213)	(106,213)
Stock-based compensation expense	—	—	16,261	—	—	16,261
Other comprehensive income	—	—	—	215	—	215
Release of restricted stock units	1,403,449	1	(1)	—	—	—
Balance as of March 31, 2025	35,296,858	$ 35	$ 12,321,510	$ 1,666	$ (9,909,543)	$ 2,413,668

See accompanying notes to condensed consolidated financial statements.

	Member's Equity	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Member's Equity
Balance as of December 31, 2023	$ 11,421,446	$ 1,066	$ (7,776,325)	$ 3,646,187
Net loss	—	—	(218,914)	(218,914)
Stock-based compensation expense	170	—	—	170
Other comprehensive loss	—	(52)	—	(52)
Contribution from member, net	312,000	—	—	312,000
Balance as of March 31, 2024	$ 11,733,616	$ 1,014	$ (7,995,239)	$ 3,739,391

See accompanying notes to condensed consolidated financial statements.

GRAIL, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW
(unaudited)
(amounts in thousands)

	Three Months Ended	
	March 31, 2025	March 31, 2024
Cash flows from operating activities		
Net loss	$ (106,213)	$ (218,914)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization of intangibles assets	34,584	34,584
Depreciation	4,695	5,413
Stock-based compensation expense	16,211	29,106
Cash payment for equity awards	—	(42,913)
Deferred income taxes	(40,199)	(4,805)
Amortization of discount on marketable securities	(6,375)	—
Bad debt expense	273	—
Other	484	53
Changes in operating assets and liabilities:		
Accounts receivable, net[1]	730	1,914
Supplies[2]	(34)	117
Operating lease right-of-use assets and liabilities, net	221	559
Prepaid expenses and other assets[3]	2,821	(3,576)
Accounts payable[4]	895	(7,709)
Accrued and other liabilities[5]	(3,105)	(1,115)
Net cash used in operating activities	(95,012)	(207,286)
Cash flows from investing activities		
Purchases of property and equipment	(62)	(2,548)
Purchases of marketable securities	(220,527)	—
Proceeds from maturities of marketable securities	235,200	—
Net cash provided by (used in) investing activities	14,611	(2,548)
Cash flows from financing activities		
Cash funding received from Illumina	—	312,000
Net cash provided by financing activities	—	312,000
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	62	(37)
Net (decrease) increase in cash, cash equivalents, and restricted cash	(80,339)	102,129
Cash, cash equivalents and restricted cash — beginning of period	217,583	101,512
Cash, cash equivalents and restricted cash — end of period	$ 137,244	$ 203,641
Represented by:		
Cash and cash equivalents	$ 133,895	$ 199,723
Restricted cash	3,349	3,918
Total	$ 137,244	$ 203,641
Supplemental cash flow information:		
Property and equipment included in accounts payable and accrued liabilities	(268)	(593)
Operating cash flows paid for operating leases, net	(4,377)	(5,004)

[1] Includes changes in related party accounts receivable of $6 and $24, respectively.
[2] Includes changes in related party supplies of $2,388 and $(115), respectively.
[3] Includes changes in related party prepaid and other current assets of $7 and $—, respectively.
[4] Includes changes in related party accounts payable of $5 and $2,121, respectively.
[5] Includes changes in related party accrued liabilities of $(29) and $243, respectively.

See accompanying notes to condensed consolidated financial statements.

GRAIL, Inc.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

NOTE 1. ORGANIZATION AND DESCRIPTION OF BUSINESS

GRAIL, Inc. ("GRAIL" or the "Company"), headquartered in Menlo Park, California, is an innovative commercial-stage healthcare company focused on saving lives and shifting the paradigm of early cancer detection. The Company's Galleri blood test is a commercially available screening test for early detection of multiple types of cancer. GRAIL's common stock is listed under the ticker symbol "GRAL" on the Nasdaq Stock Exchange.

GRAIL was previously acquired by Illumina, Inc. ("Illumina") in August 2021, at which point it became a 100% owned subsidiary of Illumina, and held separate as a part of binding hold separate commitments implemented pursuant to orders issued by the European Commission. GRAIL separated from Illumina on June 24, 2024, as described below. GRAIL was a limited liability company ("LLC") from August 19, 2021 to June 21, 2024 when it was converted into a corporation (the "Conversion") in anticipation of such separation.

Separation from Illumina

On June 24, 2024, (the "Distribution Date"), Illumina completed the previously announced spin-off of GRAIL (the "Spin-Off"). The Spin-Off was completed through a distribution of 85.5% of the Company's outstanding common stock to the holders of record of Illumina's common stock as of the close of business on June 13, 2024 (the "Distribution"), which resulted in the distribution of 31.0 million shares of common stock. As a result of the Distribution, the Company became an independent public entity. Illumina's ownership of GRAIL reduced to 4,502,126 shares of common stock representing 14.5% ownership of the Company after the Spin-Off. Unless the context otherwise requires, references to the "Company" or "GRAIL", refer to (i) GRAIL, LLC prior to the Conversion and (ii) GRAIL, Inc. and its subsidiaries following the Conversion.

In connection with the Spin-Off, the Company entered into or adopted agreements that provide a framework for the relationship between the Company and Illumina, including, but not limited to the following:

- Separation and Distribution Agreement — governed the terms and conditions of the Spin-Off and sets forth aspects of the Company's and Illumina's relationship following the Spin-Off. See *Note 7 — Legal And Regulatory Proceedings* for more information regarding the contingencies related to this agreement.
- Tax Matters Agreement — governs the respective rights, responsibilities and obligations of Illumina and the Company after the Spin-Off with respect to all tax matters and includes restrictions to preserve the tax-free status of the Distribution. See *Note 10 — Taxes* for more information regarding income taxes and *Note 7 — Legal And Regulatory Proceedings* regarding the contingencies related to this agreement.
- Employee Matters Agreement — addressed employment, compensation, and benefits matters, including the allocation and treatment of assets and liabilities relating to employees and compensation and benefits plans and programs in which GRAIL employees participate, as well as the treatment of cash-based incentive awards in connection with the Spin-Off.
- Stockholder and Registration Rights Agreement — governs the respective rights, responsibilities and obligations of Illumina and the Company after the Spin-Off with respect to Illumina's continuing ownership of GRAIL common stock.
- Supply and Commercialization Agreement Amendment — amends the Company's supply and commercialization agreement with Illumina, which governs the ongoing supply and commercial relationship, including licensing, royalty payments and intellectual property between GRAIL and Illumina. See *Note 12 — Related Party Transactions* for more information regarding the royalty arrangements with Illumina.

Illumina provided the Company with disposal funding (the "Disposal Funding") in the amount of $932.3 million in accordance with the Separation and Distribution Agreement, subject to a clawback feature in the event that the Company (i) consummates a change in control transaction, sells or licenses substantially all of its assets

or adopts a plan of liquidation (collectively, a "GRAIL Change of Control"), or (ii) (1) pays any dividend on, or makes any other distribution in respect of, any shares of its capital stock or other equity or voting interests (other than a stock dividend or a stock split), or otherwise consummates a return of capital from the Company to any of its equity holders or (2) redeems, purchases or otherwise acquires any of its outstanding shares of capital stock or other equity or voting interests (other than the acquisition of any shares in order to effectuate a "net settlement" transaction for the purposes of satisfying tax withholding obligations arising in connection with the grant, vesting, exercise and/or settlement of any outstanding incentive equity awards of GRAIL held by its current or former employees), in each case, prior to September 24, 2025 (the 15-month anniversary of the Distribution Date). If the Company consummates a transaction described in the foregoing clause (i), the Company must return to Illumina a cash amount decreasing over time calculated by reference to the number of months which have elapsed since the Distribution Date at the time of the public announcement of the event giving rise to the change of control. If the Company consummates a transaction described in the foregoing clause (ii), the Company must return to Illumina a cash amount equal to the payments made by the Company in connection with such transaction. The amount of clawback payments made cannot exceed the amount of the initial disposal funding. See *Note 7 — Legal And Regulatory Proceedings — Contingencies* for details.

Our Ability to Continue as a Going Concern

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The realization of assets and the satisfaction of liabilities in the normal course of business are dependent on, among other things, the Company's ability to manage its net loss and to become profitable and operate profitably, to manage the Company's negative cash flows from operations and to generate positive cash flows from operations, and the Company's ability to obtain financing to support working capital requirements. The Company had $137.2 million of cash, cash equivalents and restricted cash and $540.7 million of short-term marketable securities as of March 31, 2025.

The Company believes that its existing cash, cash equivalents and short-term marketable securities will be sufficient to meet its working capital and capital expenditure needs for at least the next 12 months, as of the date these condensed consolidated financial statements were filed.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements represent the historical operations of the standalone GRAIL legal entity and include purchase accounting adjustments and certain tax adjustments as if the Company filed a separate income tax return and was not included in Illumina's consolidated return for the period of time the Company was owned by Illumina. All revenues and costs as well as assets and liabilities directly associated with the business activity of the Company are included in the unaudited condensed consolidated financial statements. Certain assets and liabilities were reflected at fair value under the new basis of accounting established at the closing of Illumina's acquisition of the Company in August 2021 ("the Acquisition").

Management considered the need to allocate any historical shared costs incurred by the parent, Illumina, to the accompanying condensed consolidated financial statements. As previously discussed, the European Commission adopted an order requiring Illumina and GRAIL to be held and operated as distinct and separate entities. As no integration ever occurred, management concluded that no material allocations were required. As of March 31, 2024, the Company had generated net operating loss carryforwards for federal and state tax purposes of $4.1 billion and $2.6 billion, respectively. As a single member LLC disregarded for tax purposes, these tax attributes are the sole property of Illumina and remained the assets of Illumina following the Spin-off in accordance with the Internal Revenue Code. However, amounts recognized by the Company are not necessarily representative of the amounts that would have been reflected in the financial statements had the Company operated independently of the parent. Related party transactions with Illumina are discussed further in *Note 12 — Related Party Transactions*.

GRAIL, Inc.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

These condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. for interim financial information and pursuant to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. These unaudited condensed consolidated financial statements, reflect all normal recurring adjustments that are necessary to present the results fairly, and include the accounts of the Company and its wholly owned subsidiaries for the interim periods presented. All intercompany balances have been eliminated in consolidation.

Significant Accounting Policies

During the three months ended March 31, 2025, there were no material changes to the Company's significant accounting policies disclosed in *Note 2 — Summary of Significant Accounting Policies*, within the consolidated financial statements for the year ended December 31, 2024 included in its Annual Report on Form 10-K (filed on March 5, 2025).

Concentration Risk

Significant customers are those that represent more than ten percent of total revenue or accounts receivable, net balances for the periods and as of each condensed consolidated balance sheet date presented, respectively. Revenue from a major customer that amounts to 10% or more of total revenue is as follows:

	Three Months Ended	
	March 31, 2025	March 31, 2024
Customer A	*	10 %

*less than 10%

Customers that accounted for 10% or more of total accounts receivable balance are as follows:

	As of March 31, 2025	As of December 31, 2024
Customer A	16 %	32 %
Customer B	12 %	*

*less than 10%

Reclassification

Certain amounts relating to related party transactions in the condensed consolidated statements of operations and statements of cash flows for the three-month period ended March 31, 2024 have been conformed to the current period presentation of related party transactions.

Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. This update improves income tax disclosure requirements, primarily through enhanced transparency and decision usefulness of disclosures. This guidance is effective for annual reporting periods beginning after December 15, 2024, with early adoption permitted, and can be applied on either a prospective or retroactive basis. The Company is currently evaluating the potential impact of this guidance on its condensed consolidated financial statements and related disclosures.

GRAIL, Inc.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

In November 2024, the FASB issued ASU No. 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures. This update intends to improve financial reporting by requiring disclosure of additional information about specific expense categories. This guidance is effective for annual reporting periods beginning after December 15, 2026 and interim reporting periods beginning after December 15, 2027. Early adoption is permitted and the guidance is to be applied prospectively and may be applied retrospectively. The Company is currently evaluating the impact of this guidance on our consolidated financial statements and related disclosures.

NOTE 3. REVENUE

The following table presents the Company's revenue disaggregated by geographic areas based on the customers' locations:

	Three Months Ended	
(in thousands)	March 31, 2025	March 31, 2024
United States		
Screening	$ 28,704	$ 23,539
Development Services	255	165
International[1]		
Screening	429	—
Development Services	2,449	3,017
Total	$ 31,837	$ 26,721

[1] International region includes revenue earned from customers located outside of the United States.

The following table presents the Company's revenue disaggregated by revenue source:

	Three Months Ended	
(in thousands)	March 31, 2025	March 31, 2024
Screening		
Commercial	$ 28,781	$ 23,539
Government[1]	$ 352	$ —
Development Services		
Commercial	$ 2,704	$ 3,182
Total	$ 31,837	$ 26,721

[1] Government screening revenue primarily consists of revenue earned as part of our Galleri-Medicare clinical study.

