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 June 30, 2024

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 August 11, 2024, the registrant had 31,049,148 shares of common stock, par value $0.001 per share, outstanding.

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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 compliance, potential market opportunity, anticipated growth strategies, restructuring costs, sufficiency of cash on hand to finance our business, cost savings, budgets and strategies, restructuring and stock-based compensation costs, impact of the restructuring on our operations and 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 section entitled "Risk Factors." You should specifically consider the numerous risks described under the section entitled "Risk Factors." 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.

Summary of Material Risks Associated with Our Business

The principal risks and uncertainties affecting our business include the following:

- We operate in a rapidly evolving field and have a limited operating history, which make it difficult to evaluate our current business and predict our future performance.
- We have incurred significant net losses in each period since our inception and anticipate that we will continue to incur net losses for the coming years.
- 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.
- The clinical study process is lengthy and expensive with uncertain outcomes. We have encountered delays and may encounter future delays in, or unexpected data from, our clinical studies, and may therefore be unable to complete our clinical studies on the timelines we expect, if at all.
- A substantial majority of our revenue is generated from sales of Galleri and we are highly dependent on it for our success.
- If our products do not receive adequate coverage and reimbursement, if at all, from third-party payors, our ability to expand access to our products beyond our existing sales channels will be limited and our overall commercial success will be limited.
- Our commercial products may fail to achieve the degree of market acceptance necessary for commercial success.
- We may not be able to generate sufficient revenue to offset our ongoing operating expenses and achieve and maintain profitability, and it may be difficult for us to offset the costs of our royalties, including the high single-digit royalty that we will be required to pay to Illumina in perpetuity or our royalties payable to the Chinese University of Hong Kong.
- We may be unable to develop and commercialize new products, including enhanced versions of current products.
- If similar third-party products are developed and do not perform as intended or cause harm or injury to patients, the market for our products could be impaired.
- If we fail to obtain additional financing, we may be unable to expand our commercialization efforts with respect to Galleri and any other products that we successfully develop and commercialize, or to develop additional products.
- If our products result in direct or indirect participant or patient harm or injury, we could be subject to significant reputational and liability risks
- We rely on Illumina as a sole supplier for our next-generation sequencers and associated reagents, Madison Industries (“Madison”) (who acquired our blood collection tube manufacturer, Streck, in 2023) as a sole supplier of our blood collection tubes, and Twist Bioscience Corporation (“Twist”) as a sole supplier of our DNA panels. Additionally, we rely on a limited number of suppliers for some of our laboratory instruments and reagents, and we may not be able to immediately find replacements if necessary.
- We have launched Galleri as a laboratory developed test (“LDT”) in the United States. The FDA recently finalized a regulation pursuant to which it plans 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. The phase-in of medical device requirements to LDTs, including the potential requirement for FDA marketing authorization, will be costly and time-consuming.

- The regulatory clearance, approval, or certification processes of the FDA and comparable foreign regulatory authorities or notified bodies 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.

- Our operations and business are materially dependent on various third parties, including information technology, sample collection, processing, transfer facilities, and other patient-facing service providers, any of which could experience disruption, failure, or interruption.

- If we are unable to scale our operations to support demand for our products, our business could suffer.

- Our multi-cancer detection tests are a new approach to cancer screening, and present novel and complex issues for FDA review. Because the FDA has never cleared or approved a multi-cancer detection test, 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 if we will be able to obtain such approval on a timely basis or at all.

- If we are unable to obtain and maintain intellectual property protection for our technology, or if the scope of the intellectual property protection we obtain is not sufficiently broad, third parties could in the future develop and commercialize technology and tests similar or identical to ours, and our ability to successfully commercialize our products may be impaired.

- If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

- We could have an indemnification obligation to Illumina if the Distribution were determined not to qualify for non-recognition treatment for U.S. federal tax purposes.

- We have agreed to numerous restrictions to preserve the non-recognition treatment of the Spin-Off, which may reduce our strategic and operating flexibility.

- An active trading market for our common stock may not be sustained after the Spin-Off. Following the Spin-Off our stock price may fluctuate significantly.

- If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

- Raising additional capital may cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights to our technologies or our products.

- We are an emerging growth company and the information we provide shareholders may be different from information provided by other public companies, which may result in a less active trading market for our common stock and higher volatility in our stock price.

- Substantial sales of our common stock may occur in connection with the Spin-Off, including the disposition by Illumina of the shares of our common stock that it retains after the Spin-Off, which could cause our stock price to decline.

The summary risk factors described above should be read together with the text of the full risk factors below in “Risk Factors” and the other information set forth in this Form 10-Q, including our consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

Part I - Financial Information

Item 1. Financial Statements

GRAIL, Inc.
CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)	June 30, 2024	December 31, 2023
Assets	(unaudited)	
Current assets:		
Cash and cash equivalents.	$ 958,845	$ 97,287
Accounts receivable, net	13,374	16,862
Accounts receivable, net — related parties	32	80
Supplies	18,196	14,788
Supplies — related parties	7,310	6,907
Prepaid expenses and other current assets	20,866	20,100
Prepaid expenses and other current assets — related parties	59	41
Total current assets	1,018,682	156,065
Property and equipment, net	74,984	81,355
Property and equipment, net — related parties	3,021	3,640
Operating lease right-of-use assets	74,503	84,386
Restricted cash	3,918	4,225
Intangible assets, net	2,086,056	2,687,223
Goodwill	—	888,936
Other non-current assets	8,476	7,984
Total assets	$ 3,269,640	$ 3,913,814
Liabilities and member's/stockholders' equity		
Current liabilities:		
Accounts payable	$ 16,247	$ 18,845
Accounts payable — related parties	—	828
Accrued liabilities	56,573	73,711
Accrued liabilities — related parties	—	95
Incentive plan liabilities	—	54,513
Operating lease liabilities, current portion	13,945	14,809
Other current liabilities	1,413	809
Total current liabilities	88,178	163,610
Operating lease liabilities, net of current portion	62,165	69,598
Deferred tax liability, net	422,163	32,921
Other non-current liabilities	2,007	1,498
Total liabilities	574,513	267,627
Preferred stock, par value of $0.001 per share; 50,000,000 shares authorized, no shares issued and outstanding as of June 30, 2024 and December 31, 2023	—	—
Common stock $0.001 par value per share, 1,500,000,000 shares authorized, 31,049,148 shares issued and outstanding as of June 30, 2024, no shares authorized, issued and outstanding as of December 31, 2023	31	—
Additional paid-in capital	12,274,286	—
Member's equity	—	11,421,446
Accumulated other comprehensive income	1,386	1,066
Accumulated deficit	(9,580,576)	(7,776,325)
Total stockholders'/member's equity	2,695,127	3,646,187
Total liabilities and stockholders'/member's equity	$ 3,269,640	$ 3,913,814

See accompanying notes to condensed consolidated financial statements.

GRAIL, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

(in thousands, except per share data)	Three Months Ended		Six Months Ended	
	June 30, 2024	July 2, 2023	June 30, 2024	July 2, 2023
Revenue:				
Screening revenue	$ 28,055	$ 19,863	$ 51,465	$ 35,183
Screening revenue — related parties	108	164	237	416
Development services revenue	3,807	2,387	6,989	6,458
Total revenue	31,970	22,414	58,691	42,057
Costs and operating expenses:				
Cost of screening revenue (exclusive of amortization of intangible assets).	12,010	8,912	23,000	17,758
Cost of screening revenue — related parties	3,779	2,213	6,511	3,792
Cost of development services revenue	543	2,059	1,934	3,395
Cost of development services revenue — related parties	78	36	123	60
Cost of revenue — amortization of intangible assets	33,472	33,472	66,944	66,944
Research and development	88,727	82,311	185,117	162,832
Research and development — related parties	5,469	6,399	10,704	11,751
Sales and marketing	40,989	40,737	87,808	86,572
General and administrative	67,206	50,590	124,224	97,248
General and administrative — related parties	52	52	103	103
Goodwill and intangible impairment	1,420,936	—	1,420,936	—
Total costs and operating expenses	1,673,261	226,781	1,927,404	450,455
Loss from operations	(1,641,291)	(204,367)	(1,868,713)	(408,398)
Other income (expense):				
Interest income	2,805	1,847	5,706	4,074
Other income (expense), net	5	(320)	47	(225)
Total other income (expense), net	2,810	1,527	5,753	3,849
Loss before income taxes	(1,638,481)	(202,840)	(1,862,960)	(404,549)
Benefit from income taxes	53,144	9,796	58,709	17,839
Net loss	$ (1,585,337)	$ (193,044)	$ (1,804,251)	$ (386,710)
Net loss per share — basic and diluted	$ (51.06)	$ (6.22)	$ (58.11)	$ (12.45)
Weighted-average number of shares used in per share calculation — basic and diluted	31,049,148	31,049,148	31,049,148	31,049,148

See accompanying notes to condensed consolidated financial statements.

GRAIL, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(unaudited)

	Three months ended		Six Months Ended	
(in thousands)	June 30, 2024	July 2, 2023	June 30, 2024	July 2, 2023
Net loss	$ (1,585,337)	$ (193,044)	$ (1,804,251)	$ (386,710)
Other comprehensive income:				
Foreign currency translation adjustment	372	96	320	37
Comprehensive loss	$ (1,584,965)	$ (192,948)	$ (1,803,931)	$ (386,673)

See accompanying notes to condensed consolidated financial statements.

GRAIL, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF EQUITY
(unaudited)

(in thousands)	Common Stock Shares	Common Stock Amount	Member's Equity	Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total stockholders'/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
Net loss	—	—	—	—	—	(1,585,337)	(1,585,337)
Stock-based compensation expense	—	—	156	640	—	—	796
Other comprehensive income	—	—	—	—	372	—	372
Recognition of deferred tax liability in connection with the Spin-Off*	—	—	(447,190)	—	—	—	(447,190)
Reclassification of incentive plan liabilities to additional paid-in capital	—	—	—	54,795	—	—	54,795
Disposal funding received in connection with the Spin-Off*	—	—	932,300		—	—	932,300
Issuance of common stock in connection with the Spin-Off and reclassification of contribution from member, net*	31,049,148	31	(12,218,882)	12,218,851	—	—	—
Balance as of June 30, 2024	31,049,148	$ 31	$ —	$ 12,274,286	$ 1,386	$ (9,580,576)	$ 2,695,127

See accompanying notes to condensed consolidated financial statements.

*See *Note 1 — Organization And Description Of Business* for more information on the Spin-Off.

GRAIL, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF EQUITY
(unaudited)

(in thousands)	Common Stock Shares	Common Stock Amount	Member's Equity	Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Equity
Balance as of January 1, 2023	—	$ —	$ 10,955,907	$ —	$ 894	$ (6,310,640)	$ 4,646,161
Net loss	—	—	—	—	—	(193,666)	(193,666)
Stock-based compensation expense	—	—	799	—	—	—	799
Other comprehensive loss	—	—	—	—	(59)	—	(59)
Contribution from member, net	—	—	108,870	—	—	—	108,870
Balance as of April 2, 2023	—	$ —	$ 11,065,576	$ —	$ 835	$ (6,504,306)	$ 4,562,105
Net loss	—	—	—	—	—	(193,045)	(193,045)
Stock-based compensation expense	—	—	711	—	—	—	711
Other comprehensive loss	—	—	—	—	96	—	96
Contribution from member, net	—	—	194,905	—	—	—	194,905
Balance at July 2, 2023	—	$ —	$ 11,261,192	**$ —**	$ 931	$ (6,697,351)	$ 4,564,772

See accompanying notes to condensed consolidated financial statements.