NOTE 4. BALANCE SHEET COMPONENTS

The following tables present financial information of certain condensed consolidated balance sheet components:

Accounts receivable, net (in thousands)	March 31, 2025	December 31, 2024
Trade accounts receivable, gross	$ 23,529	$ 24,099
Allowance for credit losses	(4,220)	(3,787)
Total accounts receivable, net	$ 19,309	$ 20,312

GRAIL, Inc.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Accrued liabilities (in thousands)	March 31, 2025	December 31, 2024
Accrued compensation expenses	$ 20,522	$ 34,530
Accrued clinical studies and research and development expenses	15,361	13,026
Accrued legal and professional service expenses	9,200	2,966
Accrued other expenses	8,641	6,719
Total accrued liabilities	$ 53,724	$ 57,241

NOTE 5. FAIR VALUE MEASUREMENTS, CASH EQUIVALENTS AND MARKETABLE SECURITIES

The following tables represent the fair value hierarchy for the Company's financial assets measured at fair value on a recurring basis as of March 31, 2025 and December 31, 2024:

	March 31, 2025			
(in thousands)	Fair Value	Level 1	Level 2	Level 3
Financial Assets:				
Money market funds	$ 131,915	$ 131,915	$ —	$ —
Total cash equivalents	131,915	131,915	—	—
U.S. government treasury bills	540,688	540,688	—	—
Total short-term marketable securities	540,688	540,688	—	—
Total	$ 672,603	$ 672,603	$ —	$ —

	December 31, 2024			
(in thousands)	Fair Value	Level 1	Level 2	Level 3
Financial Assets:				
Money market funds	$ 94,697	$ 94,697	$ —	$ —
U.S. government treasury bills	117,442	117,442	—	—
Total cash equivalents	212,139	212,139	—	—
U.S. government treasury bills	549,236	549,236	—	—
Total short-term marketable securities	549,236	549,236	—	—
Total	$ 761,375	$ 761,375	$ —	$ —

The following tables summarize the Company's cash equivalents and marketable securities' amortized costs, gross unrealized gains, gross unrealized losses and estimated fair values by significant investment category:

	March 31, 2025			
(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 131,915	$ —	$ —	$ 131,915
U.S. government treasury bills	540,672	16	—	540,688
Total	$ 672,587	$ 16	$ —	$ 672,603

GRAIL, Inc.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

(in thousands)	December 31, 2024 Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 94,697	$ —	$ —	$ 94,697
U.S. government treasury bills	666,412	266	—	666,678
Total	$ 761,109	$ 266	$ —	$ 761,375

All of the Company's marketable securities had maturities of less than one year.

There were no marketable securities in an unrealized loss position as of March 31, 2025 and December 31, 2024 and none of the Company's marketable securities had been in an unrealized loss position for more than one year as of March 31, 2025 and December 31, 2024. The Company evaluates investments that are in an unrealized loss position for impairment as a result of credit loss. It was determined that no credit losses exist as of March 31, 2025 and December 31, 2024 because no securities were in an unrealized loss position.

NOTE 6. STOCK-BASED COMPENSATION

Stock-based compensation expense, which includes expense for both equity and liability-classified awards, reported in the condensed consolidated statements of operations, was as follows:

(in thousands)	Three Months Ended March 31, 2025	March 31, 2024
Cost of screening revenue (exclusive of amortization of intangible assets)	$ 745	$ 470
Cost of development services revenue	17	11
Research and development	4,043	11,443
Sales and marketing	3,045	5,463
General and administrative	8,361	11,719
Stock-based compensation expense, before taxes	16,211	29,106
Related income tax benefits	(4,394)	(7,068)
Stock-based compensation expense, net of taxes	**$ 11,817**	**$ 22,038**

2024 Incentive Award Plan

The GRAIL, Inc. 2024 Incentive Award Plan (the "2024 Plan") was adopted by GRAIL and approved by Illumina, in its capacity as GRAIL's sole stockholder, in May 2024. The 2024 Plan authorizes the issuance of stock options, stock appreciation rights, restricted stock, restricted stock units, dividend equivalents, performance-based awards, and other stock or cash based awards. The maximum number of shares authorized for issuance under the 2024 Plan increased by 1,694,670 shares to 10,351,487 shares on January 1, 2025 pursuant to the annual automatic evergreen increase provision of the 2024 Plan. As of March 31, 2025, approximately 291,756 shares remained available for future grants under the 2024 Plan.

2024 Inducement Award Plan

The GRAIL, Inc. 2024 Inducement Award Plan (the "2024 Inducement Plan") was adopted by GRAIL's board of directors on August 9, 2024. The 2024 Inducement Plan is used exclusively for the grant of equity awards to prospective employees who (i) were not previously employees of GRAIL, or (ii) are returning to GRAIL following a bona fide period of non-employment, in any case, in connection with and as an inducement material to such prospective employee's entering into employment with GRAIL pursuant to Nasdaq Listing Rule 5635(c)(4). This plan authorizes the issuance of stock options, stock appreciation rights, restricted stock, restricted stock units, dividend equivalents, performance-based awards, and other stock or cash based awards. The 2024 Inducement Plan does not have a specified limit on the number of shares authorized for issuance.

A summary of the Company's restricted stock unit activity, issued under the 2024 Plan and 2024 Inducement Plan, is as follows:

(Units in thousands)	Restricted Stock Units	Weighted-Average Grant-Date Fair Value Per Share
Outstanding at January 1, 2025	5,523	$14.22
Awarded	2,139	$40.00
Released	(1,403)	$15.37
Forfeited	(197)	$17.23
Outstanding at March 31, 2025	6,062	$22.69

2024 Employee Stock Purchase Program

The GRAIL, Inc. 2024 Employee Stock Purchase Plan (the "ESPP") was adopted by GRAIL and approved by Illumina's Board of Directors, in its capacity as GRAIL's sole stockholder, in May 2024. The maximum number of shares authorized for issuance under the ESPP increased by 338,934 shares to 752,955 shares on January 1, 2025 pursuant to the annual automatic evergreen increase provision of the ESPP. As of March 31, 2025, no shares had been granted under the ESPP plan.

Performance-Based Award

The Company has one performance-based award outstanding for a former employee for which vesting is based on future revenues. The award has an aggregate potential value of up to $78.0 million and expires, to the extent unvested, in August 2030. One-fourth of the total potential value of the award vests immediately upon the achievement of cumulative net revenues in any period of four consecutive fiscal quarters of $500.0 million, $750.0 million, $1.5 billion, and $2.0 billion. The Company assesses the probability of achieving the performance conditions associated with the award on a quarterly basis at each reporting period. If and to the extent that the liability becomes due and payable prior to 12:01 a.m. Eastern Time December 24, 2026 (the "Disposal Funding Period") and paid by GRAIL, in cash, during the Disposal Funding Period, Illumina shall reimburse GRAIL all or such portion of the liability paid by GRAIL in accordance of the terms of the Separation and Distribution Agreement. As of March 31, 2025, it was not probable that the performance conditions associated with the award will be achieved and, therefore, no stock-based compensation expense, or corresponding loss recovery asset or liability, has been recognized in the condensed consolidated financial statements.

NOTE 7. LEGAL AND REGULATORY PROCEEDINGS

The Company is subject to various claims, complaints, regulatory proceedings, and legal actions that arise from time to time in the ordinary course of business.

SEC Inquiry Letter

We may also be a party or otherwise involved in new litigation proceedings regarding the Acquisition. For example, in July 2023, Illumina was informed that the staff of the SEC was conducting an investigation relating to Illumina and was requesting documents and communications primarily related to Illumina's acquisition of GRAIL and certain statements and disclosures concerning GRAIL, our products and the acquisition, and related to the conduct and compensation of certain members of Illumina and GRAIL management, among other things. GRAIL has cooperated with the SEC in this investigation. On May 9, 2025, the Company confirmed with the SEC that the SEC has closed its investigation into this matter.

Federal Securities Class Actions

On November 11, 2023, the first of three securities class action complaints was filed against Illumina and certain of its current and former executive officers in the United States District Court for the Southern District of California. The first-filed case is captioned Kangas v. Illumina, Inc. et al., the second-filed case is captioned Roy v. Illumina, Inc. et al., and the third-filed case is captioned Louisiana Sheriffs' Pension & Relief Fund v. Illumina, Inc. et al. (collectively, the "Actions"). The complaints generally allege, among other things, that defendants made materially false and misleading statements and omitted material facts relating to Illumina's acquisition of Grail. The complaints seek unspecified damages, interest, fees, and costs. On January 9, 2024, four movants filed motions to consolidate the Actions and to appoint a lead plaintiff ("Lead Plaintiff Motions"). On April 11, 2024, the Court issued an order consolidating the Actions into a single action (captioned in re Illumina, Inc. Securities Litigation No. 23-cv-2082-LL-MMP), and appointed Universal-Investment-Gesellschaft mbH, UI BVK Kapitalverwaltungsgesellschaft mbH, and ACATIS Investment Kapitalverwaltungsgesellschaft mbH as lead plaintiffs. (the "Lead Plaintiffs"). On June 21, 2024, the Lead Plaintiffs filed a consolidated amended complaint. The amended complaint alleges that GRAIL, in addition to Illumina, and certain of their respective current and former directors and others violated sections 10(b) and 20(a) of the Securities Exchange Act and SEC Rule 10b-5 in connection with Illumina's acquisition of GRAIL and disclosures concerning the same. GRAIL has an indemnification obligation for certain current and former directors and officers involved in the matter pursuant to indemnification agreements entered into by these individuals and GRAIL. On September 13, 2024 the plaintiffs further amended the complaint. The Company denies the allegations in the complaints and intends to vigorously defend the litigation. In light of the fact that the lawsuits are in an early stage, the Company cannot predict the ultimate outcome of the suits.

Other Legal Matters

Legal matters include various claims, complaints, and legal actions that arise from time to time. In addition to direct involvement in legal matters, the Company has entered into indemnification agreements with each of its current and former directors, executive officers, and certain other officers, and has certain indemnification obligations under the Company's charter and bylaws to these individuals, that provide these directors and officers with indemnification rights that may give rise to liability for the Company even if the Company is not directly named. The Company has indemnification obligations in respect of the Actions and with respect to other legal matters that may arise, or have arisen, from time to time. There can be no assurance that existing or future legal proceedings arising in the ordinary course of business or otherwise will not have a material adverse effect on the Company's business, financial position, results of operations, or cash flows.

The company is involved in various lawsuits and claims arising in the ordinary course of business, including actions with respect to employment matters. In connection with these matters, the Company assesses, on a regular basis, the probability and range of possible loss based on the developments in these matters. A liability is recorded in the condensed consolidated financial statements if it is believed to be probable that a loss has been incurred and the amount of the loss can be reasonably estimated. Since litigation is inherently unpredictable and unfavorable resolutions could occur, assessing contingencies is highly subjective and requires judgments about future events. The Company regularly reviews outstanding legal matters to determine the adequacy of the liabilities accrued and related disclosures. The Company may change its estimates if its assessment of the various factors changes and the amount of ultimate loss may differ from estimates, resulting in a material effect on the Company's business, financial condition, results of operations, and/or cash flows. As of March 31, 2025, there were no pending litigation with any probable losses that can be reasonably estimated.

Contingencies

Contingencies primarily correspond to claims arising in the ordinary course of business. If necessary, these contingencies will be accrued, to the extent believed to be reasonably estimable to resolve the matter. The accrued contingency amounts are included in other current liabilities. Should the Company not be able to secure the terms it expects, these estimates may change and will be recognized in the period in which they are identified.

In connection with the Spin-Off, Illumina provided the Company with disposal funding in the amount of $932.3 million in accordance with the Separation and Distribution Agreement, subject to a clawback feature. The clawback is triggered if, prior to September 24, 2025 (the 15-month anniversary of the Distribution Date), the

Company (i) consummates a change in control of the Company or (ii) (1) pays any dividend on, or makes any other distribution in respect of, any shares of its capital stock or other equity or voting interests (other than a stock dividend or a stock split), or otherwise consummates a return of capital from GRAIL to any of its equity holders or (2) redeems, purchases or otherwise acquires any of its outstanding shares of capital stock or other equity or voting interests (other than the acquisition of any shares in order to effectuate a "net settlement" transaction for the purposes of satisfying tax withholding obligations arising in connection with the grant, vesting, exercise and/or settlement of any outstanding incentive equity awards of GRAIL held by its current or former employees). If the Company consummates a transaction described in the foregoing clause (i), the Company must return to Illumina a cash amount decreasing over time calculated by reference to the number of months which have elapsed since the Distribution Date at the time of the public announcement of the event giving rise to the change of control. If the Company consummates a transaction described in the foregoing clause (ii), the Company must return to Illumina a cash amount equal to the payments made by the Company in connection with such transaction. The amount of clawback payments made cannot exceed the amount of the initial disposal funding. As of March 31, 2025, no contingency liability was recorded as the contingent loss is not probable.

On June 21, 2024, in connection with the Spin-Off, Illumina and the Company also entered into the Tax Matters Agreement to govern the respective rights, responsibilities and obligations of Illumina and the Company after the Spin-Off with respect to all tax matters and will include restrictions to preserve the tax-free status of the Distribution. The Tax Matters Agreement included a number of restrictions on the Company to preserve the intended tax treatment of the Spin-Off. Breach of any covenant or representation contained in the Tax Matters Agreement will result in liability to specific separation taxes. As of March 31, 2025, as it was not probable that the Company will breach the agreement, no contingent liability was recorded in connection with the Tax Matters Agreement.

NOTE 8. RESTRUCTURING

On August 9, 2024, following a portfolio review, the Company's Board of Directors approved a restructuring plan ("Restructuring Plan") designed to re-prioritize the Company's resources to focus on its core MCED business and reduce overall spend as the Company progresses towards completion of registrational studies and premarket approval application ("PMA") submission. The Restructuring Plan was substantially completed in the fourth quarter of 2024, and the Company incurred $18.3 million of total restructuring charges from August 9, 2024 through December 31, 2024, consisting primarily of employee severance, benefits, payroll taxes, asset impairments and other associated costs. The following table presents the total restructuring charges by function for the period indicated:

	Three Months Ended March 31, 2025		
(in thousands)	Severance and related benefit costs	Other Costs	Total
Research and development	$ (47)	$ 111	$ 64
Sales and marketing	(83)	—	(83)
General and administrative	(31)	16	(15)
Total	$ (161)	$ 127	$ (34)

As of March 31, 2025, the Company had no remaining restructuring liability. The following table summarizes the restructuring-related liabilities:

(in thousands)	Severance and related benefit costs	Other Costs	Total
Amount recorded in accrued liabilities as of December 31, 2024	$ 806	$ 222	$ 1,028
Restructuring charges	(161)	127	(34)
Cash payments made	(645)	(349)	(994)
Amount recorded in accrued liabilities as of March 31, 2025	$ —	$ —	$ —

NOTE 9. NET LOSS PER SHARE

Prior to the completion of the Spin-Off from Illumina, the Company had no common shares issued and outstanding. In connection with the Spin-Off, on June 24, 2024, there were 31.0 million shares of GRAIL common stock distributed to Illumina stockholders. This share amount is utilized for the calculation of basic and diluted earnings per share for all periods presented prior to the Spin-Off. For the three months ended March 31, 2024, these shares are treated as issued and outstanding for purposes of calculating historical earnings per share.