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

(in thousands)	Six Months Ended June 30, 2024	Six Months Ended July 2, 2023
Cash flows from operating activities		
Net loss	$ (1,804,251)	$ (386,710)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization of intangibles assets	69,167	69,167
Depreciation	10,218	9,802
Stock-based compensation expense	55,053	47,064
Cash payment for equity awards	(53,807)	(24,667)
Deferred income taxes	(57,949)	(16,069)
Goodwill and intangible impairment	1,420,936	—
Other	361	(172)
Changes in operating assets and liabilities:		
Accounts receivable	3,488	4,273
Accounts receivable — related parties	48	164
Supplies	(3,408)	(1,412)
Supplies — related parties	(403)	(1,498)
Operating lease right-of-use assets and liabilities, net	1,586	4,306
Prepaid expenses and other assets	(2,509)	314
Prepaid expenses and other current assets — related parties	(18)	40
Accounts payable	(2,486)	(3,822)
Accounts payable — related parties	(828)	(1,561)
Accrued and other liabilities	(14,188)	(8,501)
Accrued and other liabilities — related parties	(95)	(109)
Net cash used by operating activities	(379,085)	(309,391)
Cash flows from investing activities		
Purchases of property and equipment	(3,934)	(4,358)
Purchases of property and equipment — related parties	—	(1,565)
Net cash used by investing activities	(3,934)	(5,923)
Cash flows from financing activities		
Cash funding received from Illumina	1,244,300	304,000
Taxes paid related to net share settlement of equity awards	—	(225)
Net cash provided by financing activities	1,244,300	303,775
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(30)	257
Net increase (decrease) in cash, cash equivalents, and restricted cash	861,251	(11,282)
Cash, cash equivalents and restricted cash — beginning of period	101,512	246,128
Cash, cash equivalents and restricted cash — end of period	$ 962,763	$ 234,846
Represented by:		
Cash and cash equivalents	$ 958,845	$ 230,621
Restricted cash	3,918	4,225
Total	$ 962,763	$ 234,846
Supplemental cash flow information:		
Property and equipment included in accounts payable and accrued liabilities	(628)	(1,135)
Operating cash flows from operating leases, net	(10,043)	(9,117)

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 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. See *Note 9 — Legal And Regulatory Proceedings* for additional details. 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 14.5% after the Spin-Off. GRAIL’s common stock is listed under the ticker symbol “GRAL” on the NASDAQ Stock Exchange. 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 9 — 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 8 — Taxes* for more information regarding income taxes and *Note 9 — Legal And Regulatory Proceedings* regarding the contingencies related to this agreement.
- Employee Matters Agreement — addresses 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. See *Note 5 — Stock-Based Compensation* for further details regarding the treatment of equity awards.
- 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 6 — 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 (collective, 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 the September 24, 2025 (the 15-month anniversary of the Distribution Date). See *Note 9 — Legal And Regulatory Proceedings — Contingencies* for details.

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 $958.8 million of cash and cash equivalents as of June 30, 2024.

The Company believes that its existing cash and cash equivalents 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.

As of June 30, 2024, the Company had no off-balance sheet concentrations of credit risk.

Fiscal Year

The Company has a fiscal year end of December 31. Prior to the Spin-Off, the Company'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. References to Q2 2023 refer to the three and six months ended July 2, 2023 which were 13 weeks and 26 weeks, respectively.

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 December 31, 2023, the Company had generated net operating loss carryforwards for federal and state tax purposes of $3.5 billion and $2.3 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 6 — Related Party Transactions*.

These unaudited condensed consolidated financial statements are prepared in accordance with United States Generally Accepted Accounting Principles ("U.S. GAAP"), 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

The significant accounting policies used in preparation of these unaudited condensed combined financial statements for the three and six months ended June 30, 2024 and July 2, 2023 are consistent with those discussed in *Note 2 — Summary of Significant Accounting Policies*, within the consolidated financial statements for the year ended December 31, 2023 included in the Form 10, except as described below.

Stock-Based Compensation Expense

The Company's stock-based compensation expense includes expenses related to cash-based equity incentive awards, restricted stock units ("RSUs"), and performance stock options. Forfeitures are accounted for as incurred.

In connection with the Spin-Off, GRAIL and Illumina entered into an Employee Matters Agreement pursuant to which the Company's equity awards were modified (the "Award Modification"). A cash-based equity incentive award (the "Cash-Based Equity Award") program was adopted following Illumina's acquisition of GRAIL in 2021 to provide GRAIL employees with dollar-denominated long-term incentive awards. The cash-settled, liability-classified awards were modified to become RSUs that will be settled in shares of the Company's common stock upon vesting. Unvested performance stock options that were previously held by certain GRAIL employees to purchase Illumina common stock were also converted to options to purchase GRAIL common stock in connection with the Spin-Off. See *Note 5 — Stock-Based Compensation* for further details of the Award Modification.

Prior to the Award Modification, the Cash-Based Equity Awards were liability-classified awards because the Cash-Based Equity Awards could be settled in cash. Until April 30, 2024, GRAIL's stand-alone value calculation was estimated by the Company based on its analysis and the input from independent valuation advisors. The value of the Cash-Based Equity Awards was recorded over the applicable vesting periods, with recognition of a corresponding liability recorded in incentive plan liabilities in the consolidated balance sheets. The Cash-Based Equity Awards were remeasured at each reporting date until settlement with changes in fair value recognized in stock-based compensation expense. On April 30, 2024, Illumina's Compensation Committee approved an adjustment of the ordinary course payouts of the Cash-Based Equity Awards providing that the Cash-Based Equity Awards would be paid based on their nominal (face) value without adjustment based on changes in equity value. Subsequent to this adjustment to the Cash-Based Equity Awards and continuing until the Award Modification, the Cash-Based Equity Awards were expensed in accordance with their applicable vesting schedules.

The grant date fair value of RSUs are determined based on the closing market price of GRAIL's common stock on the date of the grant (in the case of RSUs resulting from the Award Modification, the date of the Award Modification). Stock-based compensation expense is recognized based on the fair value on a straight-line basis over the requisite service periods of the RSUs.

The fair value of performance stock options with service conditions is determined using the Black-Scholes-Merton option-pricing model. The model assumptions include expected volatility, term, dividends, and the risk-free interest rate. The expected volatility is generally determined by weighing the historical and implied volatility of peer companies' common stock. The expected term is the Company's best estimates based on the vesting period and contractual term. Given that cash dividends were never declared or paid on the Illumina nor GRAIL common stock, the expected dividend yield is determined to be 0%. The Company does not anticipate paying cash dividends in the foreseeable future. The risk-free interest rate is based upon U.S. Treasury securities with

remaining terms similar to the expected term of the stock-based awards. The fair value of the performance stock options begins to be recognized when it is probable that the performance-based condition will be met.

Provision for (Benefit from) Income Taxes

As a standalone entity, the Company files tax returns on its own behalf, and tax balances and the effective income tax rate may differ from the amounts reported in historical periods. As of June 24, 2024 and in connection with the Spin-Off, the Company adjusted its deferred tax balances and computed its related tax provision to reflect operations as a standalone entity. During the period that Illumina held the Company, the Company's activity generated various tax attributes recognized as deferred tax assets ("DTAs"), due primarily to the generation of net operating losses ("NOLs"), IRC 174 capitalized research and experimental expenditures, and research and development ("R&D") tax credits that could not be specifically utilized by the Company as it did not generate positive taxable income and it was not a separately regarded tax paying entity from Illumina. Since the Company was not a separately regarded taxable entity from Illumina, these tax attributes were either utilized by or will be utilized by Illumina when filing its consolidated tax return. Historically, the tax attributes were only presented in the Company's stand-alone financial statements to allow the users to understand the financial position of the Company as a stand-alone taxable entity under the Separate-Return Method. The total tax-effected value of the tax attributes, net of Financial Accounting Standards Board Interpretation No. 48 ("FIN48") liabilities and valuation allowance that were deemed to be the property of Illumina, was $447.2 million. In connection with the Spin-off, the underlying $447.2 million of tax attributes were adjusted through an entry of $447.2 million to additional paid in capital.

Net Loss Per Share Attributable to Common Stockholders

The Company calculates basic net loss per share attributable to common stockholders by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period. Diluted net loss per share is computed based on the sum of the weighted average number of common shares and potentially dilutive common shares outstanding during the period. In loss periods, basic and diluted net loss per share are identical since the effect of potentially dilutive common shares is antidilutive and therefore excluded. Potentially dilutive common shares consist of shares issuable under equity awards. Potentially dilutive common shares from equity awards are determined using the average share price for each period under the treasury stock method. In addition, proceeds from exercise of equity awards and the average amount of unrecognized compensation expense for equity awards are assumed to be used to repurchase shares.

Cash Equivalents

As of June 30, 2024 and December 31, 2023, the Company's cash equivalents were held in money market funds, totaling $955.9 million and $92.6 million, respectively. In connection with the consummation of the Spin-Off, in June 2024, Illumina provided disposal funding of $932.3 million to the Company in accordance with the Separation and Distribution Agreement. Cash equivalents held in money market funds were categorized as Level 1 investments within the fair value hierarchy.

Except for the accounting policies described above, there were no changes to the Company's significant accounting policies during the three months ended June 30, 2024 as described in *Note 2 — Summary of Significant Accounting Policies* to the Company's audited Consolidated Financial Statements filed with its Form 10 Registration Statement on June 3, 2024.

Concentration Risk

The Company had sales to a single customer that accounted for approximately 10% of total sales for the three and six months ended June 30, 2024 and 10% of total sales for the six months ended July 2, 2023. Amounts

due from this same single customer represented approximately 19% and 43% as of June 30, 2024 and December 31, 2023, respectively.

Recently Adopted Accounting Pronouncements

The Company evaluates all Accounting Standards Updates (“ASUs”) issued by the Financial Accounting Standards Board (the "FASB") for consideration of their applicability. ASUs not included in the disclosures in this report were assessed and determined to be either not applicable or are not expected to have a material impact on the Company’s condensed consolidated financial statements.

Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. This update improves reportable segment disclosure requirements, primarily through enhanced disclosures of significant segment expenses. This guidance will be effective for the annual reporting periods beginning the year ended December 31, 2024, and for interim reporting periods beginning January 1, 2025, with early adoption permitted, and should be applied retrospectively. The Company is currently evaluating the potential impact of this guidance on its condensed consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvement to Income Tax Disclosures. This update improves income tax disclosure requirements, primarily through enhanced transparency and decision usefulness of disclosures. This guidance will be effective for annual reporting periods beginning the year ended December 31, 2025, 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.

NOTE 3. GOODWILL AND INTANGIBLE ASSETS

Due to the application of pushdown accounting, the Company’s balance sheet includes goodwill and intangible assets recognized by Illumina in connection with Illumina’s acquisition of the Company.

Goodwill Impairment

Goodwill represents the excess of purchase price Illumina paid over the fair value of the net identifiable assets acquired upon the acquisition of the Company.

During Q2 2024, prior to the Spin-Off, the approval of the Spin-Off by Illumina’s board of directors represented a potential indicator of impairment, which also aligned with the timing of Illumina’s annual goodwill impairment test date for 2024. The assessment was performed using a market approach to determine the fair value of goodwill which utilized the valuation ranges prepared by the divestment financial advisors engaged by Illumina in connection with the Spin-Off. The valuation ranges were determined using revenue multiples from public company peers for 2024 and 2025. The implied discount rate for the goodwill impairment assessment was 51.5%. These estimates and assumptions represent a Level 3 measurement because they include unobservable inputs that are supported by little or no market activity and reflect Company-determined and judgmental factors for these assumptions in measuring fair value. The assumptions in the assessment of an impairment analysis are inherently subjective due to uncertainty and any slight changes in these rates and assumptions could have a significant impact on the concluded value of goodwill.

The Company recognized a goodwill impairment of $888.9 million as a result of the impairment assessment, primarily due to changes to the forecast of GRAIL’s value and the method for valuing GRAIL.

Intangible Assets

Intangible assets identified in the Acquisition include trade names, developed technology, and in-process research and development ("IPR&D") and were measured at fair value as of the closing date of Illumina's acquisition of the Company ("Closing Date").

	June 30, 2024			
(in thousands)	Gross Carrying Amount	Accumulated Amortization	Impairment	Net Intangible Assets
Developed Technologies	$ 2,410,000	$ (379,352)	$ —	$ 2,030,64
Trade Names	40,000	(12,592)	—	27,40
Total Finite-Lived Intangible Assets	2,450,000	(391,944)	—	2,058,05
In-process Research and Development (IPR&D)	560,000	—	(532,000)	28,00
Total Intangible Assets	$ 3,010,000	$ (391,944)	$ (532,000)	$ 2,086,05

	December 31, 2023			
(in thousands)	Gross Carrying Amount	Accumulated Amortization	Impairment	Net Intangible Assets
Developed Technologies	$ 2,410,000	$ (312,408)	$ —	$ 2,097,59
Trade Names	40,000	(10,369)	—	29,63
Total Finite-Lived Intangible Assets	2,450,000	(322,777)	—	2,127,22
In-process Research and Development (IPR&D)	670,000	—	(110,000)	560,00
Total Intangible Assets	$ 3,120,000	$ (322,777)	$ (110,000)	$ 2,687,22

The fair values of the developed technologies, trade names and IPR&D were estimated using an income approach, under which an intangible asset's fair value is equal to the present value of future economic benefits to be derived from ownership of the asset. The estimated fair values were developed by discounting future net cash flows to their present value at market-based rates of return and inclusive of an assumption for technology obsolescence. The useful lives of the intangible assets for amortization purposes were determined by considering the period of expected cash flows used to measure the fair values of the intangible assets, adjusted as appropriate for entity-specific factors including legal, regulatory, contractual, competitive, economic, and other factors that may limit the useful life. The developed technology and trade names assets are amortized on a straight-line basis over their estimated useful lives.

In conjunction with Illumina's Q2 2024 goodwill impairment assessment, the IPR&D intangible asset of the GRAIL reporting unit was evaluated for potential impairment by Illumina prior to the Spin-Off. The evaluation for a potential impairment of the IPR&D intangible asset was performed by comparing its carrying value to the assessed estimated fair value, which was determined by the income approach, using a discounted cash flow model. Estimates and assumptions used in the income approach included projected cash flows and a discount rate. The discount rate selected at the time of the IPR&D intangible impairment assessment was 46.5%. Based on the impairment test performed, Illumina assessed and determined that the carrying value of GRAIL's IPR&D intangible asset exceeded its estimated fair value. As a result of push down accounting, the Company recognized an impairment of $420.0 million primarily due to changes to revenue projections and the discount rate utilized.

Subsequent to the Spin-Off, the Company performed a portfolio review and determined to decrease investment in the development of the IPR&D asset, which impacted the amount and timing of expected future cash flows attributable to IPR&D. This determination was driven by the impact of our post-Spin-Off capital structure, constitution of our Board at the time of the Spin-Off as the key decision maker for the determination, and increased ability to revisit our business strategy and portfolio as a standalone public company without regulatory oversight. This represented a potential impairment indicator. An impairment assessment was performed using a discounted cash flow model utilizing the updated projected cash flows and discount rate. The discount rate selected was 20%. Based on the impairment test performed, the Company assessed and determined that the carrying value of the IPR&D intangible asset exceeded its estimated fair value. As a result, the Company recognized an additional impairment of $112.0 million, primarily due to a decrease in projected cash flows. As of

June 30, 2024, the IPR&D intangible asset had a remaining balance of $28.0 million and had not been completed or abandoned. The IPR&D intangible asset is not currently subject to amortization.

The estimates and assumptions updated in each of these evaluations represent a Level 3 measurement because they include unobservable inputs that are supported by little or no market activity and reflect Company- determined and judgmental factors for these assumptions in measuring a fair value. The assumptions in the assessment of an impairment analysis are inherently subjective due to uncertainty and any slight changes in these rates and assumptions could have a significant impact on the concluded value of the IPR&D intangible asset.

A recoverability test for the finite-lived intangible assets, which includes developed technology and trade names, was also performed. Based on the assessment performed, no impairment was noted for the finite-lived intangibles.

The estimated future annual amortization of finite-lived intangible assets is shown in the following table. Actual amortization expense to be reported in future periods could differ from these estimates as a result of acquisitions, divestitures, and asset impairments, among other factors.

(in thousands)	Estimated Annual Amortization
Remainder of 2024	$ 69,166
2025	138,333
2026	138,333
2027	138,333
2028	138,333
2029	138,333
Thereafter	1,297,225
Total	$ 2,058,056

NOTE 4. BALANCE SHEET COMPONENTS

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

Accounts receivable, net (in thousands)	June 30, 2024	December 31, 2023
Trade accounts receivable, gross	$ 16,465	$ 19,924
Allowance for credit losses	(3,091)	(3,062)
Total accounts receivable, net	$ 13,374	$ 16,862

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Prepaid expenses and other current assets (in thousands)	June 30, 2024	December 31, 2023
Prepaid service and maintenance	$ 2,218	$ 1,179
Prepaid software	6,590	4,734
Prepaid insurance	247	814
Prepaid other	6,486	6,579
Tax receivable	4,160	5,411
Indirect taxes	1,165	1,383
Total prepaid expenses and other current assets	$ 20,866	$ 20,100

Accrued liabilities (in thousands)	June 30, 2024	December 31, 2023
Accrued compensation expenses	$ 31,738	$ 41,484
Accrued legal and professional expenses	3,180	7,770
Accrued clinical studies expenses	6,475	6,897
Accrued research and development expenses	6,258	6,647
Accrued marketing	650	1,882
Accrued other expenses	8,272	9,031
Total accrued liabilities	$ 56,573	$ 73,711

NOTE 5. 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:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2024	July 2, 2023	June 30, 2024	July 2, 2023
Cost of screening revenue (exclusive of amortization of intangible assets)	$ 451	$ 446	$ 921	$ 819
Cost of development services revenue	12	4	23	4
Research and development	9,625	10,343	21,068	19,303
Sales and marketing	4,889	4,844	10,352	8,886
General and administrative	10,970	9,912	22,689	18,053
Stock-based compensation expense, before taxes	25,947	25,549	55,053	47,065
Related income tax benefits	(6,300)	(6,163)	(13,368)	(11,353)
Stock-based compensation expense, net of taxes	**$ 19,647**	**$ 19,386**	**$ 41,685**	**$ 35,712**

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 to facilitate the grant of cash and equity incentive awards to non-employee directors, employees, and consultants of the Company and its subsidiaries and to enhance the ability of the Company and any of its subsidiaries to obtain and retain the services of these individuals following the Spin-Off. 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 maximum number of shares authorized for issuance under the 2024 Plan is the sum of (a)

8,656,817 shares; and (b) annual increase on the first day of each calendar year beginning on and including January 1, 2025 and ending on and including January 1, 2034, equal to the lesser of (i) 5% of the aggregate number of shares outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares as is determined by the GRAIL board of directors. As of June 30, 2024, approximately 2.1 million shares remained available for future grants under the 2024 Plan.

A summary of the Company's restricted stock unit activity is as follows:

(Units in thousands)	Restricted Stock Units	Weighted-Average Grant-Date Fair Value Per Share
Outstanding at January 1, 2024	—	$—
Conversion	6,485	$15.37
Awarded	79	$17.00
Vested	—	$—
Cancelled	—	$—
Outstanding at June 30, 2024	6,564	$15.39

2024 Employee Stock Purchase Program

The GRAIL, Inc. 2024 Employee Stock Purchase Plan (the "ESPP") was adopted by GRAIL and approved by Illumina, in its capacity as GRAIL's sole stockholder, in May 2024. As previously disclosed in the Information Statement, the number of shares of Company common stock initially available under the ESPP is equal to (a) 414,021 (b) an annual increase on the first day of each calendar year beginning on and including January 1, 2025 and ending on and including January 1, 2034, equal to the lesser of (i) 1% of the aggregate number of shares outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares as is determined by the GRAIL board of directors. There are 0.4 million shares of Company common stock initially available for issuance pursuant to the ESPP. As of June 30, 2024, no shares had been granted under the ESPP plan.

2024 Transition Incentive Award

During the second quarter of 2024, one-time cash-based incentive awards were granted to GRAIL employees, including executives, for retention purposes ("2024 Transition Incentive Awards") with a total grant date fair value of $40.2 million which were treated as a liability-classified awards. Each award vests entirely in one year or less from its grant date, subject to the applicable holder's continued service through the vesting date or, if earlier upon (i) the applicable holder's termination due to death or disability or (ii) following a "change in control" (as defined in the award agreement evidencing the 2024 Transition Incentive Award), the applicable holder's termination without "cause" or for "good reason" (each as defined in the award agreement evidencing the 2024 Transition Incentive Award). In connection with the Spin-Off, the 2024 Transition Incentive Awards were converted into GRAIL RSUs in accordance with the Employee Matters Agreement by dividing the aggregate award value by the volume-weighted average share price over the first four trading days following the Spin-Off. On the modification date, June 28, 2024, the liability-classified awards in the amount of $4.4 million were reclassified to Additional Paid-In Capital. As the result of this modification, the 2024 Transition Incentive Awards that were outstanding on the Distribution Date were converted into GRAIL RSUs covering 2.5 million shares.