The following table presents the calculation of the Company's basic and diluted net loss per share attributable to common stockholders:

	Three Months Ended	
(in thousands, except share and per share data)	March 31, 2025	March 31, 2024
Numerator		
Net loss	$ (106,213)	$ (218,914)
Denominator		
Weighted average shares of common stock—basic and diluted	34,308,435	31,049,148
Net loss per share attributable to common stockholders		
Basic	$ (3.10)	$ (7.05)
Diluted	$ (3.10)	$ (7.05)

Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share, as the inclusion of all potential shares of common stock outstanding would have been anti-dilutive. The following common stock equivalents were excluded from the calculation of diluted net loss per share for the periods presented as they had an anti-dilutive effect:

	Three Months Ended	
	March 31, 2025	March 31, 2024
Unvested restricted stock units	6,053,715	—
Shares subject to options to purchase common stock	104,315	104,315
Total	6,158,030	104,315

NOTE 10. TAXES

For interim financial statement purposes, U.S. GAAP provision (benefit) for taxes related to ordinary income is determined by applying an estimated annual effective income tax rate against a company's ordinary income, subject to certain limitations on the benefit of losses. Provision (benefit) for taxes related to items not characterized as ordinary income is recognized as a discrete item when incurred. The estimation of the Company's income tax provision requires the use of management forecasts and other estimates, application of statutory income tax rates, and an evaluation of valuation allowances. The Company's estimated annual effective income tax rate may be revised, if necessary, in each interim period.

The worldwide effective income tax rates for the three months ended March 31, 2025 and March 31, 2024 were 27.41% and 2.50%, respectively. The increase for the three months ended March 31, 2025 as compared to the three months ended March 31, 2024 primarily relates to the Company's 2024 valuation allowance impacts against pre-tax losses prior to the Spin-off.

The effective tax rate was higher than the 21% U.S. federal statutory rate for the three months ended March 31, 2025, primarily due to state taxes, offset by discrete tax benefits from stock-based compensation.

The Company accounts for uncertain tax positions using a more-likely-than-not threshold for recognizing and resolving uncertain tax positions. This evaluation is based on factors including, but not limited to, changes in facts or circumstances, changes in tax law, effectively settled issues under audit, and new audit activity. Interest and penalties related to unrecognized tax benefits are included within income tax expense. For the three months ended March 31, 2025, the Company recorded income tax expense related to its Federal and California R&D Credits of $0.2 million and $0.1 million, respectively.

The Company files income tax returns in the U.S. federal jurisdiction and various states. As of the date of this filing, the Company is not currently under examination by income tax authorities in federal, state, or other jurisdictions. All tax returns will remain open for examination by the federal and state authorities for three and four years, respectively, from the date of utilization of any net operating loss or credits.

As discussed in *Note 1 — Organization And Description Of Business and Note 2 — Summary Of Significant Accounting Policies — Basis of Presentation*, prior to the Spin-Off, for tax purposes, the Company operated as a subsidiary of Illumina and not as a separately regarded taxable entity. Accordingly, the effective worldwide income tax rate for the three months ended March 31, 2024 was calculated using the separate return method as if the Company filed income tax returns on both a standalone basis and on a carve-out basis.

NOTE 11. SEGMENT INFORMATION

The Company operates and manages its business as one reportable operating segment which provides multi-cancer early detection testing and services. The Company's chief operating decision maker (“CODM”) is the chief executive officer. The chief operating decision maker reviews financial information on an aggregate basis for the purposes of evaluating financial performance and allocating resources based on net income (loss), adjusted gross margin and adjusted EBITDA. Net income (loss) is the measure of segment profit most consistent with U.S. GAAP that is regularly reviewed by the CODM to allocate resources and assess performance. The CODM does not evaluate operating segment performance using asset information.

The following table is representative of the significant expense categories regularly provided to the CODM when managing the Company’s single reporting segment. A reconciliation to the consolidated net loss for the three months ended March 31, 2025 and March 31, 2024 is included in the table below:

GRAIL, Inc.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

(in thousands)	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024
Revenue:		
Screening revenue	$ 29,133	$ 23,539
Development services revenue	2,704	3,182
Total revenue	31,837	26,721
Costs and operating expenses:		
Cost of screening revenue (exclusive of amortization of intangible assets) [1]	17,123	13,722
Cost of development services revenue [1]	1,171	1,436
Compensation	63,517	89,621
Depreciation and intangible assets amortization expense	39,279	39,996
Stock-based compensation	15,450	28,625
Professional services	9,195	15,484
Cloud computing and information technology	7,390	8,374
Clinical studies	5,922	14,905
Laboratory supplies and research collaborations	4,529	17,411
Facilities	2,520	4,752
Other segment expenses [2]	19,348	19,817
Total costs and operating expenses	185,444	254,143
Loss from Operations	(153,607)	(227,422)
Other income (expense):		
Interest income	7,779	2,901
Other income (expense), net	(584)	42
Benefit from income taxes	40,199	5,565
Net Loss	$ (106,213)	$ (218,914)

[1] Cost of screening revenue (exclusive of amortization of intangible assets) and cost of development services revenue include stock-based compensation expense. See *Note 6 — Stock-Based Compensation* for further details.

[2] Other segment expenses primarily includes costs related to contractors and temporary labor, marketing expenses, legal expenses, and bad debt expense

NOTE 12. RELATED PARTY TRANSACTIONS

Illumina Purchases and Sales

The Company was a subsidiary of Illumina, Inc. between August 19, 2021 to June 23, 2024. Subsequent to the Spin-Off, Illumina retained a 14.5% stake in the Company. As of March 31, 2025, Illumina held 4,502,126 shares of common stock representing a 12.8% stake in the Company. Illumina is both a customer of the Company and a major supplier of the Company's reagents and capital equipment. Goods and services transactions with Illumina are invoiced and paid when due.

GRAIL, Inc.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Goods and services transactions with Illumina have been reflected in the condensed consolidated financial statements as follows:

(in thousands)	March 31, 2025	December 31, 2024
Accounts receivable	$ 59	$ 65
Supplies	742	3,130
Prepaid expenses and other current assets	70	77
Property and equipment, net	1,978	2,227
Accounts payable	5	—
Accrued liabilities	75	104

	Three Months Ended	
(in thousands)	March 31, 2025	March 31, 2024
Screening revenue	$ 77	$ 129
Cost of screening revenue	1,511	2,669
Cost of development services revenue	163	45
Operating expenses—Research and development	1,396	4,802
Operating expenses—General and administrative	—	51

In June 2024, the Company entered into an amendment to its Supply and Commercialization Agreement with Illumina. Under the terms of the amended agreement, regardless of whether its products incorporate any Illumina technology, the Company has agreed to pay to Illumina a high single-digit royalty, subject to certain reductions, in perpetuity on net sales generated by its products or revenues otherwise generated or received by the Company, subject to certain exceptions, in the field of oncology. Per the terms of the Separation and Distribution Agreement with Illumina, the royalty arrangement is suspended until the earlier of December 24, 2026 or any earlier change of control of the Company, at which time a high-single digit royalty payments will be payable.

Contributions from Member, Net

The following related party transactions between the Company and Illumina have been included in these condensed consolidated financial statements. As there was no intercompany loan agreement between Illumina and GRAIL and because these transactions had no history of being settled and were not settled per the terms of the Separation and Distribution Agreement, the total net effect of these transactions are reflected in the condensed consolidated statements of cash flows as cash provided by financing activities and in the condensed consolidated balance sheets as contribution from member, net, in member's equity. The following table presents the components of the net transfers to and from Illumina prior to the Spin-Off:

	Three Months Ended
(in thousands)	March 31, 2024
Cash funding received from Illumina	$ 312,000
Total contribution from member, net	**$ 312,000**

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion of our results of operations and financial condition together with our accompanying unaudited condensed consolidated financial statements and the notes thereto included under Item 1. "Financial Statements". This discussion contains forward-looking statements that involve risks and uncertainties. The forward-looking statements are not historical facts, but rather are based on current expectations, estimates, assumptions and projections about our industry and our business and financial results. Our actual results could differ materially from the results contemplated by these forward-looking statements due to a number of factors, including those discussed in the sections entitled "Risk Factors" in Part II, Item 1A of this Form 10-Q and in Part I, Item 1A of our Form 10-K and the section entitled "Cautionary Statement Concerning Forward-Looking Statements" of this Form 10-Q.

GRAIL, LLC, previously named SDG Ops, LLC, was formed in the state of Delaware as a wholly owned subsidiary of Illumina, Inc. ("Illumina"). SDG Ops, LLC, along with SDG Ops, Inc., a Delaware corporation and wholly owned subsidiary of Illumina, were formed for the purpose of completing a merger transaction between GRAIL, Inc., and Illumina (the "Acquisition") in order to carry on the business of GRAIL, Inc. and its subsidiaries.

On September 20, 2020, GRAIL, Inc., Illumina and its subsidiaries, SDG Ops, LLC, and SDG Ops, Inc., entered into an agreement and plan of merger (the "Merger Agreement"). On August 18, 2021 (the "Closing Date"), Illumina completed its acquisition of GRAIL, Inc. According to the terms and conditions of the Merger Agreement, SDG Ops, Inc. and GRAIL, Inc. merged, with GRAIL, Inc. surviving and became a wholly owned subsidiary of Illumina (the "First Merger"). Immediately following the First Merger and as part of the same overall transaction, GRAIL, Inc., as the surviving corporation, merged with SDG Ops, LLC (the "Second Merger"). According to the terms and conditions of the Merger Agreement, SDG Ops, LLC became the surviving company and was renamed GRAIL, LLC.

On June 24, 2024, Illumina completed the previously announced spin-off of GRAIL (the "Spin-Off") through a distribution of approximately 85.5% of our outstanding common stock to the holders of record of Illumina's common stock as of the close of business on June 13, 2024 (the "Distribution"). As a result of this Distribution, GRAIL became an independent public entity.

In 2021, in connection with the Acquisition, the European Commission accepted a request for a referral of the Acquisition for European Union merger review. Although the European Commission's assertion of jurisdiction was set aside by the Court of Justice of the European Union on September 3, 2024, GRAIL was held separate from Illumina from October 29, 2021 until the completion of the Distribution under binding hold separate commitments implemented pursuant to orders issued by the European Commission.

Unless the context otherwise requires, references to "GRAIL," "we," "us," and the "Company" refer to (i) GRAIL, LLC and its consolidated subsidiaries prior to the Spin-Off as a carve-out business of Illumina and (ii) GRAIL, Inc. and its subsidiaries following the Spin-Off.

Overview

Our Business

We are an innovative commercial-stage healthcare company focused on saving lives and shifting the paradigm in early cancer detection. We believe screening individuals for many types of cancer with a single test represents a significant opportunity to reduce the global burden of cancer. Our Galleri test is a commercially available screening test for early detection of multiple types of cancer, which we termed multi-cancer early detection ("MCED"). We believe Galleri is clinically validated based on the results of its clinical studies completed to date, including the results of its foundational case-control Circulating Cell-free Genome Atlas ("CCGA") study and interventional PATHFINDER study which together enrolled more than 21,000 participants. In these studies, Galleri demonstrated an ability to detect a shared cancer signal across more than 50 types of cancer, accurately predict the specific organ or tissue type where the cancer signal originated, and yield high positive predictive values and low false positive rates, all from a simple blood draw. Galleri results can help guide next steps for diagnosis of cancer by healthcare providers in required follow-up diagnostic testing. We launched Galleri in the United States in mid-2021. We have sold more than 325,000 commercial tests to-date, including more than

37,000 in the first quarter of 2025, which have detected some of the most aggressive cancers in early stages including, among others, endometrial, esophageal, gastric, head and neck, liver, pancreatic, and rectal cancers.

Since our inception, we have incurred net losses each year. We incurred net losses of $106.2 million and $218.9 million for the three months ended March 31, 2025 and March 31, 2024, respectively (see "Basis of Presentation" below for a description of applicable fiscal periods). Adjusted EBITDA was $(98.7) million and $(152.0) million for the three months ended March 31, 2025 and March 31, 2024, respectively. Adjusted EBITDA is a non-GAAP financial measure. For a reconciliation of Adjusted EBITDA to the most directly comparable U.S. generally accepted accounting principle ("GAAP") financial measure, information about why we consider Adjusted EBITDA useful and a discussion of the material risks and limitations of these measures, please see "Non-GAAP Financial Measures" below. Substantially all of our net losses resulted from the application of pushdown accounting, including goodwill and intangible assets impairment, amortization of intangible assets, as well as our research and development programs, general and administrative ("G&A") costs associated with our operations and sales and marketing costs associated with commercializing our products. Additionally, due to the application of pushdown accounting, our balance sheet includes intangible assets recognized by Illumina in connection with their acquisition of us that may be subject to additional impairment over time. We expect to continue to incur operating losses over at least the next several years as we continue to invest in research and development and commercialization of existing products.