Cash-Based Equity Awards

The Cash-Based Equity Award program was adopted following Illumina's acquisition of GRAIL in 2021 to provide GRAIL employees with dollar-denominated long-term incentive awards that increased or decreased in value based on corresponding changes in GRAIL's calculated value. GRAIL's stand-alone value calculation was estimated by the Company based on its analysis and on input from independent valuation advisors. To estimate

the value of GRAIL for the purposes of the Cash-Based Equity Awards, various assumptions were used, including long-range financial projections, as well as the discount rate and terminal growth rate. The awards generally vested in four equal installments on the first four anniversaries of the grant date, subject to continued employment through the applicable vesting date. In April 2024, Illumina's Compensation Committee and Board of Directors (as applicable) approved an adjustment of the ordinary course payouts for all outstanding Cash-Based Equity Awards providing that the Cash-Based Equity Awards would be paid based on their nominal (face) values without adjustment based on changes in equity value. Subsequent to this adjustment to the Cash-Based Equity Awards and continuing until the Award Modification, the Cash-Based Equity Awards were expensed based on such nominal (face) value in accordance with their applicable vesting schedules. The payments in respect of the Cash-Based Equity Awards between the adoption of such adjustment and the Distribution Date were paid out in cash at the applicable Cash-Based Equity Awards' nominal (face) value. Payments in respect of the Cash-Based Equity Awards before such adjustment were paid out in cash based on the adjusted value of the Cash-Based Equity Award on the applicable vesting date.

In connection with the Spin-Off, outstanding Cash-Based Equity Awards were modified and converted into GRAIL RSUs in accordance with the Employee Matters Agreement determined by dividing the Aggregate Award Value (as discussed below) for such Cash-Based Equity Award by the volume-weighted average share price of GRAIL stock on the first four trading days following the Spin-Off. All other terms and conditions of the awards, including vesting and payment terms, were unaffected by the conversion. All other terms and conditions of the awards, including vesting and payment terms, were unaffected by the conversion.

For each Cash-Based Equity Award, the "Aggregate Award Value" is equal to, (i) for the portion of such award originally scheduled to vest in 2024, the initial grant value of such portion, and (ii) for the remaining unvested portion of such award, the initial grant value of such portion adjusted up or down based on a percentage, with such percentage determined by (A) GRAIL's average closing market capitalization for the four trading days immediately following the distribution date minus the aggregate equity value of GRAIL at the time the Cash-Based Equity Award was granted, as reflected in the consolidated financial statements of Illumina (the "Baseline Equity Value"), divided by (B) the Baseline Equity Value.

Upon modification, the awards became equity-classified. The value of tranches of the Cash-Based Equity Awards that vest in future years (exclusive of the 2024 Transition Incentive Awards described above) was reduced and, as a result, there was no incremental compensation cost. Approximately 1,300 grantees were impacted by this modification. On the modification date, June 28, 2024, the liability-classified awards were reclassified to Additional Paid-In Capital at their fair value in the amount of $50.3 million. Due to the higher value of the 2024 tranche of the Cash-Based Equity Awards, compensation cost will be recognized over the vesting period to ensure compensation cost has been recognized at least equal to the amount that is legally vested. As the result of this modification, the Cash-Based Equity Awards that were outstanding on the Distribution Date were converted to 4.0 million RSUs to be settled in GRAIL shares.

Cash-Based Equity Award activity was as follows:

(in thousands)		
Beginning balance December 31, 2023	$	292,189
Granted		66,864
Cancelled		(11,751)
Vested and paid in cash		(53,807)
Change in fair value		(9,535)
Outstanding balance, June 28, 2024 (Award Modification Date)	$	283,960
Conversion of outstanding awards to GRAIL RSUs		(283,960)
Outstanding balance, June 30, 2024	$	—

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 June 30, 2024, 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.

Performance Options

In connection with the Spin-Off, unvested performance-based stock options previously issued to GRAIL employees to purchase Illumina common stock were converted into performance-based stock options to purchase GRAIL common stock ("Performance Options") in accordance with the Employee Matters Agreement. As of the Distribution Date, there were two remaining unvested Performance Options. On June 28, 2024, the modification date, the Company accounted for the modification of these two Performance Options as Type I and Type IV modifications, respectively. These options were converted at a ratio equal to the average of the volume weighted average per share price of Illumina stock trading during the four days immediately preceding the Distribution Date divided by the average of volume weighted average per share price of GRAIL common stock on the first four trading days immediately following the Distribution Date. For the Performance Option with Type I modification, the incremental charge recognized of the difference in the fair value of the option before and immediately after the modification was immaterial. As the result of this modification, the Performance Options that were outstanding on the Distribution Date were converted to 0.1 million options which remain outstanding as of June 30, 2024. For the Performance Option with Type IV modification, the fair value of the award as of the Modification Date will be used for expense purposes once the award becomes probable of achievement.

As of June 30, 2024, approximately $2.2 million of total unrecognized compensation cost related to the Performance Options was expected to be recognized over a period of approximately 3.2 years. There were no outstanding Performance Options exercisable as of June 30, 2024. The aggregate intrinsic value of the Performance Options outstanding as of June 30, 2024 and December 31, 2023 was $0.2 million and $0.9 million, respectively. The outstanding Performance Options, in general, have contractual terms of ten years from the respective grant dates. The Performance Options generally vest monthly over three years upon the achievement of Company-specified performance targets and are subject to continued service through the applicable vesting date.

NOTE 6. 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. 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.

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

(in thousands)	As of June 30, 2024	As of December 31, 2023
Accounts receivable, net — related parties	$ 32	$ 80
Supplies — related parties	6,259	5,855
Prepaid expenses and other current assets — related parties	59	41
Property and equipment, net — related parties	3,021	3,640
Accounts payable — related parties	—	168
Accrued liabilities — related parties	—	95

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2024	July 2, 2023	June 30, 2024	July 2, 2023
Screening revenue — related parties	$ 108	$ 164	$ 237	$ 416
Cost of screening revenue — related parties	3,457	2,213	6,126	3,792
Cost of development services revenue — related parties	71	36	116	60
Operating expenses — Research and development — related parties	5,310	6,386	10,112	11,166
Operating expenses — General and administrative — related parties	52	52	103	103

The Company has 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:

	Six Months Ended	
(in thousands)	June 30, 2024	July 2, 2023
Cash funding received from Illumina	$ 1,244,300	$ 304,000
Taxes paid related to net share settlement of equity awards	—	(225)
Total contribution from member, net	**$ 1,244,300**	**$ 303,775**

Twist Bioscience Relationship

Mr. Robert Ragusa was appointed as the Company's chief executive officer in October 2021. Mr. Ragusa also serves on the board of directors of Twist Bioscience ("Twist"), a supplier to the Company. Transactions with Twist beginning when Mr. Ragusa became the Company's chief executive officer are reflected in the condensed consolidated financial statements as related party transactions.

Related party transactions with Twist have been reflected in the condensed consolidated financial statements as follows:

(in thousands)	As of June 30, 2024	As of December 31, 2023
Supplies — related parties	$ 1,051	$ 1,052
Accounts payable — related parties	—	660

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2024	July 2, 2023	June 30, 2024	July 2, 2023
Cost of screening revenue — related parties	$ 322	$ —	$ 385	$ —
Cost of development services revenue — related parties	7	—	7	—
Operating expenses — Research and development — related parties	159	13	592	585

NOTE 7. 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 and six months ended June 30, 2024 and July 2, 2023, these shares are treated as issued and outstanding for purposes of calculating historical earnings per share. 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. For the three and six months ended June 30, 2024 and July 2, 2023 the amount of common stock equivalents excluded from the calculation of diluted net loss per share for the periods presented was 6.7 million shares of common stock equivalents.

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

	Three Months Ended		Six Months Ended	
(in thousands, except share and per share data)	June 30, 2024	July 2, 2023	June 30, 2024	July 2, 2023
Numerator				
Net loss	$ (1,585,337)	$ (193,044)	$ (1,804,251)	$ (386,710)
Denominator				
Weighted average shares of common stock—basic and diluted	31,049,148	31,049,148	31,049,148	31,049,148
Net loss per share attributable to common stockholders				
Basic	$ (51.06)	$(6.22)	$ (58.11)	$(12.45)
Diluted	$ (51.06)	$(6.22)	$ (58.11)	$(12.45)

NOTE 8. 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 fiscal six months ended June 30, 2024 and July 2, 2023 were 3.37% and 4.41%, respectively. The decrease for the six months ended June 30, 2024 as compared to the six months ended July 2, 2023 primarily relates to the Company's valuation allowance impacts against pre-tax losses prior to the Spin-off.

As discussed in *Note 1 — Organization And Description Of Business and Note 2 — Summary Of Significant Accounting Policies — Basis of Presentation*, prior to June 30, 2024, 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 six months ended July 2, 2023 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.

During the period that Illumina held the Company, the Company's activity generated various tax attributes recognized as deferred tax assets ("DTAs"), due primarily to the generation of NOLs, IRC 174 capitalized research and experimental expenditures, and research and development ("R&D") tax credits that could not be specifically utilized by the Company as it did not yet generate positive taxable income and it was not a separately regarded tax paying entity from Illumina. Because the Company was not a separately regarded taxable entity from Illumina, these tax attributes were either utilized by or will be utilized by Illumina when filing its consolidated tax return; therefore, the tax attributes were only presented in the Company's stand-alone financial statements to allow the users to understand the financial position of the Company as a stand-alone taxable entity under the Separate-Return Method. The total tax-effected value of the tax attributes, net of FIN48 liabilities and valuation allowance that were deemed to be the property of Illumina, was $447.2 million. In connection with the Spin-off, the underlying $447.2 million of tax attributes were adjusted through an entry of $447.2 million to additional paid in capital.

NOTE 9. 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.

Antitrust and Competition Proceedings

On March 30, 2021, the U.S. Federal Trade Commission ("FTC") issued an administrative complaint seeking to prevent the Acquisition. On September 1, 2022, an administrative law judge issued a decision in favor of the transaction and dismissed the FTC's complaint. The FTC's complaint counsel appealed to the full FTC Commission. On March 31, 2023, the FTC Commission issued a decision overturning the administrative law judge's prior ruling. GRAIL and Illumina appealed the FTC's decision to the U.S. Court of Appeals for the Fifth Circuit ("Fifth Circuit"). On December 15, 2023, the Fifth Circuit issued its opinion and order, in which the court ruled that the FTC applied the incorrect standard in assessing Illumina's open offer contract and, on that basis, vacated the FTC order and remanded the case to the FTC for reconsideration of the effects of the open offer contract under the proper standard as described in the Fifth Circuit Court's decision, and in all other respects upheld the FTC's decision. The Company expects that completion of the Spin-Off will facilitate prompt resolution of the FTC proceedings. Based on the fact that Illumina had a 14.5% ownership interest in GRAIL at the time of the Acquisition, the Company does not expect that Illumina's retention of a 14.5% ownership interest in GRAIL as a result of completion of the Spin-Off will affect the resolution of these proceedings.

On April 19, 2021, the European Commission accepted a request for a referral of the GRAIL, Inc. acquisition for European Union merger review, submitted by a Member State of the European Union (France), and joined by several other EEA Member States (Belgium, Greece, Iceland, the Netherlands, and Norway), under Article 22(1) of Council Regulation (EC) No 139/2004 (the "EU Merger Regulation"). On April 28, 2021, Illumina filed an action in the General Court of the European Union (the "EU General Court") asking for annulment of the European Commission's assertion of jurisdiction to review the acquisition under Article 22 of the EU Merger Regulation, as the acquisition does not meet the jurisdictional criteria under the EU Merger Regulation or under the national merger control laws of any Member State of the European Union. On July 13, 2022, the EU General Court confirmed the European Commission's jurisdiction to examine the Acquisition ("EU General Court Article 22 Judgment"). On September 22 and 30, 2022, Illumina and the Company each asked for annulment of the EU General Court Article 22 Judgment and their appeal is currently pending before the Court of Justice of the European Union ("EU Court of Justice"). On March 21, 2024, the Advocate General recommended, in a non-binding Opinion, that the EU Court of Justice annul the General Court's judgment and the European Commission's decisions accepting the referral of the GRAIL acquisition for EU merger review. The EU Court of Justice is set to issue its ruling on September 3, 2024.