Separation from Illumina

On June 24, 2024, Illumina completed the previously announced spin-off of GRAIL (the "Spin-Off"). The Spin-Off was completed through a distribution of approximately 85.5% of our outstanding common stock to the holders of record of Illumina's common stock as of the close of business on June 13, 2024 (the "Distribution"), which resulted in the issuance of 31,049,148 shares of common stock. As a result of this Distribution, GRAIL became an independent public entity. GRAIL's common stock is listed under the ticker symbol "GRAL" on the Nasdaq Stock Exchange.

We entered into or adopted agreements that provide a framework for the relationship between us and Illumina in connection with the Spin-Off. See *Note 1 — Organization And Description Of Business* for details. In connection with the Spin-Off, certain equity and liability classified awards were converted in accordance with the employee matters agreement. As a result of the separation, our member's equity balance was reclassified to additional paid-in capital.

On June 21, 2024, in connection with the Spin-Off, we received a cash contribution of $932.3 million from Illumina. In connection with the Spin-Off, we incurred $6.3 million of legal and professional fees in the three month period ended March 31, 2024 related to the 2021 acquisition of GRAIL by Illumina, and corresponding antitrust litigation, including compliance with the hold separate arrangements imposed by the European Commission, and divestiture of GRAIL from Illumina through the Spin-Off. See "Non-GAAP Financial Measures — Adjusted EBITDA" for further details. In addition, from 2021 to 2024, we spent $143.8 million on legal and professional service fees related to the antitrust litigation and compliance with the hold separate order and transaction costs related to Illumina's acquisition of GRAIL and the Spin-Off.

Restructuring Plan

On August 9, 2024, following a portfolio review, our Board of Directors (the "Board") approved a restructuring plan ("Restructuring Plan") designed to reprioritize our resources to focus on our core MCED business and reduce overall spend as we progress towards completion of registrational studies and premarket approval application ("PMA") submission to the U.S. Food and Drug Administration ("FDA") for Galleri.

As a result, we have taken actions to streamline our commercial sales forces and focus their field-based activities on the current customers expected to be more productive and high priority opportunities. We maintained sales force coverage for the majority of our current Galleri volume and active prescribers. As part of this approach, we also streamlined our current and planned investment in our enterprise business, which included our employer and life insurance businesses. Reductions in the commercial organization included management layers and commercial roles without sales responsibilities. In addition to reductions in the commercial organization, we made reductions in medical affairs teams involved with U.S. Galleri provider engagement.

We also substantially decreased investment and planned investment in research and development activities related to our product programs beyond Galleri, including our diagnostic aid for cancer and minimal residual disease programs. In addition, we made reductions in general and administrative expenses to reflect the focus on the MCED opportunity. We plan to continue to invest in our biopharmaceutical partnerships and work with our partners to leverage our proprietary methylation technology in precision oncology applications.

The decision was based on cost-reduction initiatives intended to reduce our ongoing operating expenses and maximize shareholder value.

The Restructuring Plan included a reduction in our existing headcount and planned 2024 hires of approximately 30%, inclusive of 350 then full-time employees, or approximately 25% of the workforce in place as of June 30, 2024.

The Restructuring Plan was substantially completed in the fourth quarter of 2024, and we incurred $18.3 million of total charges through the fourth quarter of 2024, consisting primarily of employee severance, benefits, payroll taxes, and other associated costs. For the three months ended March 31, 2025, we incurred an immaterial amount of restructuring charges.

Prevalent Screening Round Results for NHS-Galleri

In May 2025, we completed a review of Galleri test performance results in the intervention arm from the prevalent screening round of the registrational NHS-Galleri trial. The prevalent screening round is the first round of blood draws (of the three total blood draw rounds in the trial) with one year of follow up.

Data from the prevalent screening round showed a substantially higher positive predictive value (PPV) than that observed in the PATHFINDER study, which was previously published in the *Lancet*. Cancer signal of origin (CSO) accuracy and specificity were consistent with that observed in the PATHFINDER study. In PATHFINDER, Galleri demonstrated a PPV of 43%, CSO accuracy of 88%, and specificity of 99.5%. There were no serious safety concerns in the NHS-Galleri prevalent screening round.

The NHS-Galleri trial is a clinical utility trial of over 140,000 participants to evaluate the implementation of Galleri alongside the existing NHS standard of care screenings. The NHS-Galleri trial was designed as three annual blood draws, plus 12 months follow up, in order to evaluate Galleri's ability to move forward the stage of cancer diagnosis relative to standard of care (primary endpoint). Cancer screening trials designed to show clinical utility are commonly conducted over three years with an annual screening interval, because data can be influenced by the fact that the first screening round detects many prevalent late-stage asymptomatic cancers that have not yet been diagnosed. This and other factors are likely to cause final results of the three year trial to differ from a review of the first round results.

Final clinical utility results from all three years of the trial are expected in mid-2026. We plan to submit data from the prevalent screening round of the NHS-Galleri trial, the first 25,000 participants in the PATHFINDER 2 study, and a bridging study (comparing the version of Galleri used in the NHS-Galleri and the PATHFINDER 2 trials to the updated version that we plan to submit to the FDA for premarket approval) as part of our premarket approval application in the first half of 2026.

Real World Evidence Results

In April 2025, we presented results from more than 100,000 patients at the American Association for Cancer Research (AACR) Annual Meeting collected in a real-world setting from over 9,000 healthcare providers across all U.S. states who ordered Galleri tests and had results returned to their patients. Clinical cancer outcomes were voluntarily provided by ordering providers to us in compliance with the requirements of the US Health Insurance Portability and Accountability Act (HIPAA) of 1996 and its implementing regulations through our quality assurance program. In this population, 1,011 patients received a positive Galleri test result. Of those, 459 patients had follow up information reported to us by their provider. 411 of those patients had a completed diagnostic workup, 259 of whom had received their Galleri test for asymptomatic screening. Test performance in these 259 patients was consistent with that observed in our prior clinical studies for asymptomatic screening, with a positive predictive value of the Galleri test of 49% and cancer signal of origin accuracy of 87%. Because of differences in sample

size, age distributions, the limitations of collecting data in a real-world setting through voluntary reporting, the importance of work ups and other factors, these results are not directly comparable to the results of our clinical studies, such as our PATHFINDER trial or the prevalent screening round or full trial results of our NHS-Galleri trial.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared on a standalone basis using the consolidated financial statements and accounting records of Illumina prior to the Spin-Off, and the accounting records of GRAIL, Inc. subsequent to the Spin-Off. These unaudited condensed consolidated financial statements reflect our consolidated historical financial position, results of operations and cash flows as historically managed, in accordance with GAAP. The unaudited condensed consolidated financial statements may not be indicative of our future performance and do not necessarily reflect what the financial position, results of operations and cash flows would have been, and may not include all expenses that would have been incurred, had GRAIL been operated as an independent, publicly traded company during the periods presented prior to the Spin-Off. Certain situations require management to make estimates based on judgments and assumptions, which may affect the reported amounts of assets and respective disclosures at the date of the financial statements. Management's judgments and assumptions may also affect the reported amounts of net sales and expenses during the reporting periods. Actual results could differ from these management estimates.

While GRAIL was a subsidiary of Illumina, GRAIL's fiscal year was the 52 or 53 weeks ending the Sunday closest to December 31, with quarters of 13 or 14 weeks ending the Sunday closest to March 31, June 30, September 30, and December 31. The three months ended March 31, 2025 and March 31, 2024, respectively, were both 13 weeks. Upon the closing of the Spin-Off, GRAIL adopted a fiscal year end of December 31.

Illumina's acquisition of GRAIL on August 18, 2021 ("the Acquisition") represented a change of control with respect to GRAIL. Given GRAIL, Inc. merged with SDG Ops, Inc., which then merged with SDG Ops LLC, authoritative guidance (ASC 805-50-30) required pushdown accounting to be applied for the Second Merger amongst entities under common control. As a result of the application of pushdown accounting, the separately issued financial statements of GRAIL reflect Illumina's basis in the assets and liabilities of GRAIL which were remeasured to fair value as of the Closing Date. Intangible assets included developed technology, in-process research and development, and trade names, as well as goodwill.

We have incurred and expect to incur additional costs as a separate public company. These additional costs are primarily related to certain supporting functions that may differ from and be higher than the costs historically incurred or allocated to us.

The additional costs we expect to incur as a separate public company are summarized as follows:

- Accounting and audit related costs, professional services, and new systems and software to support the accounting, financial reporting, and audits as a standalone public company;
- Professional service costs, for additional support to enhance our capabilities in areas such as investor relations, accounting, financial reporting, treasury, risk management, and equity administration, among others; and
- Corporate governance costs, including but not limited to board of directors compensation and expenses, insurance, legal and other professional services fees, annual report and proxy statement costs, SEC filing fees, transfer agent fees, and stock exchange listing fees.

In addition, we have entered into a supply and commercialization agreement with Illumina. Under the terms of the agreement, regardless of whether our products incorporate any Illumina technology, we have agreed to pay to Illumina a high single-digit royalty, subject to certain reductions, in perpetuity on net sales generated by our products or revenues otherwise generated or received by us, subject to certain exceptions, in the field of oncology. Per the terms of the Separation and Distribution Agreement with Illumina, the royalty arrangement is suspended until the earlier of December 24, 2026 or any earlier GRAIL Change of Control (as defined in that agreement), at which time the high single-digit royalty will become payable.

Certain factors could impact the nature and amount of these separate public company costs, including the finalization of our staffing and infrastructure needs.

Key Factors Affecting Performance

We believe there are several important factors that have impacted and that we expect will impact our operating performance and results of operations, including:

- ***FDA and other regulatory approval and reimbursement***. Our performance will be impacted by the extent to which we can secure reimbursement and coverage for Galleri. Prior to broader coverage and reimbursement in the United States, we will continue our work with clinics and health systems to accelerate utilization, and with self-insured employers and health insurers to offer and cover Galleri. Galleri is currently available as a laboratory developed test ("LDT") in the United States and we have established private reimbursement from a number of self-insured employers and health plans, including coverage from TRICARE, but we do not currently have broader coverage and reimbursement by Medicare or large commercial insurers. While Galleri has not been approved or cleared by the FDA, FDA approval is currently not required to market our test in the United States. We plan to pursue FDA approval to help support broad access for Galleri in the United States. We plan to complete a PMA submission with the FDA in the first half of 2026. The timing of this submission is subject to various risks and other factors, including the completion of clinical studies and our ongoing discussions with the FDA. Obtaining PMA approval can take several years from the time an application is submitted, if at all. Moreover, the FDA requirements that will govern MCED tests, as well as the breadth and nature of data we must provide the FDA to support the proposed intended use, may be subject to change, and as such it is difficult to predict what information we will need to submit to obtain approval of a PMA from the FDA for a proposed intended use or at all. Moreover, the regulatory requirements surrounding the pathway to PMA for LDTs like Galleri may be subject to change, including through a recent court decision that has successfully challenged the FDA's authority to implement medical device requirements with respect to LDTs. We continue to interact with the FDA regarding the data we must provide the FDA to support our PMA submission for the proposed intended use. We believe that FDA approval, if obtained, could unlock large commercial payors in the United States and we are supporting proposed legislation in the United States to enable coverage of FDA-approved MCED tests by Medicare. If we obtain FDA approval, we expect to pursue inclusion of Galleri in the USPSTF's guideline recommendation, although such inclusion is not certain even with FDA approval. We believe such inclusion would further increase adoption and market acceptance of our tests. Over time, to the extent Galleri becomes more accessible in the United States, we may opt to reduce pricing in order to access a broader population base and accelerate adoption. In the United Kingdom, we are working with NHS England to complete our NHS-Galleri Trial. The NHS will evaluate the final results from the NHS-Galleri Trial, which are expected to be available in 2026, before determining whether to implement the Galleri test in the NHS. We believe the decision will include considerations such as NHS budget, political priorities, cost-effectiveness and implementation constraints in addition to an evaluation of the final results. We believe our work with the NHS and data generated from our NHS-Galleri Trial, if favorable, could help facilitate adoption in other single-payor systems around the world and support evidence of clinical utility worldwide.

- ***International expansion***. A component of our long-term growth strategy is to expand our commercial reach internationally. We have expanded our research internationally into the United Kingdom through our partnership with NHS England in the NHS-Galleri Trial, and we expect to launch Galleri in the United Kingdom, subject to the results of our NHS-Galleri Trial. We continue to evaluate international expansion opportunities and we have begun expansion in select additional geographies through distributors. We expect to continue selectively engaging with international opportunities over time.

- ***Continued development of the market for MCED testing***. Multi-cancer early detection is a relatively novel technology and the market for MCED tests is evolving. We continue to drive MCED as a solution to one of healthcare's most important challenges. Our performance depends on the extent to which key stakeholders, including current and potential commercial partners, payors and health systems, regulators, policy makers, academic and community medical centers, and key opinion leaders and advocates, understand and support MCED testing as an effective solution for cancer screening. We make significant efforts to educate these key stakeholders regarding the benefits of MCED and the

clinical and economic value of our products, which we believe will continue to drive awareness of MCED and expand the commercial opportunity for our products.

- ***Demand for our products and customer mix***. A key factor to our future success is and will be our ability to increase demand for, and sales of, Galleri from new and existing customers. Our commercial strategy is focused on innovative value-oriented partnerships and targets health systems, employers, payors, and life insurance providers. As Galleri is not currently broadly reimbursed, our ability to drive demand from these customers is directly linked to our ability to demonstrate the clinical and economic value of our test through clinical validation and real-world experience. As of March 31, 2025, we have entered into commercial partnerships, including with leading healthcare systems, employers, payors, and life insurance providers, and have established a network of over 14,000 prescribers across the United States in a pre-reimbursement setting. We believe this commercial network represents a significant opportunity to drive further demand for Galleri. The mix of customers from which we generate revenue from period to period has an impact on our revenue and gross margin. Galleri test pricing is generally based on our list price or, for certain customers, such as larger, higher-volume customers, negotiated contractual rates. For certain customers, we also offer rebates or discounts from time to time. Revenue generated from customers with negotiated contractual rates, or with rebates or discounts, is generally lower margin as compared to revenue generated based on list pricing. We expect the number or magnitude of these rates, discounts and rebates to reduce our average selling price over time. In addition, we have entered into a number of biopharmaceutical research partnerships for our research-use-only ("RUO") offering under our precision oncology portfolio. Large customers, such as healthcare systems, employers, and biopharmaceutical partners, generally begin using our products by initiating pilots involving a limited number of tests. We believe that our ability to convert these initial pilots into long-term customer relationships has the potential to drive substantial long-term revenue. We also expect to increase demand from new customers through our efforts to further develop the market for MCED testing.

- ***Investment in clinical studies and innovation to support our strategy and growth***. A significant aspect of our business is our investment in research and development and the ongoing evidence generation supporting the clinical performance and utility of Galleri. In particular, we have invested heavily in clinical studies and designed and executed what we believe is the largest clinical program in genomic medicine to date. These studies include: CCGA, NHS-Galleri, PATHFINDER, PATHFINDER 2, REACH/Galleri-Medicare, REFLECTION, STRIVE, SUMMIT, and SYMPLIFY. We have established and maintained a leading voice in conversations regarding the early detection of multiple cancer types in the peer-reviewed literature. We have published data from these studies in high-profile journals and have presented such data at renowned medical conferences. We believe these studies are critical to driving adoption of our tests, as well as favorable coverage decisions, and expect to continue investment in data generation. In addition, we have invested heavily in the development of our methylation platform and extensive technological infrastructure. We expect our research and development expenses to decrease over the next three years as, in conjunction with our portfolio review, we determined to decrease investment in product programs beyond Galleri. Additionally, some of our large clinical trials are moving into follow-up phase and the development of our automated platform is expected to substantially conclude in 2025. We will continue to prioritize key objectives for Galleri, including completion of our registrational studies and our premarket approval application.

- ***Leverage our operational infrastructure***. We have made significant investments to build a scalable infrastructure capable of meeting significant demand of up to one million tests per year while satisfying applicable certification requirements. Our Durham, North Carolina facility is CAP-accredited and CLIA-certified. In addition, we engineered custom technology infrastructure and cloud-based tools to enable scalable data collection and analysis capabilities. With this foundational infrastructure in place, we have been able to generate scale efficiencies as the volume of tests sold has increased. As demand for our products increases, we expect to further leverage the scale efficiencies of our infrastructure and platform technology, which we believe will positively impact margins over time. In the future, it is possible that we may invest significant amounts in infrastructure to support new products or existing products in new markets.

While each of these areas presents significant opportunities for us, they also pose significant risks and challenges that we must address. See the “Risk Factors” section of our 2024 Form 10-K for the year ended December 31, 2024 (filed on March 5, 2025) and the “Risk Factors” section of this Form 10-Q, alongside other information set forth in this Form 10-Q and in other documents that we file with the SEC, for more information. Seasonal fluctuations, underlying business trends have also affected, and are likely to continue to affect, our business. We may experience this seasonality, in particular in the third quarter due to primary care physician and patient summer vacation period, with relatively lower volume in the first and third quarters, and relatively higher volume in the second and fourth quarters. These seasonal trends have caused, and will likely continue to cause, fluctuations in our quarterly results, including fluctuations in sequential revenue growth rates.

Components of Results of Operations

Screening Revenue

We currently derive screening revenue through the sale of Galleri primarily within the United States and primarily through primary care physicians, health systems, employers, payors, and life insurance providers. Galleri is not currently broadly reimbursed. The test price is based on the negotiated contractual rate with our contracted customers, otherwise our standard list price applies. We identify each sale of our test to our customer as a single performance obligation; therefore, revenue is recognized at the point of time when the test result report is delivered. For self-pay patients, we have concluded that an implied contract exists, however the transaction price for the implied contract represents variable consideration as there are situations in which we do not expect to collect the full invoiced amounts from self-pay patients due to price concessions. We utilize the expected value approach to estimate the transaction price and apply a constraint for such variable consideration, on a portfolio basis. We monitor the estimated amounts to be collected at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required.

Development Services Revenue

We also derive revenue through our development services, which consist of research services we provide to biopharmaceutical and clinical customers including support of ongoing clinical studies, pilot testing, research, and therapy development. We evaluate the terms and conditions included within our development services contracts with biopharmaceutical customers to ensure appropriate revenue recognition, including whether services are considered distinct performance obligations that should be accounted for separately versus together. Revenue from pilot and research services performed is recognized as performance obligations are achieved. We recognize revenue from development service agreements related to regulatory filings to support clinical study and companion diagnostic device development and regulatory submissions for the developed product(s) using an input method based on costs incurred to measure its progress toward the completion and satisfaction of the performance obligations.

Cost of Screening Revenue (Exclusive of Amortization of Intangible Assets) and Cost of Development Services Revenue

Cost of revenue represents expenses that are incurred to produce and sell our products and services. For screening revenue, these costs consist of materials, labor including salaries and wages, bonus, benefits and stock-based compensation, blood collection kits and shipping, phlebotomy, royalties, electronic medical records, equipment depreciation, and allocations of overhead expenses such as facilities and information technology costs. For development services, these costs consist of materials and patient sample acquisition, labor including salaries and wages, bonus, benefits and stock-based compensation, royalties, equipment depreciation, and allocations of overhead expenses such as facilities and information technology costs.

Cost of Revenue — Amortization of Intangible Assets

As a result of the application of pushdown accounting, intangible assets recognized in our standalone financial statements relate to our own technology, and consist of developed technologies and in-process research and development that were measured at fair value upon the Acquisition. Our developed technology includes intangible assets related to Galleri, designed as a cancer screening test for asymptomatic individuals over 50 years of age, as well as our diagnostic aid for cancer (“DAC”) that is being designed to accelerate diagnostic

resolution for patients for whom there is a clinical suspicion of cancer. As part of our Restructuring Plan, we are reducing investment in the development of products beyond Galleri, including DAC. The cost of identifiable intangible assets with finite lives, such as developed technology assets, are amortized on a straight-line basis over the assets' respective estimated useful lives of 18 years.

Research and Development

Research and development expenses include costs incurred to develop our technology (prior to establishing technological feasibility), collect clinical samples, and conduct clinical studies to develop and support our products. These costs consist of personnel costs, including salaries, benefits, and stock-based compensation expense associated with our research and development personnel, costs associated with setting up and conducting clinical studies at domestic and international sites, laboratory supplies, consulting costs, depreciation, and allocated overhead including facilities and information technology expenses, which we do not allocate by product. We expense both internal and external research and development costs in the periods in which they are incurred. Nonrefundable advance payments for goods and services that will be used or rendered in future research and development activities are deferred and recognized as expense in the period in which the related goods are delivered or services are performed. We expect our research and development expenses to decrease over the next three years as, in conjunction with our portfolio review, we determined to decrease investment in product programs beyond Galleri. Additionally, some of our large clinical studies and development of our automated platform are expected to substantially conclude in this period.

Sales and Marketing

Sales and marketing expenses consist primarily of personnel costs, including salaries, benefits and stock- based compensation expense, consulting costs, allocated overhead including facilities and information technology expenses, and travel associated with our commercial organization. Also included are costs associated with advertising programs that consist of brand and product awareness activities and trade events and conferences. Sales and marketing expense also includes amortization of the trade name intangible asset that was recognized upon the Acquisition, which has been recorded in our financial statements as a result of the application of pushdown accounting. The cost of identifiable intangible assets with finite lives, such as trade names, are amortized on a straight-line basis over the assets' respective estimated useful lives of 9 years. We expect our sales and marketing expenses to decrease in the near term as a result of the implementation of the Restructuring Plan, and then to remain flat-to-increasing and continue to decrease as a percentage of revenue over the next three years and long term.

General and Administrative

G&A expenses consist of personnel expenses, including salaries, benefits and stock-based compensation expense, for executive, finance and accounting, legal, human resources, business development, corporate communications, medical affairs and management information systems personnel. Also included are professional fees, legal costs, including patent and trademark-related expenses and educational activities. The related party amount in the prior year period represents allocated stock administration expenses from Illumina. We have incurred and will incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, director and officer insurance premiums, investor relations activities, and other expenses related to administrative and professional services. We expect our G&A expenses to decrease in the near term following implementation of the Restructuring Plan in the third and fourth quarter 2024, and then to remain flat-to-increasing and continue to decrease as a percentage of revenue over the next three years and long term.

Goodwill and Intangible Assets Impairments

Upon the Acquisition, excess consideration over the aggregate fair value of tangible and intangible assets, net of liabilities assumed, was recognized by Illumina as goodwill. As a result of the application of pushdown accounting, the separately issued financial statements of GRAIL reflect the goodwill recorded by Illumina upon the Acquisition.

We evaluate goodwill impairment annually or more frequently if an event occurs or circumstances change in the interim that would more likely than not reduce the fair value of the asset below its carrying amount. See *Note 2 — Summary of Significant Accounting Policies — Goodwill and Intangible Assets* to our Consolidated Financial Statements filed with our 2024 Form 10-K (filed on March 5, 2025).

Interest Income

Interest income consists primarily of interest income earned on our cash, cash equivalents, and short-term marketable securities.

Other Income (Expense), Net

Other income (expense), net primarily consists of foreign currency gains and losses as a result of our intercompany agreements.

Benefit from Income Taxes

Upon closing of the Acquisition, as a wholly owned subsidiary of Illumina, we were no longer subject to U.S. income tax on a standalone basis and U.S. income tax was combined into Illumina's consolidated income tax return as a subsidiary of Illumina. However, for financial statement purposes, we have elected to compute our income tax provision, including current and deferred taxes, as if we filed a separate income tax return and were not included in Illumina's consolidated return for the period GRAIL was owned by Illumina. Including the provision for income taxes in our standalone financials is more representative of our financial position as a standalone company. As such, the income tax provisions and related deferred tax assets and liabilities reflected in our financial statements for the period ending March 31, 2024 has been estimated as if we were a separate taxpayer.

Under this method, various tax attributes, such as net operating losses and tax credits, are also presented on a separate return basis. For income tax purposes, since we were not a separate taxpayer and merely a subsidiary of Illumina, these tax attributes, including net operating losses and tax credits, are the property of Illumina and have either already been utilized by Illumina in its consolidated or combined income tax returns or will be utilized by Illumina in its returns in the future. Accordingly, such tax attributes will not be available to us as a standalone entity on our income tax returns in the future; therefore, in connection with the Spin-off, we recorded an entry to additional paid in capital in order to remove the tax-effected deferred tax assets, net of any valuation allowance, for the tax attributes that remained the property of Illumina. Beginning in 2024 after the Spin-off, as a standalone entity, GRAIL will file tax returns on its own behalf and its deferred taxes and actual income tax rate may differ from those in historical periods.

Results of Operations

Comparisons of the Three Months Ended March 31, 2025 and March 31, 2024

The following table summarizes our results of operations for the three months ended March 31, 2025 and March 31, 2024.

(in thousands)	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024
Revenue:		
Screening revenue	$ 29,133	$ 23,539
Development services revenue	2,704	3,182
Total revenue	31,837	26,721
Costs and operating expenses:		
Cost of screening revenue (exclusive of amortization of intangible assets)	17,123	13,722
Cost of development services revenue	1,171	1,436
Cost of revenue — amortization of intangible assets	33,472	33,472
Research and development	53,625	101,625
Sales and marketing	34,979	46,819
General and administrative	45,074	57,069
Total costs and operating expenses	185,444	254,143
Loss from operations	(153,607)	(227,422)
Other income:		
Interest income	7,779	2,901
Other income (expense), net	(584)	42
Total other income, net	7,195	2,943
Loss before income taxes	(146,412)	(224,479)
Benefit from income taxes	40,199	5,565
Net loss	$ (106,213)	$ (218,914)

Comparison of the Three Months Ended March 31, 2025 and March 31, 2024

Revenue

(in thousands)	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024	Change $	Change %
Screening revenue	$ 29,133	$ 23,539	$ 5,594	24 %

Screening Revenue

The increase in screening revenue of $5.6 million was primarily attributable to a 31% increase in Galleri sales volume, offset by a 5% decrease in average selling price (“ASP”). The Galleri sales volume increased in the first three months of 2025 as a result of the continued ramp in our commercial activity and partnerships, expansion of our network of ordering providers, and new promotional campaigns.

Cost of Screening Revenue (Exclusive of Amortization of Intangible Assets)

(in thousands)	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024	Change $	Change %
Cost of screening revenue (exclusive of amortization of intangible assets)	$ 17,123	$ 13,722	$ 3,401	25 %

The increase in cost of screening revenue (exclusive of amortization of intangible assets) of $3.4 million was primarily attributable to an increase in test volume. Cost of screening revenue (exclusive of amortization of intangible assets) as a percent of revenue decreased in 2025 primarily due to the launch of our automated platform, however this decrease was offset by the 5% decrease in average selling price.