On October 29, 2021, the European Commission adopted an order imposing interim measures (the "Initial Interim Measures Order"). As the Initial Interim Measures Order was set to expire in 2022, the European Commission adopted new interim measures on October 28, 2022 (the "Second Interim Measures Order"). The Company and Illumina both sought the annulment of the Initial Interim Measures Order, and Illumina also sought the annulment of the Second Interim Measures Order (the Company intervened in this procedure in support of Illumina). All requests for annulment were stayed pending the appeal asking for annulment of the EU General Court Article 22 Judgment.

On September 6, 2022, the European Commission adopted a decision finding Illumina's acquisition of GRAIL, Inc. incompatible with the internal market in the European Union. On November 17, 2022, Illumina asked for annulment of this decision before the EU General Court (the Company was admitted to intervene in support of Illumina).

On October 12, 2023, the European Commission adopted a decision requiring Illumina to divest the Company and to restore the situation prevailing before the Company's acquisition by Illumina (the "EC Divestment Decision"). At the Spin-Off, Illumina provided the Company with the required capitalization (two-and-a-half years of funding based on the Company's long-range plan). The order also permitted Illumina to maintain its royalty arrangement with the Company. On December 22, 2023, Illumina sought the annulment of the EC Divestment Decision before the EU General Court.

On December 17, 2023, following a review of the Fifth Circuit's opinion, Illumina elected not to pursue further appeals of the decision and announced Illumina's decision to divest GRAIL through a third-party sale or capital markets transaction. On December 22, 2023, Illumina submitted a divestment plan to the European Commission outlining proposed terms of the divestiture. The divestment plan, outlining the terms of the Company's divestiture, was approved by the European Commission on April 12, 2024. On June 24, 2024, the Spin-Off was completed in accordance with the terms outlined in the divestment plan and completed the divestment of the Company required by the EC Divestment Decision.

With the completion of the Spin-Off, the Company expects that its role in and the significance to it of these matters will be substantially reduced.

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. The Company denies the allegations in the complaints and intend 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. 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 June 30, 2024, 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 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 June 30, 2024, no contingency liability was recorded as the contingency 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 June 30, 2024, as it was not probable that the Company will breach the agreement, no contingency liability was recorded in connection with the Tax Matters Agreement.

NOTE 10. SUBSEQUENT EVENTS

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 includes a reduction in the Company's existing headcount and planned 2024 hires of approximately 30%, inclusive of approximately 350 current full-time employees, or approximately 25% of the existing workforce as of June 30, 2024.

In connection with the Restructuring Plan to be effected in the third and fourth quarters of 2024, the Company estimates that it will incur a restructuring charge in Q3 2024 in the range of approximately $18 to $23 million which primarily consists of severance, benefits, payroll taxes, and other termination related costs, excluding an estimated net benefit in stock based compensation due to the reversal of previously recorded stock-based compensation expenses related to award cancellations.

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 section entitled "Risk Factors" in Par II, Item 1A of this Form 10-Q and the section titled "Cautionary Statement Concerning Forward-Looking Statements" of this Quarterly Report on Form 10-Q.

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. See "Business—Our Products: Galleri and Beyond" and "—Our Clinical Studies" sections of our final Information Statement filed with our Registration Statement on Form 10, as amended (the "Form 10"), as filed with the SEC. Galleri results can help guide next steps for diagnosis of cancer by healthcare providers in required follow-up diagnostic testing. Galleri is not a diagnostic test and has not been approved or cleared by the U.S. Food and Drug Administration. We launched Galleri in the United States in mid-2021. As of June 30, 2024, we have sold more than 215,000 commercial tests and established over 140 commercial partnerships, including leading healthcare systems, employers, payors, and life insurance providers. Commercial use of Galleri has detected some of the most aggressive cancers in early stages including, among others, endometrial, esophageal, gastrointestinal stromal, head and neck, liver, pancreatic, and rectal cancers.

Since our inception, we have incurred net losses each year. We incurred net losses of $1.6 billion and $193.0 million for the three months ended June 30, 2024 and July 2, 2023, respectively and $1.8 billion and $386.7 million for the six months ended June 30, 2024 and July 2, 2023, respectively (see "Basis of Presentation" below for a description of applicable fiscal periods). Adjusted EBITDA was $(139.4) million and $(136.5) million for the three months ended June 30, 2024 and July 2, 2023, respectively and $(291.4) million and $(274.3) million for the six months ended June 30, 2024 and July 2, 2023, 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 asset impairment, amortization of intangible assets, as well as our research and development programs, general and administrative ("G&A") expenses 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 included goodwill and 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 of new and 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 further described in *Note 5 — Stock-Based Compensation*. 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 $21.9 million of legal and professional fees in the six month period ended June 30, 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 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 2023, we spent $121.7 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 are streamlining our commercial sales forces and focusing its field-based activities on the current customers expected to be more productive and high priority opportunities. We are maintaining sales force coverage for the majority of our current Galleri volume and active prescribers. As part of this approach,we are also streamlining investments in its enterprise business, which includes our employer and life insurance businesses. Reductions in the commercial organization include management layers and commercial roles without sales responsibilities. In addition to reductions in the commercial organization, we are making reductions in medical affairs teams involved with U.S. Galleri provider engagement.

We are substantially decreasing 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 are making 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 Board's decision was based on cost-reduction initiatives intended to reduce the Company's ongoing operating expenses and maximize shareholder value.

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

In connection with the Restructuring Plan to be effected in the third and fourth quarters of 2024, we estimate that we will incur a restructuring charge in Q3 2024 in the range of approximately $18 to $23 million which consists of severance, benefits, payroll taxes, and other termination related costs, excluding an estimated net benefit in stock based compensation due to the reversal of previously recorded stock-based compensation expenses related to award cancellations. We expect the headcount reductions to enable future cost savings of

approximately $120 million on an annual basis, with approximately $27 million in savings, net of severance and benefits, in 2024. We estimate that the Restructuring Plan extends our anticipated cash runway from the second half of 2026 into 2028.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared on a stand-alone basis using the consolidated financial statements and accounting records of Illumina prior to the Spin-Off. Since the Spin-Off, we present our financial statements on a consolidated basis as a standalone publicly traded company. 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. References to Q2 2024 and Q2 2023 refer to the three and six months ended June 30, 2024 and July 2, 2023, respectively, which 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 of Illumina's acquisition of GRAIL ("Closing Date"). Intangible assets included developed technology, in-process research and development, and trade names, as well as goodwill. There were also various other purchase price adjustment entries made in connection with the Acquisition that impacted the GRAIL standalone financial statements. We have explained these fluctuations within the section titled "—Results of Operations" below.

We 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, 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, but do not currently have broader coverage and reimbursement by government healthcare programs, such as Medicare. 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 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. We continue to work 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 our work with the NHS and data generated from our NHS-Galleri Trial could 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 internationally into the United Kingdom through our partnership with NHS England, 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 expect to expand into additional select geographies over time, including through distributors.

- ***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 coined the term "multi-cancer early detection" and 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 June 30, 2024, we have entered into over 140 commercial partnerships, including with leading healthcare systems, employers, payors, and life insurance providers, and have established a network of over 11,000 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. 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: NHS-Galleri, CCGA, SUMMIT, STRIVE, SYMPLIFY, PATHFINDER, PATHFINDER 2, REFLECTION and REACH/Galleri-Medicare. 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 studies and development of our automated platform are expected to conclude over the next three years. 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 while satisfying applicable certification requirements. Our facilities are able to process a substantial number of tests annually and are 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 this Quarterly Report on Form 10-Q for more information.

Components of Results of Operations

Screening Revenue and Screening Revenue — Related Parties

We currently derive screening revenue through the sale of Galleri 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 services we provide to biopharmaceutical and clinical customers including support of 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 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 progress toward the completion and satisfaction of performance obligations.

Cost of Screening Revenue (Exclusive of Amortization of Intangible Assets), Cost of Development Services Revenue, Cost of Screening Revenue — Related Parties, and Cost of Development Services Revenue — Related Parties

Cost of revenue represents expenses that are incurred to produce and sell our products and services. For screening revenue, these costs consist of direct materials, direct labor including salaries and wages, bonus, benefits and stock-based compensation, shipping, royalties, and allocations of overhead and equipment depreciation. For development services, these costs consist of direct materials and patient sample acquisition, direct labor including salaries and wages, bonus, benefits and stock-based compensation, royalties, and allocations of overhead and equipment depreciation. Cost of screening revenue — related parties and cost of development services revenue — related parties represent the costs of supplies purchased from related parties used in the generation of revenue from all customers.

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 and Research and Development — Related Parties

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. Research and development — related parties expenses include only those costs incurred with related parties as further discussed in *Note 6 — Related Party Transactions* in Item 1. Financial Statements of this Quarterly Report on Form 10-Q. 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 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 expenses also includes amortization of the trade name intangible assets 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 immediately following implementation of the Restructuring Plan and to continue to decrease as a percentage of revenue over the next three years and long term.

General and Administrative and General and Administrative — Related Parties

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 represents allocated stock administration expenses from Illumina. We 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 following implementation of the Restructuring Plan and to decrease as a percentage of revenue over the next three years and long term.

Goodwill Impairment

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 Form 10. See *Note 3 — Goodwill and Intangible Assets* in Item 1. Financial Statements of this Quarterly Report on Form 10-Q for more information.

Interest Income

Interest income consists primarily of interest income earned on our cash and cash equivalents.

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 for the successor periods 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.

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.

Results of Operations

Comparisons of the Three and Six Months Ended June 30, 2024 and July 2, 2023

The following table summarizes our results of operations for the three and six months ended June 30, 2024 and July 2, 2023.

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2024	July 2, 2023	June 30, 2024	July 2, 2023
Revenue:				
Screening revenue	$ 28,055	$ 19,863	$ 51,465	$ 35,183
Screening revenue — related parties	108	164	237	416
Development services revenue	3,807	2,387	6,989	6,458
Total revenue	31,970	22,414	58,691	42,057
Costs and operating expenses:				
Cost of screening revenue (exclusive of amortization of intangible assets)	12,010	8,912	23,000	17,758
Cost of screening revenue — related parties	3,779	2,213	6,511	3,792
Cost of development services revenue	543	2,059	1,934	3,395
Cost of development services revenue — related parties	78	36	123	60
Cost of revenue — amortization of intangible assets	33,472	33,472	66,944	66,944
Research and development	88,727	82,311	185,117	162,832
Research and development — related parties	5,469	6,399	10,704	11,751
Sales and marketing	40,989	40,737	87,808	86,572
General and administrative	67,206	50,590	124,224	97,248
General and administrative — related parties	52	52	103	103
Goodwill and intangible impairment	1,420,936	—	1,420,936	—
Total costs and operating expenses	1,673,261	226,781	1,927,404	450,455
Loss from operations	(1,641,291)	(204,367)	(1,868,713)	(408,398)
Other income:				
Interest income	2,805	1,847	5,706	4,074
Other income (expense), net	5	(320)	47	(225)
Total other income (expense), net	2,810	1,527	5,753	3,849
Loss before income taxes	(1,638,481)	(202,840)	(1,862,960)	(404,549)
Benefit from income taxes	53,144	9,796	58,709	17,839
Net loss	$ (1,585,337)	$ (193,044)	$ (1,804,251)	$ (386,710)

Comparison of the Three Months Ended June 30, 2024 and July 2, 2023

Revenue

	Three Months Ended		Change	
(in thousands)	June 30, 2024	July 2, 2023	$	%
Screening revenue and screening revenue — related parties	$ 28,163	$ 20,027	$ 8,136	41 %
Development services revenue	3,807	2,387	1,420	59 %
Total revenue	31,970	22,414	9,556	43 %

Screening Revenue and Screening Revenue — Related Parties

The increase in screening revenue of $8.1 million was primarily attributable to an increase in Galleri sales volume. The Galleri sales volume increased in 2024 as a result of the continued ramp in our commercial activity,

expansion of our network of ordering providers, additional commercial partnerships and new promotional campaigns.

Development Services Revenue

The increase in development services revenue of $1.4 million was primarily driven by an increase of $1.0 million in clinical development revenue, an increase of $0.6 million in revenue earned from research services and an increase of $0.3 million in revenue from pilots with biopharmaceutical partners, partially offset by a decrease of $0.5 million in other services revenue.

Cost of Screening Revenue (Exclusive of Amortization of Intangible Assets) and Cost of Screening Revenue — Related Parties

	Three Months Ended		Change	
(in thousands)	June 30, 2024	July 2, 2023	$	%
Cost of screening revenue (exclusive of amortization of intangible assets) and Cost of screening revenue — related parties	$ 15,789	$ 11,125	$ 4,664	42 %

The increase in cost of screening revenue (exclusive of amortization of intangible assets) and cost of screening revenue — related parties of $4.7 million was primarily attributable to an increase in test volume. Cost of screening revenue (exclusive of amortization of intangible assets) and cost of screening revenue — related parties as a percent of revenue decreased in the second quarter of 2024 compared to the same period in 2023 primarily due to improved efficiency in Galleri testing related to increased Galleri sales volume.

Cost of Development Services Revenue and Cost of Development Services Revenue — Related Parties

	Three Months Ended		Change	
(in thousands)	June 30, 2024	July 2, 2023	$	%
Cost of development services revenue and Cost of development services revenue — related parties	$ 621	$ 2,095	$ (1,474)	(70 %)

The cost of development services revenue and cost of development services revenue — related parties decreased due to an decrease in labor costs associated with development services projects completed during the periods.

Research and Development and Research and Development — Related Parties

Research and development and research and development — related parties expenses for the three months ended June 30, 2024 and July 2, 2023 were as follows:

	Three Months Ended		Change	
(in thousands)	June 30, 2024	July 2, 2023	$	%
Compensation expenses	$ 44,790	$ 44,852	$ (62)	— %
Clinical studies and research collaboration expenses	16,690	17,071	(381)	(2)%
Laboratory supplies and expenses	11,860	10,786	1,074	10 %
Other expenses	20,856	16,001	4,855	30 %
Total research and development and research and development — related parties expenses	$ 94,196	$ 88,710	$ 5,486	6 %

The increase in research and development expenses by $5.5 million was primarily driven by an increase of $4.9 million in other expenses as a result of increases of $2.3 million in professional services expenses, an increase of $2.1 million driven by higher software, IT, and facilities expenses being allocated to the research and development function, and an increase of $0.5 million in the use of contractors and temporary labor. The increase

in laboratory supplies and expenses of $1.1 million was primarily driven by increased research and development, clinical study sample processing, and validation testing.

Sales and Marketing

	Three Months Ended		Change	
(in thousands)	June 30, 2024	July 2, 2023	$	%
Sales and marketing	$ 40,989	$ 40,737	$ 252	1 %

The increase in sales and marketing expenses of $0.3 million was primarily attributable to an increase of $0.8 million in compensation expenses, primarily due to increased headcount. This increase was partially offset by a decrease of $0.5 million in third-party marketing and professional services expenses as well as decreases in allocated facilities expenses.

General and Administrative

	Three Months Ended		Change	
(in thousands)	June 30, 2024	July 2, 2023	$	%
General and administrative	$ 67,258	$ 50,642	$ 16,616	33 %

The increase in general and administrative expenses of $16.6 million was primarily attributable to an increase of $13.6 million in legal and professional services expenses associated with divestiture related costs related to our Spin-Off completed on June 24, 2024. Compensation costs increased by $1.5 million due to increased headcount and employee long-term incentive awards. Costs associated with the use of contractors and temporary labor increased by $0.7 million. Other expenses increased by $0.8 million primarily driven by increases in corporate IT expenses and facilities costs, net of allocated expenses.

Goodwill and Intangible Impairment

	Three Months Ended		Change	
(in thousands)	June 30, 2024	July 2, 2023	$	%
Goodwill and intangible impairment	$ 1,420,936	$ —	$ 1,420,936	100 %

As a result of a goodwill impairment assessment performed by Illumina in the second quarter of 2024, a goodwill impairment charge of $888.9 million was recorded, which represents the amount by which the net carrying value of GRAIL exceeded the fair value of GRAIL at the time the quantitative test was performed, primarily due to changes to the forecast of GRAIL's value and the method for valuing GRAIL. In conjunction with the goodwill impairment assessment, an impairment assessment for our IPR&D intangible assets was performed by Illumina which resulted in an impairment charge of $420.0 million primarily due to changes to revenue projections and the discount rate utilized.

Subsequent to the Spin-Off, in conjunction with a portfolio review, we determined to reduce investment in the development of the IPR&D asset, which impacted the amount and timing of expected future cash flows attributable to IPR&D which we concluded was a possible indicator of impairment and another IPR&D impairment test was performed. The impairment assessment resulted in an additional impairment charge of $112.0 million primarily due to a decrease in projected cash flows.

Interest Income

	Three Months Ended		Change	
(in thousands)	June 30, 2024	July 2, 2023	$	%
Interest income	$ 2,805	$ 1,847	$ 958	52 %

The increase in interest income of $1.0 million was primarily driven by an increase in interest earned on our money market funds primarily due to an increase in the balance of money market funds held.

Other Income (Expense)

(in thousands)	Three Months Ended June 30, 2024	Three Months Ended July 2, 2023	Change $	Change %
Other income (expense), net	$ 5	$ (320)	$ 325	(102 %)

The increase in other income was primarily a result the fluctuation of foreign currency exchange rates.

Benefit from Income Taxes

(in thousands)	Three Months Ended June 30, 2024	Three Months Ended July 2, 2023	Change $	Change %
Benefit from income taxes	$ 53,144	$ 9,796	$ 43,348	443 %

The increase in benefit from income taxes was primarily driven by the increase in pretax tax book losses for the three months ended June 30, 2024 when compared to the three months ended July, 2, 2023, including the impairments of intangibles that reduced the Company's net deferred tax liabilities.

Comparison of the Six Months Ended June 30, 2024 and July 2, 2023

Revenue

(in thousands)	Six Months Ended June 30, 2024	Six Months Ended July 2, 2023	Change $	Change %
Screening revenue and screening revenue — related parties	$ 51,702	$ 35,599	$ 16,103	45 %
Development services revenue	6,989	6,458	531	8 %
Total revenue	58,691	42,057	16,634	40 %

Screening Revenue and Screening Revenue — Related Parties

The increase in screening revenue of $16.1 million was primarily attributable to an increase in Galleri sales volume. The Galleri sales volume increased in 2024 as a result of the continued ramp in our commercial activity, expansion of our network of ordering providers, additional commercial partnerships and new promotional campaigns.

Development Services Revenue

The increase in development services revenue of $0.5 million was primarily driven by an increase in revenue earned from research and clinical development revenue, partially offset by a decrease in revenue from pilots with biopharmaceutical partners as a result of milestones earned in 2023 that did not reoccur.

Cost of Screening Revenue (Exclusive of Amortization of Intangible Assets) and Cost of Screening Revenue — Related Parties

(in thousands)	Six Months Ended June 30, 2024	Six Months Ended July 2, 2023	Change $	Change %
Cost of screening revenue (exclusive of amortization of intangible assets) and Cost of screening revenue—related parties	$ 29,511	$ 21,550	$ 7,961	37 %

The increase in cost of screening revenue (exclusive of amortization of intangible assets) and cost of screening revenue — related parties of $8.0 million was primarily attributable to an increase in test volume. Cost of screening revenue (exclusive of amortization of intangible assets) and cost of screening revenue — related parties as a percent of revenue decreased in the first half of 2024 primarily due to improved efficiency in Galleri testing related to increased Galleri sales volume.

Cost of Development Services Revenue and Cost of Development Services Revenue — Related Parties

(in thousands)	Six Months Ended June 30, 2024	Six Months Ended July 2, 2023	Change $	Change %
Cost of development services revenue and Cost of development services revenue—related parties	$ 2,057	$ 3,455	$ (1,398)	(40 %)

The cost of development services revenue and cost of development services revenue — related parties decreased due to an decrease in labor costs associated with development services projects completed during the periods.

Research and Development and Research and Development — Related Parties

Research and development and research and development — related parties expenses for the six months ended June 30, 2024 and July 2, 2023 were as follows:

(in thousands)	Six Months Ended June 30, 2024	Six Months Ended July 2, 2023	Change $	Change %
Compensation expenses	$ 95,081	$ 88,839	$ 6,242	7 %
Clinical studies and research collaboration expenses	32,773	31,453	1,320	4 %
Laboratory supplies and expenses	28,128	21,138	6,990	33 %
Other expenses	39,839	33,153	6,686	20 %
Total research and development and research and development — related parties expenses	$ 195,821	$ 174,583	$ 21,238	12 %

The increase in research and development expenses by $21.2 million was primarily attributable to the increase in laboratory supplies and expenses, other expenses, and compensation expenses. The increase in laboratory supplies and expenses of $7.0 million was primarily driven by increased clinical study sample processing, development and validation testing of our automated platform. The increase of $6.7 million in other expenses was primarily driven by an increase of $2.1 million in professional services expenses, an increase of $3.5 million driven by higher software, IT, and facilities expenses being allocated to the research and development function, and an increase of $1.1 million in the use of contractors and temporary labor. The increase in the compensation expenses of $6.2 million was primarily attributable to increased headcount and employee long-term incentive awards. The increase in clinical studies and research collaboration expenses of $1.3 million was primarily driven by an increase in clinical study enrollment activity and an increase in research collaboration expenses.

Sales and Marketing

(in thousands)	Six Months Ended June 30, 2024	Six Months Ended July 2, 2023	Change $	Change %
Sales and marketing	$ 87,808	$ 86,572	1,236	1 %

The increase in sales and marketing expenses of $1.2 million was primarily attributable to an increase of $2.7 million in compensation expenses, primarily due to increased headcount. This increase was partially offset by a decrease of $1.5 million in third-party marketing and professional services expenses as well as decreases in allocated facilities expenses.