Research and Development

Research and development expenses for the three months ended March 31, 2025 and March 31, 2024 were as follows:

(in thousands)	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024	Change $	Change %
Compensation expenses	$ 29,705	$ 50,291	$ (20,586)	(41 %)
Allocated expenses	6,384	9,787	(3,403)	(35) %
Clinical studies	5,922	14,905	(8,983)	(60 %)
Laboratory supplies and research collaboration expenses	4,559	17,411	(12,852)	(74 %)
Depreciation expenses	2,494	3,281	(787)	(24 %)
Other expenses	4,561	5,950	(1,389)	(23 %)
Total research and development	$ 53,625	$ 101,625	$ (48,000)	(47 %)

The decrease in research and development expenses by $48.0 million was primarily attributable to decreases in compensation expenses, laboratory supplies and research collaboration expenses and clinical study expenses.

The decrease of $20.6 million in compensation expenses was primarily related to a decrease of $12.4 million in salaries and wages, a decrease of $7.9 million in stock-based compensation, and a decrease of $1.0 million in variable compensation expense primarily due to the reduction in workforce related to the Restructuring Plan, partially offset by an increase of $0.7 million in severance and benefits.

The decrease of $3.4 million in allocated expenses was primarily attributable to lower software, IT, and facilities expenses being allocated to the research and development function.

The decrease in clinical studies of $9.0 million was primarily due to a decrease of $10.1 million primarily related to completion of enrollment in our PATHFINDER 2 study and completion of final study visits in our NHS-Galleri Trial, partially offset by an increase of $1.1 million due to enrollment in our REACH/Galleri-Medicare study.

The decrease in laboratory supplies and research collaboration expenses of $12.9 million was primarily driven by the completion of the development and validation of our automated platform at the end of 2024 as well as the completion of enrollment in our PATHFINDER 2 study and completion of final study visits in our NHS-Galleri Trial.

The decrease of $1.4 million in other expenses was primarily driven by a decrease in the use of contractors and temporary labor due to cost optimization efforts.

Sales and Marketing

(in thousands)	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024	Change $	Change %
Sales and marketing	$ 34,979	$ 46,819	(11,840)	(25)%

The decrease in sales and marketing expenses of $11.8 million was primarily attributable to a decrease of $9.6 million in compensation expenses primarily related to a decrease in salaries and wages of $7.2 million and a decrease in stock-based compensation of $2.4 million primarily due to the reduction in workforce related to the Restructuring Plan. Third-party marketing professional services expenses decreased by $1.6 million due to cost optimization efforts.

General and Administrative

(in thousands)	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024	Change $	Change %
General and administrative	$ 45,074	$ 57,069	$ (11,995)	(21 %)

The decrease in general and administrative expenses of $12.0 million was primarily attributable to a decrease of $9.1 million in compensation expenses primarily related to a decrease in salaries and wages of $5.8 million and a decrease of $3.2 million in stock-based compensation primarily due to the reduction in workforce related to the Restructuring Plan. Legal and professional services expenses decreased by $2.5 million due to no longer incurring legal and professional service fees related to compliance with the European Commission hold separate order and transaction costs related to our Spin-Off, which completed on June 24, 2024. Costs associated with the use of contractors and temporary labor decreased by $1.1 million due to cost optimization efforts.

Interest Income

(in thousands)	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024	Change $	Change %
Interest income	$ 7,779	$ 2,901	$ 4,878	168 %

The increase in interest income of $4.9 million was primarily driven by an increase in interest earned on our money market funds and short-term marketable securities primarily due to an increase in the balance on hand as a result of the disposal funding provided by Illumina in connection with the Spin-Off.

Benefit from Income Taxes

(in thousands)	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024	Change $	Change %
Benefit from income taxes	$ 40,199	$ 5,565	$ 34,634	622 %

The increase in benefit from income taxes was primarily driven by the increase in effective tax rate for the three months ended March 31, 2025 when compared to the effective tax rate for the three months ended March 31, 2024. The increase in effective tax rate for the three months ended March 31, 2025 as compared to the three months ended March 31, 2024 primarily relates to the Company's 2024 valuation allowance impacts against pre-tax losses prior to the Spin-off.

Non-GAAP Financial Measures

In addition to our results provided throughout this Form 10-Q that are determined in accordance with GAAP, this Form 10-Q also includes the following non-GAAP financial measures for the three months ended March 31,

2025 and March 31, 2024, which information should be read in conjunction with our unaudited Condensed Consolidated Financial Statements and the related notes included elsewhere in this Form 10-Q:

Adjusted Gross Profit/(Loss)

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.

	Three Months Ended	
(in thousands)	March 31, 2025	March 31, 2024
Gross loss [(1)]	$ (19,929)	$ (21,909)
Amortization of intangible assets	33,472	33,472
Stock-based compensation	762	481
Adjusted Gross Profit	$ 14,305	$ 12,044

[(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.

Adjusted EBITDA

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.

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 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.

	Three Months Ended	
(in thousands)	March 31, 2025	March 31, 2024
Net loss	$ (106,213)	$ (218,914)
Adjusted to exclude the following:		
Interest income	(7,779)	(2,901)
Benefit from income tax expense	(40,199)	(5,565)
Amortization of intangible assets [1]	34,584	34,584
Depreciation	4,695	5,413
Illumina/GRAIL merger & divestiture legal and professional services costs [2]	—	6,308
Stock-based compensation[3]	16,211	29,106
Restructuring[4]	(34)	—
Adjusted EBITDA	$ (98,735)	$ (151,969)

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

(2) 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.

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

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

Liquidity and Capital Resources

Sources of Liquidity

From inception through the closing date of Illumina's acquisition of GRAIL, we had funded our operations primarily through the sale and issuance of redeemable convertible preferred stock and receipt of continuation payments from Illumina. Post- Acquisition until completion of the Spin-Off, we received funding on a quarterly basis directly from Illumina. On June 21, 2024, in connection with the Spin-Off we received a cash contribution of $932.3 million from Illumina. As of March 31, 2025, our cash, cash equivalents and restricted cash totaled $137.2 million and our short-term marketable securities totaled $540.7 million.

Future Funding Requirements

We began generating revenue in mid-2021, but we have continued to incur significant losses and negative cash flows from operations. Subsequent to the acquisition of GRAIL by Illumina, we have incurred net losses of $9.9 billion which include charges for impairment of goodwill and intangible assets and amortization of intangible assets. We expect to continue to incur operating losses over at least the next several years as we continue to invest in research and development and seek to achieve broad reimbursement of our current commercialized products. We believe that our existing cash, cash equivalents and short-term marketable securities will be sufficient to meet our working capital and capital expenditure needs for at least the next 12 months, as of the date of this Form 10-Q. However, we anticipate that we will need to raise additional financing in the future to fund our operations. Our future capital requirements will depend on many factors, including the timing and extent of spending to support commercialization, market acceptance of our products prior to broad reimbursement, the timing of broad reimbursement, and launch of pipeline products. We are subject to typical risks associated with an

early-stage commercial company and are developing the market for multi-cancer early detection. We may encounter complications with executing our business plans that may cause unforeseen expenses and adversely affect our business.

We may in the future enter into arrangements to acquire or invest in complementary businesses, services, technologies, and intellectual property rights. We may be required to seek additional capital through equity or debt financing. In the event that additional financing is required, we may not be able to raise it on terms acceptable to us or at all. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders, increased fixed payment obligations, and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations. We are also restricted in our ability to raise money through certain transactions or with certain parties pursuant to the terms of the Tax Matters Agreement we entered into with Illumina on June 24, 2024 in connection with the Spin-Off. We may also choose to raise funds through collaborations and licensing arrangements, in which case we may relinquish significant rights or grant licenses on terms that are not favorable to us. If we are unable to raise additional capital when desired, our business, results of operations, and financial condition would be adversely affected.

The following table summarizes our cash flows for the periods presented:

(in thousands)	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024
Net cash used in operating activities	$ (95,012)	$ (207,286)
Net cash provided by (used in) investing activities	14,611	(2,548)
Net cash provided by financing activities	—	312,000
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	62	(37)
Net (decrease) increase in cash, cash equivalents, and restricted cash	$ (80,339)	$ 102,129

Net Cash Used in Operating Activities

During the three months ended March 31, 2025, net cash used by operating activities consisted of a net loss of $106.2 million offset by non-cash charges of $9.7 million and cash provided by changes in our operating assets and liabilities of $1.5 million. The non-cash adjustments primarily consisted of depreciation and amortization of $39.3 million, and stock-based compensation expense of $16.2 million, which was partially offset by a non-cash benefit of $40.2 million relating to deferred taxes and amortization of discount on marketable securities of $6.4 million. Changes in operating assets and liabilities was predominantly driven by a decrease in prepaids and other current assets of $2.8 million, a decrease in accounts receivable of $0.7 million, an increase in accounts payable of $0.9 million and a decrease in net operating lease assets and liabilities of $0.2 million, partially offset by a decrease in accrued and other liabilities of $3.1 million.

During the three months ended March 31, 2024, net cash used by operating activities consisted of a net loss of $218.9 million, $42.9 million cash payments for equity awards, and cash used by changes in our operating assets and liabilities of $9.8 million, partially offset by non-cash charges of $64.4 million. The non-cash adjustments primarily consisted of depreciation and amortization of $40.0 million and stock-based compensation expense of $29.1 million, which was partially offset by a non-cash benefit of $4.8 million relating to deferred taxes. Changes in operating assets and liabilities was predominantly driven by a decrease in accounts payable of $7.7 million, an increase in prepaids and other current assets of $3.6 million, and a decrease in accrued and other liabilities of $1.1 million, partially offset by a decrease in accounts receivable of $1.9 million, a decrease in net operating lease assets and liabilities of $0.6 million, and a decrease in supplies of $0.1 million.

Net Cash Provided by (Used in) Investing Activities

During the three months ended March 31, 2025, net cash provided by investing activities primarily consisted of proceeds from maturities of marketable securities of $235.2 million, partially offset by purchases of marketable

securities of $220.5 million and $0.1 million for capital expenditures primarily related to purchases of machinery and equipment for use in our laboratories.

During the three months ended March 31, 2024, net cash used by investing activities primarily consisted of $2.5 million for capital expenditures primarily related to purchases of machinery and equipment for use in our laboratories.

Net Cash Provided by Financing Activities

During the three months ended March 31, 2025, there was no cash provided by or used in financing activities.

During the three months ended March 31, 2024, net cash provided by financing activities primarily consisted of $312.0 million in funding received from Illumina.

Material Cash Requirements

There have been no material changes to our material cash requirements from those disclosed in our 2024 Form 10-K. Refer to Notes 8 and 9 to our Consolidated Financial Statements for a discussion of our operating lease obligations and purchase commitments, respectively.

Critical Accounting Estimates

This discussion and analysis of our financial condition and results of operations is based on our unaudited Condensed Consolidated Financial Statements, which have been prepared in accordance with U.S. GAAP. The preparation of these unaudited Condensed Consolidated Financial Statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the unaudited Condensed Consolidated Financial Statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. During the three months ended March 31, 2025, there were no material changes to our critical accounting policies from those disclosed within the consolidated financial statements for the year ended December 31, 2024 included in our 2024 Form 10-K (filed on March 5, 2025).

JOBS Act

We are an emerging growth company under the Jumpstart our Business Startups Act of 2012 (the “JOBS Act”). As an emerging growth company, we may delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have nonetheless irrevocably elected not to avail ourselves of this exemption and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We will remain an emerging growth company until the earliest to occur of the following: (i) the last day of the fiscal year in which our total annual gross revenues first meet or exceed at least $1.235 billion (as adjusted for inflation), (ii) the date on which we have, during the prior three-year period, issued more than $1.0 billion in non-convertible debt, (iii) the last day of the fiscal year in which we (a) have an aggregate worldwide market value of common stock held by non-affiliates of $700 million or more (measured at the end of each fiscal year) as of the last business day of our most recently completed second fiscal quarter and (b) have been a reporting company under the Exchange Act for at least one year (and have filed at least one annual report under the Exchange Act), or (iv) the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement under the Securities Act.

Recent Accounting Pronouncements

See *Note 2 — Summary Of Significant Accounting Policies* to our unaudited Condensed Consolidated Financial Statements included in *Item 1. Financial Statements* for details of recent accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Sensitivity

We are exposed to market risk related to changes in interest rates related primarily to our cash, cash equivalents and marketable securities. We had cash, cash equivalents, and restricted cash of $137.2 as of March 31, 2025, which consisted primarily of bank deposits, money market funds and marketable securities. Our marketable securities are held in U.S. government treasury bills. As of March 31, 2025, we had short-term marketable securities of $540.7 million. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of the interest rates in the United States. The primary objective of our investment activities is to preserve capital to fund our operations. We do not enter into investments for trading or speculative purposes.

Our investments are subject to interest rate risk and could fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low-risk profile of our investments, a hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material impact on our Condensed Consolidated Financial Statements.

Foreign Currency Sensitivity

The majority of our transactions occur in U.S. dollars. However, we do have certain transactions that are denominated in currencies other than the U.S. dollar, primarily the British pound, and we therefore are subject to foreign exchange risk. The fluctuation in the value of the U.S. dollar against the foreign currencies affects the reported amounts of expenses, assets, and liabilities associated with certain activities. We do not currently engage in any hedging activity to reduce our potential exposure to currency fluctuations, although we may choose to do so in the future. A hypothetical 10% change in foreign exchange rates during any of the periods presented would not have had a material impact on our Condensed Consolidated Financial Statements.

Item 4. Controls and Procedures

Limitation on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated, as of the end of the period covered by this Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our principal executive officer and principal financial officer concluded that, as of March 31, 2025, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Part II - Other Information

Item 1. Legal Proceedings

For information with respect to Legal Proceedings, see *Note 7 — Legal And Regulatory Proceedings* to our condensed consolidated financial statements included in this Form 10-Q.