General and Administrative

(in thousands)	Six Months Ended June 30, 2024	Six Months Ended July 2, 2023	Change $	Change %
General and administrative	$ 124,327	$ 97,351	$ 26,976	28 %

The increase in general and administrative expenses of $27.0 million was primarily attributable an increase of $16.5 million in legal and professional services expenses primarily associated with divestiture related advisory

costs related to our Spin-Off completed on June 24, 2024. Compensation expenses increased by $9.0 million due to increased headcount and employee long-term incentive awards. Corporate IT expenses increased by $0.8 million to support the increase in headcount. Other expenses increased by $0.6 million primarily driven by the use of contractors and temporary labor as well as increases in facilities costs, net of allocated expenses.

Goodwill and Intangible Impairment

	Six Months Ended		Change	
(in thousands)	June 30, 2024	July 2, 2023	$	%
Goodwill and intangible impairment	$ 1,420,936	$ —	$ 1,420,936	100 %

As a result of a goodwill impairment assessment performed by Illumina in the second quarter of 2024, a goodwill impairment charge of $888.9 million was recorded, which represents the amount by which the net carrying value of GRAIL exceeded the fair value of GRAIL at the time the quantitative test was performed, primarily due to changes to the forecast of GRAIL's value and the method for valuing GRAIL. In conjunction with the goodwill impairment assessment, an impairment assessment for our IPR&D intangible assets was performed by Illumina which resulted an impairment charge of $420.0 million primarily due to changes to revenue projections and the discount rate utilized.

Subsequent to the Spin-Off, in conjunction with a portfolio review, we determined to reduce investment in the development of the IPR&D asset, which impacted the amount and timing of expected future cash flows attributable to IPR&D which we concluded was a possible indicator of impairment and another IPR&D impairment test was performed. The impairment assessment resulted in an additional impairment charge of $112.0 million primarily due to a decrease in projected cash flows.

Interest Income

	Six Months Ended		Change	
(in thousands)	June 30, 2024	July 2, 2023	$	%
Interest income	$ 5,706	$ 4,074	$ 1,632	40 %

The increase in interest income of $1.6 million was primarily driven by an increase in interest earned on our money market accounts primarily due an increase in the balance of money market funds held.

Other Income (Expense)

	Six Months Ended		Change	
(in thousands)	June 30, 2024	July 2, 2023	$	%
Other income (expense), net	$ 47	$ (225)	$ 272	(121 %)

The increase in other income was primarily a result the fluctuation of foreign currency exchange rates.

Benefit from Income Taxes

	Six Months Ended		Change	
(in thousands)	June 30, 2024	July 2, 2023	$	%
Benefit from income taxes	$ 58,709	$ 17,839	$ 40,870	229 %

The increase in benefit from income taxes was primarily driven by the increase in pretax tax book losses for the six months ended June 30, 2024 when compared to the six months ended July, 2, 2023, including the impairments of intangibles that reduced the Company's net deferred tax liabilities.

Non-GAAP Financial Measures

In addition to our results provided throughout this Quarterly Report on Form 10-Q that are determined in accordance with GAAP, this Quarterly Report on Form 10-Q also includes the following non-GAAP financial measures for the three and six months ended June 30, 2024 and July 2, 2023, which information should be read

in conjunction with our unaudited Condensed Consolidated Financial Statements and the related notes and accompanying notes included elsewhere in this Quarterly Report on 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		Six Months Ended	
(in thousands)	June 30, 2024	July 2, 2023	June 30, 2024	July 2, 2023
Gross loss [1]	$ (17,912)	$ (24,278)	$ (39,821)	$ (49,892)
Amortization of intangible assets	33,472	33,472	66,944	66,944
Stock-based compensation	463	450	944	823
Adjusted Gross Profit	$ 16,023	$ 9,644	$ 28,067	$ 17,875

[1] Gross loss is calculated as total revenue less cost of revenue (exclusive of amortization of intangible assets), cost of revenue — related parties, and cost of revenue — amortization of intangible assets.

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

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

(2) Reflects impairment of goodwill and intangible assets recognized as a result of the Acquisition.

(3) Represents legal and professional services costs associated with the Acquisition and corresponding antitrust litigation, including compliance with the hold separate arrangements imposed by the European Commission, and legal and professional services costs associated with the divestiture.

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

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 June 30, 2024, our cash and cash equivalents totaled $958.8 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 $9.6 billion which include charges for impairment of goodwill and intangible assets and amortization of intangible assets. We expect to incur additional losses as we conduct our research and development efforts and seek to achieve broad reimbursement of our current commercialized products. We believe that our existing cash and cash equivalents, including the funding that Illumina provided in connection with the Spin-Off, 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 Quarterly Report on 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 costs of obtaining regulatory approvals, the timing of broad reimbursement, market acceptance of our products prior to

broad reimbursement, the timing and extent of spending to support commercialization, launch of pipeline products, and the efficiency of our operations. 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, which may require additional financing.

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 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)	Six Months Ended	
	June 30, 2024	July 2, 2023
Net cash used by operating activities	$ (379,085)	$ (309,391)
Net cash used by investing activities	(3,934)	(5,923)
Net cash provided by financing activities	1,244,300	303,775
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(30)	257
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 861,251	$ (11,282)

Net Cash Used by Operating Activities

During the six months ended June 30, 2024, net cash used by operating activities consisted of a net loss of $1.8 billion, $53.8 million cash payments for equity awards, and cash used by changes in our operating assets and liabilities of $18.8 million, offset by non-cash charges of $1.5 billion. The non-cash adjustments primarily consisted of goodwill and intangible impairment expense of $1.4 billion, depreciation and amortization of $79.4 million, and stock-based compensation expense of $55.1 million, which was partially offset by a non-cash benefit of $57.9 million relating to deferred taxes. Changes in operating assets and liabilities was predominantly driven by a decrease in accounts payable of $3.3 million, an increase in prepaids and other current assets of $2.5 million, an increase in supplies and supplies — related parties of $3.8 million, and a decrease in accrued and other liabilities of $14.3 million, partially offset by a decrease in accounts receivable of $3.5 million, and a decrease in net operating lease assets and liabilities of $1.6 million.

During the six months ended July 2, 2023, net cash used by operating activities consisted of a net loss of $386.7 million, $24.7 million cash payments for equity awards, and cash used by changes in our operating assets and liabilities of $7.8 million, partially offset by adjusted by non-cash charges of $109.8 million. The non-cash adjustments primarily consisted of depreciation and amortization of $79.0 million, and stock-based compensation expense of $47.1 million, which was partially offset by a non-cash benefit of $16.1 million relating to deferred taxes. Changes in operating assets and liabilities was predominantly driven a decrease in accrued and other liabilities of $8.6 million, a decrease in accounts payable of $5.4 million, an increase in supplies and supplies—related parties of $2.9 million, partially offset by a decrease in accounts receivable of $4.4 million and a decrease in net operating lease assets and liabilities of $4.3 million, and a decrease in prepaids and other current assets of $0.4 million.

Net Cash Provided by Investing Activities

During the six months ended June 30, 2024, net cash used by investing activities primarily consisted of $3.9 million for capital expenditures primarily related to purchases of machinery and equipment for use in our laboratories.

During the six months ended July 2, 2023, net cash used by investing activities primarily consisted of $5.9 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 six months ended June 30, 2024, net cash provided by financing activities primarily consisted of $1.2 billion in funding received from Illumina.

During the six months ended July 2, 2023, net cash provided by financing activities primarily consisted of $304.0 million in funding received from Illumina, offset by $0.2 million of taxes paid related to net share settlement of equity awards.

Material Cash Requirements

Other than as noted below, there have been no material changes to our material cash requirements from those disclosed in our Form 10. Refer to Notes 5 and 6 to our Consolidated Financial Statements and notes thereto for a discussion of our debt and operating lease obligations, respectively.

Royalties

We have entered into an amendment to our Supply and Commercialization Agreement with Illumina. Under the terms of the amended 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 change of control of GRAIL, at which time royalty payments will resume.

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. While our significant accounting policies are described in more detail in the notes to our audited Consolidated Financial Statements included in the Form 10, we believe that the following accounting policies are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Revenue

Our revenue is derived from screening and development services. Screening revenue includes cancer screening testing services provided to patients. Patients obtain tests via their employers, healthcare systems,

payors, concierge medicine practices, or life insurance providers, or they can order the test via telemedicine (collectively referred to as our direct customers).

Screening Revenue

We recognize screening revenue from the sale of cancer screening testing services for patients. The test price is based on the negotiated contractual rate with our direct customers, otherwise our standard list price applies. For each specimen received, testing services are performed and test results are electronically delivered to the ordering physician. We identify each sale of our test to a 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 and assess whether a revision to the estimate is required based on the actual cash collections. Both the estimate and any subsequent revisions are subject to uncertainty and require significant judgment in the estimation and application of the constraint for such variable consideration. We analyze our actual cash collections over the expected collection period and compare it with the estimated variable consideration for each portfolio. The difference is then recognized as an adjustment to revenue when we do not believe there is a probable revenue reversal.

Development Services Revenue

We have developed a breakthrough methylation-based technology which is utilized by biopharmaceutical companies in research and clinical studies, and companion diagnostic development. For contracts with multiple performance obligations, the transaction price is allocated to the separate performance obligations on a relative standalone selling price basis. We determine standalone selling price by considering the historical selling price of these performance obligations in similar transactions as well as other factors, including, but not limited to, the price that customers in the market would be willing to pay, competitive pricing of other vendors, industry publications and current pricing practices, and expected costs of satisfying each performance obligation plus appropriate margin; or by using the residual approach if standalone selling price is not observable, by reference to the total transaction price less the sum of the observable standalone selling prices of other performance obligations promised in the contract.

Biopharmaceutical partners engage with us to run pilot and research studies by sending patient samples and comparing our test result to their expected result for evaluation of performance and application. We recognize revenue as performance obligations are completed.

Following favorable results from pilot and research studies, biopharmaceutical partners may enter into development service agreements with us related to clinical study and companion diagnostic device development and regulatory submissions for the developed product(s). These agreements typically have multiple commitments of services and therefore, have longer performance periods. We use an input method based on costs incurred to measure our progress toward the completion and satisfaction of the performance obligations. We assess the changes to the total expected cost estimates as well as any incremental fees negotiated resulting from changes to the scope of the original contract in determining the revenue recognized at each reporting period.

Accrued Clinical Studies and Research and Development Expenses

We accrue for estimated costs of research and development activities conducted by third-party service providers, including those conducting clinical studies. We record the estimated costs of research and development activities based upon the estimated amount of services provided and include these costs in accrued liabilities and accrued liabilities — related parties in our consolidated balance sheets and within research and development and research and development — related parties expenses in our consolidated statements of operations. These costs are a significant component of our research and development expenses. We accrue for these costs based on factors such as estimates of the work completed and in accordance with agreements

established with our third-party service providers. We make judgments and estimates in determining the accrued liabilities balance in each reporting period.