Item 1A. Risk Factors

Our business, financial condition and operating results are affected by a number of factors, whether currently known or unknown, including risks specific to us or the healthcare industry as well as risks that affect businesses in general. In addition to the information set forth in this Form 10-Q, you should consider carefully the factors discussed in Part I, Item 1A, "Risk Factors" in our 2024 Form 10-K (filed with the SEC on March 5, 2025). The risks and uncertainties disclosed in such Annual Report and in this Form 10-Q could materially adversely affect our business, financial condition, cash flows or results of operations and thus our stock price.

These risk factors may be important to understanding other statements in this Form 10-Q and should be read in conjunction with the unaudited condensed consolidated financial statements and related notes in Part I, Item 1, "Financial Statements" and Part I, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Form 10-Q. Because of such risk factors, as well as other factors affecting our financial condition and operating results, past financial performance should not be considered to be a reliable indicator of future performance, and investors should not use historical trends to anticipate results or trends in future periods.

Our products or future products may not perform as expected, and the results of our clinical studies may not support the launch or use of our products or future products and may not comply with the requirements, or be replicated in later studies or in the post-market or real-world setting, required to support a commercial opportunity or for any necessary or desirable regulatory clearances, approvals, or certifications, or reimbursement or coverage.

Our success depends on our ability to provide reliable, high-quality products that perform as indicated in our product labeling, marketing, and advertising material, as well as our ability to complete clinical studies and comply with applicable regulatory requirements that enable us to commercialize our products and future products. Our commercial product, Galleri, which we have launched as a laboratory developed test ("LDT") in the United States and for which we are pursuing a premarket approval application ("PMA") with the U.S. Food and Drug Administration (the "FDA") and our precision oncology portfolio, which we currently offer on a research-use-only basis, and any future products in development, may not perform as expected. Results from our ongoing or future studies, or from the post-market or real-world setting, involving current or future products or our methylation platform may be inconsistent with certain results obtained from our previous studies, or from interim results initially reported on those studies. In addition, results from our ongoing or future studies may not support certain product launch opportunities. For example, we have prepared two separate analyses of Galleri test performance results in the intervention arm from the prevalent screening round of the registrational NHS-Galleri trial. The prevalent screening round is the first round of blood draws (of the three total blood draw rounds in the trial) with one year of follow up. The first early analysis was prepared for the NHS to determine whether the results were compelling enough to commence an implementation pilot in England prior to the final trial results. In May 2024, the NHS determined not to initiate the pilot on the basis of those available data and will evaluate the final results from the NHS-Galleri Trial, which are expected to be available in 2026, before determining whether to implement the Galleri test in the NHS. We believe the decision will include considerations such as NHS budget, political priorities, cost-effectiveness and implementation constraints in addition to an evaluation of the final results. We reported results from the second analysis in May 2025, which we plan to submit together with data from the first 25,000 participants in the PATHFINDER 2 study and a bridging study (comparing the version of Galleri used in the NHS-Galleri trial and the updated version that we plan to submit to the FDA for premarket approval) as part of our premarket approval application in the first half of 2026. Various factors are likely to cause the final results to differ from a review of the first round results only. For example, cancer screening trials designed to show clinical utility are commonly conducted over three years with an annual screening period, because data from the first screening round only can be influenced by the fact that screening detects many prevalent late-stage asymptomatic cancers

that have not yet been diagnosed. It is possible that the final results will be unsuitable or unavailable, which could have a significant adverse impact on the success of our commercial efforts for Galleri, our ability to achieve FDA authorization at all or within our anticipated timelines, our brand and reputation, our business, and our growth prospects. Furthermore, other studies have been or may be conducted in populations (such as our SUMMIT study which was conducted in a population of tobacco users) or under other circumstances which make their results more complicated to interpret or result in data that is more difficult to compare. In addition, as Galleri and our research-use-only offering are currently available to customers and others, any studies, including those conducted by third parties, that use our current or future products, or that examine elements of our methylation platform, may produce results that are inconsistent to evaluate independently or comparatively from our own studies. If any such inconsistent results were to be produced, either before or after launch of a product or future product, our reputation, business, financial condition, results of operations, and growth prospects would suffer.

Our products require a number of complex and sophisticated biochemical and bioinformatics processes, which could be adversely impacted by a number of different factors. An operational or technological failure in one of these complex processes or fluctuations in external variables may result in performance characteristics, such as sensitivity or specificity rates, that are lower than we anticipate or that vary between test runs or in a higher than anticipated number of tests that fail to produce results. In addition, we continue to evaluate and refine our algorithms and other processes under development. These refinements may inadvertently result in unanticipated issues that may reduce our performance characteristics, such as sensitivity or specificity rates, or otherwise adversely affect the performance of our tests and their results. Galleri was launched in the United States as an LDT in mid-2021 and an updated version was launched in December 2024. The FDA has granted breakthrough device designation for Galleri. We plan to complete a PMA submission for a further updated version of our Galleri test. We may also be required or decide voluntarily to seek clearance or approval from the FDA for future products. However, the FDA recently finalized a regulation pursuant to which would subject LDTs to the FDA's medical device requirements through a phase-out of its historical policy of enforcement discretion over LDTs over a period of four years. On March 31, 2025, the United States District Court for the Eastern District of Texas vacated the LDT Final Rule, reasoning that LDTs are not medical devices, and remanded the matter to the FDA for further consideration. The District Court's decision remains subject to appeal and it remains uncertain whether such appeal will be sought and if it would be successful. Accordingly, it is unclear whether or when the FDA may be able to implement the LDT Final Rule, or otherwise exercise enforcement authority with respect to LDTs. If the LDT Final Rule were to be implemented consistent with the FDA's previously stated plans, the phase-in of medical device requirements to LDTs, including the potential requirement for FDA marketing authorization, if it imposes new, different or earlier significant obligations, would be costly and time-consuming, and if we were to fail to comply with such requirements, or if we could not ultimately obtain marketing authorization for our LDTs where required, our business would be substantially harmed.

Moreover, FDA, other regulators, and notified bodies may require that we generate additional clinical data to support any clearance, approval, or certification we may seek, which could result in delays, increased costs, or other limitations or negative impacts on our ability to receive such clearance, approval, or certification, if at all, including narrowed indication or labeling than expected or desired. For additional information, see "-Risks Relating to Regulation and Legal Compliance-The regulatory clearance, approval, or certification processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming, and unpredictable. If we are ultimately unable to obtain any necessary or desirable regulatory approvals, clearances, or certifications, or if such approvals, clearances, or certifications are significantly delayed, our business will be substantially harmed." in our 2024 Form 10-K.

Further, we plan to improve our products to enhance performance, offerings, scalability, and/or cost of goods. However, we may not be successful in transitioning our products to a new or enhanced version or iteration. Product development involves a lengthy and complex process and we may be unable to commercialize, validate, or improve performance of any of our products on a timely basis, or at all. For example, to the extent an enhanced version of an existing product is developed, we may be required to conduct a non-inferiority study involving such enhanced version as compared to the relevant then-current version of the test using data (for example, clinical data and/or real world evidence data obtained through Galleri's commercial use as an LDT), or could be required to undertake other regulatory requirements if the enhanced version is not considered similar enough to the then- current version to conduct a non-inferiority study. With respect to Galleri, we intend to conduct one or more bridging studies to measure and evaluate concordance, performance and safety of the subsequent, updated version of Galleri (for which we are submitting our PMA) using previously collected clinical study data and other

samples. Any such bridging study will need to be agreed upon with regulatory authorities and may be unsuccessful or insufficient to support approval. If unsuccessful or insufficient, we would be required to revert to the existing version of the test and forego, or be delayed in, implementing any perceived or potential updates, including enhancements. Reverting to the existing version of the test may cause delays in our PMA submission timeline. Additionally, planned improvements to our products may cause unintentional technical, logistical or other issues. For example, in late 2024, we began use of a new version of Galleri in commercial channels which incorporates significant automation and is intended to enable us to scale more efficiently with future demand. In connection with implementation of this new version of Galleri, we have experienced increased turnaround times and order cancellations. If we are unable to adequately prevent these issues from occurring, or to adequately identify and remedy these issues, we may experience reputational harm, lose customers, need to offer discounts, or suffer other negative consequences. Our failure to successfully develop new and/or improved products (including new versions of existing products) on a timely basis could have a material adverse effect on our results of operations and business.

Data from our clinical trials that we announce or publish from time to time before our trials are complete may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our clinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available. Audits, internal or external, including by the FDA's Bioresearch Monitoring ("BIMO") program, of our studies or associated data, can require substantial amounts of time, personnel, and other resources to comply with, and may not be anticipated.

From time to time, we may also disclose interim data from our clinical studies. Interim data from these studies that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more data become available. Adverse differences between interim data and top-line, preliminary, or final data could significantly harm our business prospects. Further, disclosure of interim data by us or by third parties could result in volatility in the price of our common stock.

In particular, in the United Kingdom, we are working with NHS England to complete our NHS-Galleri Trial. In May 2024, the NHS determined, based on data from an early analysis of Galleri test performance results in the intervention arm from the prevalent screening round of the NHS-Galleri trial, not to initiate an implementation pilot in England prior to the final trial results. In May 2025, we disclosed information from a second analysis of the prevalent screening round. Various factors are likely to cause the final results to differ from the prevalent screening round results. Further, it is possible that the early preliminary, interim or final data may not be as we expect, may be inconsistent with prior NHS-Galleri data, or with other studies we have conducted, or may be unsuitable to the NHS or FDA, any of which could have a significant adverse impact on the success of our commercial efforts for Galleri, our ability to achieve FDA authorization at all or within our anticipated timelines, our ability to achieve CMS or private payor reimbursement or coverage, our brand and reputation, our business, and our growth prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, and our ability to receive regulatory clearance or approval or commercialize a particular product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical study is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding our business. If the data that we

report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to commercialize or obtain regulatory clearance or approval for our products may be harmed, which could harm our reputation, business, operating results, prospects or financial condition.

We face risks associated with tariffs and other trade restrictions, which may have a material adverse impact on our results of operations and financial condition.

Our business is subject to risks associated with conducting business internationally. For example, some parties with whom we have collaborative relationships are located outside the United States, including in the United Kingdom and Israel. Additionally, while a significant majority of our supplier spend is with vendors located within the United States, whose products are produced in the United States, we also rely on suppliers and vendors located outside of the United States or who produce the products that we use outside the United States, including in China, Mexico, South Africa and various European Union member states. We expect to continue to increase our international presence over time, which could increase these risks or introduce new risks. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability, in particular non-U.S. economies and markets;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign jurisdictions that do not respect and protect intellectual property rights to the same extent as the United States;
- trade protection measures, import or export controls and licensing requirements (including possible restrictions on licensing intellectual property to certain non-U.S. persons) or other restrictive actions by U.S. or non-U.S. governments;
- changes in non-U.S. laws, regulations and customs, tariffs, and trade barriers;
- changes in non-U.S. laws, regulations, and policies related to data privacy, data protection, and cybersecurity in the transfer or transmittal of data across boundaries and geographies;
- exchange rate risk we may face from denominating a portion of our transactions in currencies other than the U.S. dollar;
- changes in a specific country's or region's political or economic environment;
- negative consequences from changes in tax laws;
- negative consequences from changes in U.S. national security laws, including those governing non-U.S. investors' ownership of U.S. biotech and other technology companies and U.S. companies' ability to enter into joint ventures with non-U.S. entities;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad, or for employee non-U.S. employees in the United States;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- potential liability under the Foreign Corrupt Practices Act ("FCPA") or comparable foreign laws; and
- business interruptions resulting from geopolitical actions, including war and terrorism, such as recent conflicts in the Middle East, pandemics, or natural disasters more common in certain regions, including earthquakes, typhoons, floods, and fires.

In addition, in recent years, U.S. administrations have publicly supported potential trade proposals that may affect U.S. trade relations with other countries. It is unclear at this point how, if at all, such actions or other potential actions, including under the new U.S. Presidential administration, may impact our business or operations, and the uncertainty surrounding these matters might create difficulties in our efforts to partner with certain healthcare providers, suppliers, and insurance carriers. The United States has recently imposed significant tariffs on imports from other countries, including a baseline tariff of 10% on imports into the United States and higher tariffs on multiple designated countries (including the EU Member States, China, Canada, and Mexico) at varying rates. Such tariffs have prompted retaliatory measures from several countries, which may further escalate. On April 9, 2025, the United States announced that the imposition of most "reciprocal" tariffs would be paused for 90 days pending negotiations with the relevant countries. Discussions between the United States and various other countries remain ongoing as of the date of this Form 10-Q. Should these tariffs be implemented and sustained for an extended period of time, they could increase our expenses, reduce our margins or increase our prices, make it difficult to obtain inputs we need for our products or have a material adverse effect on the broader economy. These risks and impacts may be exacerbated by additional tariffs in the United States or retaliatory tariffs imposed by other governments.

Moreover, future operational expansion into other geographies will subject us to additional political and regulatory regimes that will require us to invest further in compliance efforts and may result in additional risks, including, among others, exposure to various and potentially conflicting regulations, international sanctions and compliance rules, country-specific requirements for testing, approval, and processing of patient information and biological samples, as well as the risks associated with political and macroeconomic climates in any such geographies. For example, the potential commercialization of Galleri with the NHS, subject to the results of the NHS-Galleri Trial, may be delayed or otherwise impacted if there is a change in the government in the United Kingdom. These and other risks associated with our planned international operations may materially and adversely affect our business, costs and growth prospects.

We also face risks from our international operations for Galleri, our precision oncology portfolio and other products we may develop. Our clinical trials to date have been conducted in the United States and the United Kingdom, and use of our tests in populations outside of these regions could result in differences in performance. Any performance differences experienced in screening populations outside of the United States or United Kingdom could result in customer dissatisfaction, reputational harm, real world data or adverse events that would be reportable to the FDA or other regulators, regulatory actions by regulators in international jurisdictions and other risks, all of which could have a material and adverse impact on our business, regulatory pathway, results of operations and growth prospects.

Our ability to successfully and efficiently conduct any required in-country studies in other countries or regions in which we seek to expand may also be impacted, or may be impossible, due to the regulatory requirements of such countries. Some countries may require that we carry out testing of our products or future products through government partnerships, which may be difficult to navigate or which may limit our ability to deliver the results we intend. Moreover, the demographics in other countries or regions may differ vastly, such that study results may not appear as successful, due to, for example, a lower incidence of cancer in the local population. Such outcomes may adversely impact demand for our products in other countries. Finally, our ability to expand internationally may be limited by the availability of international laboratory space or requirements that will permit us to store, collect, and analyze biological samples required for current or future products, including space that could be made available through potential partners in such countries or regions. These and other unknown risks make it difficult for us to assess the potential success of our international expansion and the costs associated therewith. For additional information, see “—Risks Relating to Regulation and Legal Compliance.”

We have launched Galleri as an LDT in the United States. The FDA recently finalized a regulation that has been successfully challenged in federal court, pursuant to which the FDA planned to subject LDTs to medical device requirements through a phase-out of its historical policy of enforcement discretion over LDTs over a period of four years. Although a federal court recently vacated this rule, if the court decision is appealed and reversed, or if the FDA were to maintain authority over LDTs as medical devices and subject them to medical device requirements as the rule contemplates, it would be costly and time-consuming, and if we were to fail to comply with such requirements, including the potential requirement to obtain marketing authorization for our LDTs, our business will be substantially harmed.

While we plan to complete our PMA submission seeking regulatory approval from the FDA for Galleri, we launched Galleri in the United States as an LDT. LDTs are *in vitro* diagnostic ("IVD") tests that are intended for clinical use and are designed, manufactured, and used within a single laboratory certified for high complexity testing under CLIA. Although the FDA believes that LDTs are medical devices subject to its medical device authority, the FDA has historically exercised enforcement discretion and has not enforced certain otherwise applicable FDA requirements, including premarket review, with respect to LDTs, with certain exceptions such as in the case of tests for public health emergencies, where the tests are available directly to the consumer, where the tests represented a significant public health concern, or where the FDA has concerns that a company's performance claims related to its tests are not sufficiently validated by clinical data.

Even under that enforcement discretion policy, the FDA has issued warning letters to and safety communications about IVD device manufacturers for commercializing laboratory tests that were purported to be LDTs but that the FDA alleged failed to meet the definition of an LDT or otherwise were not subject to the FDA's enforcement discretion policy.

Even for those LDTs that were subject to the historical enforcement discretion policy, the FDA has for a number of years stated its intention to modify this policy and impose applicable medical device requirements to LDTs more broadly. To this end, on May 6, 2024, the FDA issued the LDT Final Rule in an effort to clarify the FDA's historical view that LDTs are medical devices subject to the requirements applicable to other IVDs, and to phase out its enforcement discretion policy over a period of four years from issuance of the LDT Final Rule, which would involve a phase-in of medical device requirements to these products over this time period. If implemented, the LDT Final Rule would subject our products currently marketed as LDTs and any future products that we may market as LDTs in the future to the FDA's standard regulatory requirements applicable to medical devices in accordance with this phase-in period, including the potential requirement for FDA premarket review and marketing authorization.

Specifically, in connection with the LDT Final Rule, the FDA sought to establish certain new, targeted enforcement discretion policies, including, among others, for LDTs marketed as of the date of publication of the LDT Final Rule (May 6, 2024), as well as for LDTs that have received approval from New York State's Clinical Laboratory Evaluation Program ("NY CLEP"). Specifically, if the LDT Final Rule were implemented, the FDA planned to exercise enforcement discretion and not enforce certain medical device requirements (including the requirements for marketing authorization and compliance with certain elements of the Quality System Regulation ("QSR")) with respect to LDTs that were marketed as of the date of the LDT Final Rule's publication, although such products would still by required to comply with certain other FDA requirements, such as registration and listing, relevant portions of the QSR, medical device reporting, labeling, and corrections and removals reporting. However, where these tests are modified in certain ways from the version of the test marketed as of the LDT Final Rule's publication date, this enforcement discretion policy, if implemented, would no longer apply and the FDA would enforce all applicable FDA requirements (including premarket review and marketing authorization requirements) consistent with the stated phase-in policy. In addition, for LDTs that received approval from NY CLEP, the FDA planned not to enforce marketing authorization requirements when these requirements were phased in more generally at either three and a half or four years following the date of publication of the LDT Final Rule. However, these tests would still be subject to the remaining medical device requirements, including registration and listing, medical device reporting, and quality system requirements, at the time that such requirements were phased in more generally.

However, on March 31, 2025, the United States District Court for the Eastern District of Texas vacated the LDT Final Rule, reasoning that LDTs are not medical devices, and remanded the matter to the FDA for further consideration (the "LDT Final Rule Decision"). The District Court's decision remains subject to appeal and it remains uncertain whether such appeal will be sought and if it would be successful. Accordingly, it is unclear whether or when the FDA may be able to implement the LDT Final Rule, or otherwise exercise its medical device authority with respect to LDTs. This uncertainty could adversely affect the FDA's ability to apply and enforce its medical device requirements with respect to diagnostic tests more broadly, including any LDTs for which we were to have obtained a PMA. Such uncertainty, and the final resolution of the litigation over the LDT Final Rule, could have a material adverse effect on our business and operations.

In light of the uncertainty regarding the future status and potential implementation of the LDT Final Rule, the associated planned new enforcement discretion policies, and the FDA's actions in response the District Court's

decision as it relates to LDTs, we do not know when or if our LDTs could become or will remain subject to, FDA medical device requirements, including the requirement to seek and obtain marketing authorization, at the time that such medical device requirements may be phased in, if at all. If we were unable to comply with medical device requirements applicable to our LDTs, if and when they become applicable, we could be required to cease marketing any products that we market as LDTs. Further, if the FDA decides to no longer review voluntary marketing authorizations for LDTs in response to the LDT Final Rule Decision, and we decide to pursue a PMA for Galleri or any of our future LDT products, we may be required to make changes to our PMA application, our laboratory testing or other elements of our test platform, or otherwise take actions to allow the FDA to treat Galleri or future LDT products as medical devices, notwithstanding the LDT Final Rule Decision. These changes could require us to change the PMA application we have begun, which could delay our PMA application or any potential approval, require additional expenditures, require additional development and validation on the changes we may decide to make and could subject us to additional regulation by the FDA. If we are not able to manage these risks and changes, there could be a material adverse effect on our business and operations. In addition, further efforts by the FDA or Congress to impose more regulation on LDTs could create a negative public perception about the validity, safety, effectiveness, or performance of LDTs, including our products, that could adversely affect patient, provider, and customer perception about, and confidence in, our products.

Moreover, the FDA may assert that we are improperly marketing our tests as LDTs, or if FDA succeeds in maintaining asserted authority over LDTs as medical devices, the FDA may assert we do not comply with applicable medical device requirements, and in such cases may take enforcement action against us and/or require us to seek premarket review and obtain marketing authorizations, which may require that we cease marketing any LDT products until such marketing authorizations are obtained or the relevant applications are submitted. There can be no assurance that we will be able to obtain any required marketing authorization for our LDTs or that any labeling claims will be consistent with the claims we have made or intend to make for such products when launched as LDTs, or that such claims would be adequate to support continued adoption of and reimbursement for our products. In the event we are required to seek FDA marketing authorization for any current or planned LDTs, the FDA may request that we provide additional analyses and information beyond that which we intend to produce based on the designs of our current and planned clinical studies, or that we modify or narrow our intended use or product claims. It is possible that the FDA, among other things, could disagree with our interpretation of data we have relied on to support our LDT launches for our intended uses. If we are required to provide additional analyses or additional data or perform additional clinical studies beyond those we currently contemplate to support the intended uses of our products or future products, our planned commercial launches may be delayed and we may be required to cease commercialization of any products we currently market as LDTs. A delay in the launch of our products or new versions of existing products, or significantly narrowing their intended uses, could negatively impact our financial condition and results of operations.

In addition, Congress has, for over the past decade, considered a number of proposals, which if enacted, would subject LDTs to additional regulatory requirements. For example, in recent years, Congress has worked on legislation to create a novel regulatory framework governing a new category of FDA-regulated products, referred to as in vitro clinical tests (“IVCTs”), which would govern LDTs and would be separate and distinct from the existing medical device regulatory framework. For example, most recently, in March 2023, the Verifying Accurate Leading-edge IVCT Development Act of 2023 (the “VALID Act”) was introduced. The bill would have established a risk-based approach to imposing requirements related to premarket review, quality systems, and labeling requirements on all IVCTs, including LDTs, but would grandfather certain LDTs marketed before the effective date of the bill and exempt them from certain requirements. It is unclear whether legislative proposals such as the VALID Act (including any proposals that would, in contrast, reduce FDA oversight of LDTs) will be introduced or passed by Congress or signed into law by the President. Depending on the approach adopted under any potential legislation or regulation, certain LDTs (likely those of higher risk) may be required to undergo some form of premarket review, potentially with a transition period for compliance and a grandfathering provision. Any such legislation could substantially alter our commercial offering and marketing of LDTs and negatively impact our financial condition and results of operations. If the LDT Final Rule is successfully challenged, abandoned or delayed, the regulatory environment around LDTs could be significantly relaxed, which could increase competition and reduce the effectiveness of our regulatory and reimbursement strategy.

If the LDT Final Rule Decision is not appealed, or if the LDT Final Rule Decision is appealed but the decision is affirmed, or if the FDA otherwise does not have authority to regulate LDTs as medical devices, there could be significant impacts to us and our industry, and our ability to compete could be impaired.

We have invested significantly in pursuing a PMA for Galleri, including conducting our NHS-Galleri and PATHFINDER 2 studies to support our PMA. We believe PMA approval for Galleri, if obtained, could bolster our position in the MCED market, and increase or accelerate provider and patient adoption, commercial and government reimbursement and coverage, and international opportunities. In the event the FDA is not able to implement the LDT Final Rule, or otherwise exercise its medical device authority with respect to LDTs, our competitors or potential competitors in the MCED market may face less stringent regulatory requirements to enter the market or to continue to market their tests and we may face increased competition in our industry, and adapting to the new regulatory and competitive environment could be difficult, costly and time-consuming. If we are not able to adapt to the changed regulatory environment and increased competition, our business and prospects could be materially impacted.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

(a) None.

(b) None.

(c) **Rule 10b5-1 Trading Plans**

During the quarter ended March 31, 2025, the following of our directors and officers (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended) adopted, modified or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement”, as each term is defined in Item 408(a) of Regulation S-K. None of our other directors or officers adopted, modified or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement” during this period.

On March 13, 2025, Aaron Freidin, our Chief Financial Officer, entered into a Rule 10b5-1 trading arrangement intended to satisfy the affirmative defense of Rule 10b5-1(c) for the sale of up to 64,000 shares of common stock until March 14, 2027.

On March 13, 2025, Joshua Ofman, our President, entered into a Rule 10b5-1 trading arrangement intended to satisfy the affirmative defense of Rule 10b5-1(c) for the sale of up to 100% of the net shares of common stock received by Mr. Ofman from his RSU award covering 92,269 shares of common stock until May 29, 2026.

On March 13, 2025, Sarah Krevans, a member of the Board of Directors, entered into a Rule 10b5-1 trading arrangement intended to satisfy the affirmative defense of Rule 10b5-1(c) for the sale of up to 6,210 shares of common stock until June 19, 2026.

Item 6. Exhibits

The following documents are filed as exhibits hereto:

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
2.1	Separation and Distribution Agreement, dated June 21, 2024, between Illumina, Inc. and GRAIL, Inc.	8-K	6/24/24	2.1	
3.1	Certificate of Incorporation of GRAIL, Inc., dated June 21, 2024	S-8	6/21/24	4.1	
3.2	Amended and Restated Bylaws of GRAIL, Inc., dated June 21, 2024	S-8	6/21/24	4.2	
3.3	Certificate of Conversion	8-K	6/24/24	3.3	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				*
32.1+	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				**
32.2+	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				**
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document				***
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents				***
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				***
101.DEF	Inline XBRL Extension Definition Linkbase Document				***
101.LAB	Inline XBRL Taxonomy Label Linkbase Document				***
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				***
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				***

+ This certification accompanies the Quarterly Report on Form 10-Q pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

* Filed herewith

** Furnished herewith

*** Submitted electronically herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GRAIL, Inc.

Date: May 14, 2025

By: /s/ Robert Ragusa

Robert Ragusa
Chief Executive Officer
(Principal Executive Officer)

Date: May 14, 2025

By: /s/ Aaron Freidin

Aaron Freidin
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATION

I, Robert Ragusa, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of GRAIL, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. [Reserved];
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 14, 2025

/s/ Robert Ragusa
Robert Ragusa
Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Aaron Freidin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of GRAIL, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. [Reserved];
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 14, 2025

/s/ Aaron Freidin
Aaron Freidin
Chief Financial Officer

Exhibit 32.1

Certification of Chief Executive Officer, Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of GRAIL, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert Ragusa, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 14, 2025

/s/ Robert Ragusa
Robert Ragusa
Chief Executive Officer

Exhibit 32.2

Certification of Chief Financial Officer,
Pursuant to 18 U.S.C. Section 1350,
As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of GRAIL, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Aaron Freidin, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 14, 2025

/s/ Aaron Freidin
Aaron Freidin
Chief Financial Officer