Stock-Based Compensation

Prior to the Spin-Off, we compensated our employees through a long-term incentive program that included GRAIL cash-based equity incentive awards ("Cash-Based Equity Awards"). As these awards were indexed to the value of GRAIL and settled in cash, they were accounted for under ASC 718 *Compensation - Stock Compensation* as a liability- classified award because the substantive terms of the award require cash settlement on each vesting date. Under ASC 718, we elected to expense the compensation cost over the life of the award via a straight-line method, recognized in stock-based compensation expense. This method resulted in the amount of compensation cost recognized as of any date to be at least equal to the earned portion of the expected fair value of the awards on the vest date. Given we did not have an actively traded standalone stock, GRAIL's stand-alone value calculation was estimated by the Company based on its analysis and on input from independent valuation advisors. To estimate the value of GRAIL, various assumptions were be used, such as our long-range financial projections, as well as the discount rate and terminal growth rate. The assumptions used were inherently subject to uncertainty and we noted that small changes in these assumptions could have had a significant impact on the concluded value.

In connection with the Spin-Off, GRAIL and Illumina entered into an Employee Matters Agreement pursuant to which GRAIL's equity awards were modified (the "Award Modification"). Our cash settled, liability-classified awards were modified to become RSUs that will be settled in shares of our common stock upon vesting. The unvested performance stock options held by certain GRAIL employees to purchase Illumina stock were converted to options to purchase our common stock. See *Note 5 — Stock-Based Compensation* for further details of the Award Modification.

Prior to the Award Modification, the Cash-Based Equity Awards were liability-classified awards because the Cash-Based Equity Awards could be settled in cash. Until April 30, 2024, we estimated our stand-alone value calculation based on our analysis and on input from independent valuation advisors. The value of the Cash-Based Equity Awards was recorded over the respective vesting periods of the Cash-Based Equity Awards, with recognition of a corresponding liability recorded in incentive plan liabilities in the consolidated balance sheets. The Cash-Based Equity Awards were remeasured at each reporting date until settlement, with changes in value recognized in stock-based compensation expense. On April 30, 2024, Illumina's Compensation Committee approved an adjustment of the ordinary course payouts of the Cash-Based Equity Awards providing that the Cash-Based Equity Awards would be paid based on their nominal (face) value without adjustment based on changes in equity value. Subsequent to this adjustment to the Cash-Based Equity Awards and continuing until the Award Modification, the Cash-Based Equity Awards expensed based on such nominal (face) value in accordance with their applicable vesting schedules.

The grant date fair value of RSUs are determined based on the closing market price of our common stock on the date of the grant (in the case of RSUs resulting from the Award Modification, the date of the Award Modification). Stock-based compensation expense is recognized based on the fair value on a straight-line basis over the requisite service periods of the RSUs.

The fair value of performance stock options with service conditions is determined using the Black-Scholes-Merton option-pricing model. The model assumptions include expected volatility, term, dividends, and the risk-free interest rate. The expected volatility is generally determined by weighing the historical and implied volatility of peer companies' common stock. The expected term is our best estimates based on the vesting period and contractual term. Given that cash dividends were never declared or paid on the Illumina nor our common stock, the expected dividend yield is determined to be 0%. We do not anticipate paying cash dividends in the foreseeable future. The risk-free interest rate is based upon U.S. Treasury securities with remaining terms similar to the expected term of the stock-based awards. The fair value of the performance stock options begins to be recognized when it is probable that the performance-based condition will be met.

Goodwill and Indefinite-Lived Intangible Impairment

Goodwill represents the costs in excess of the fair value of net assets of GRAIL acquired by Illumina in August 2021. Indefinite-lived intangible assets consist of GRAIL's in-process research and development ("IPR&D") and were measured by Illumina at fair value as of the Closing Date.

We test goodwill and indefinite-lived intangible assets for 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. Goodwill and indefinite-lived intangible assets are considered to be impaired when the carrying value of a reporting unit or asset exceeds its fair value. GRAIL currently has only one reporting unit; and therefore, we measure the carrying value against the fair value of the Company.

In the evaluation of goodwill for impairment, we first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting entity is less than its carrying value. If we determine that it is more likely than not for a reporting unit's fair value to be greater than its carrying value, a calculation of the fair value is not performed. If we determine that it is more likely than not for a reporting unit's fair value to be less than its carrying value, a calculation of the fair value is performed and compared to the carrying value of that reporting unit. In certain instances, we may elect to forgo the qualitative assessment and proceed directly to the quantitative impairment test. If the carrying value of a reporting unit exceeds its fair value, goodwill of that reporting unit is impaired and an impairment loss is recorded equal to the excess of the carrying value over its fair value.

Generally, we measure the fair value of the reporting unit based on a present value of future discounted cash flows. The discounted cash flow models indicate the fair value of the reporting units based on the present value of the cash flows that the reporting units are expected to generate in the future. Significant estimates in the discounted cash flow models include the weighted average cost of capital, revenue growth rates, long-term rate of growth, and profitability of our business.

Discount rates were determined using a weighted average cost of capital for risk factors specific to us and other market and industry data. In the most recent analysis, a discount rate of 51.5% was used for the goodwill assessment and 46.5% and 20% was used for the intangible assets assessments. The estimates and assumptions used in our assessment represent a Level 3 measurement because they are supported by little or no market activity and reflect our own assumptions in measuring fair value. Specifically for the recent goodwill impairment analysis, valuation estimates from financial advisors derived from revenue multiples from peer public companies was used. The assumptions used are inherently subject to uncertainty and we note that small changes in these assumptions could have a significant impact on the concluded value.

Income Taxes

Our provision for income taxes, deferred tax assets and liabilities, and reserves for unrecognized tax benefits reflect our best assessment of estimated future taxes to be paid. Judgments and estimates based on interpretations of existing tax laws or regulations in the United States and foreign jurisdictions where we are subject to income tax are required in determining our provision for income taxes. Changes in tax laws, regulations, or statutory tax rates (including the implementation of global minimum tax rates in certain jurisdictions), and estimates of our future taxable income could impact the deferred tax assets and liabilities provided for in the condensed consolidated financial statements and would require an adjustment to the provision for income taxes.

Deferred tax assets are regularly assessed to determine the likelihood they will be recovered from future taxable income. A valuation allowance is established when we believe it is more likely than not the future realization of all or some of a deferred tax asset will not be achieved. In evaluating our ability to recover deferred tax assets within the jurisdiction which they arise, we consider all available positive and negative evidence.

We recognize the impact of a tax position in our condensed consolidated financial statements only if that position is more likely than not of being sustained upon examination by taxing authorities, based on the technical merits of the position. Due to the complexity of some of the uncertainties, the ultimate resolution may result in payments that are materially different from our current estimate of the tax liability. These differences, as well as

any interest and penalties, will be reflected in the provision for income taxes in the period in which they are determined.

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. We had cash and cash equivalents of $958.8 million as of June 30, 2024, which consisted primarily of bank deposits and money market funds. 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 Quarterly Report on 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 June 30, 2024, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

Following the Spin-Off, new corporate and governance functions, such as finance, tax, information technology, human resources, treasury and legal, have been implemented to meet all regulatory requirements for a standalone public company. Apart from the foregoing changes, there were no changes in our internal controls over financial reporting the period covered by this Quarterly Report on 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 9 — Legal And Regulatory Proceedings*" to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Item 1A. Risk Factors

You should carefully consider the following risks and other information described in "Risk Factors" in this Quarterly Report on Form 10-Q in evaluating GRAIL and GRAIL common stock (Nasdaq: GRAL). Any of the following risks and uncertainties could materially adversely affect our business, financial condition, and results of operations. The following risks have generally been separated into five groups: risks relating to our business and industry, risks relating to regulation and legal compliance, risks relating to intellectual property, risks relating to the Spin-Off, and risks relating to our common stock. References to "we," "our," "us," and words of similar import in this section refer to GRAIL and, unless otherwise specified, its consolidated subsidiaries. References to this Quarterly Report refer to this Quarterly Report on Form 10-Q for the period ended June 30, 2024 and references to the Information Statement refer to our Information Statement, which is included as Exhibit 99.1 to Amendment No. 2 to GRAIL's Registration Statement on Form 10 (File No. 001-42045) filed with the Securities and Exchange Commission on June 3, 2024.

Risks Relating to Our Business and Industry

We operate in a rapidly evolving field and have a limited operating history, which makes it difficult to evaluate our current business and predict our future performance.

We operate in a rapidly evolving field and, having commenced operations in January 2016, have a limited operating history. We completed our first sale of our multi-cancer early detection test, Galleri, in mid-2021 and our other products and products in development have an even more limited history, with most still not in commercial distribution. We have funded our operations to date primarily with the proceeds from the sale of equity securities and capital contributions from Illumina and, to a lesser extent, revenue derived from sales of Galleri and biopharmaceutical business revenue. Our short operating history as a company, evolving business strategies, rapid growth and significant events such as our separation from Illumina and the Restructuring Plan may make it difficult to evaluate our current business or our future success and the risks and challenges we may encounter, and may increase the risk that we will not continue to grow at or near historical rates.

If we fail to address the risks and difficulties that we face, including those described elsewhere in this "Risk Factors" section, our business, financial condition, results of operations, and growth prospects could be materially adversely affected. We have encountered in the past, and expect to encounter in the future, risks and difficulties frequently experienced by companies with limited operating histories in new and rapidly evolving fields. If our assumptions regarding these risks and difficulties, which we use to plan and operate our business, are incorrect or change, or if we do not address these risks and difficulties, our results of operations could differ materially from our expectations and our business, financial condition, results of operations, and growth prospects could be adversely affected.

We have incurred significant net losses in each period since our inception and anticipate that we will continue to incur net losses for the coming years.

Since our inception, we have incurred significant net losses. Our net loss was $1.8 billion and $386.7 million in the six months ended June 30, 2024 and 2023 respectively. Substantially all of our net losses since inception have resulted from our research and development programs, commercialization efforts, investments in our facilities, payments to licensors, and general and administrative costs associated with our operations, as well as intangible asset amortization and the impairments of $1.4 billion during the six months ended June 30, 2024, related to the intangible assets and goodwill recorded by Illumina upon the acquisition of GRAIL. As of June 30, 2024, we had an accumulated deficit of $9.6 billion.

We have invested significant financial resources in research and development activities, including to develop our methylation platform, and to develop our products, such as Galleri and our precision oncology portfolio. We have also invested significant resources to conduct large scale clinical studies to evaluate and improve Galleri and current and future products, and to commercialize Galleri and plan for potential commercial launches of our future and current products in other markets. The amount of our future net losses will depend, in part, on the level of our future expenditures and our ability to generate additional revenue. Moreover, our net losses may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good or reliable indication of our future performance.

We expect to continue to incur significant expenses and operating losses as we:

- attract, hire, and retain qualified personnel;
- seek regulatory approvals, clearances, or certifications, or coverage and reimbursement, that may be necessary or desired for our products and future products;
- conduct our ongoing clinical studies and initiate and conduct additional clinical studies to support the development and commercialization of our products and potential future products;
- continue our research and development activities;
- maintain and potentially expand our laboratory capacity and enhance operating capabilities for greater commercial scale;
- maintain sales, marketing, and distribution infrastructure for purchases of our products;
- acquire or in-license additional intellectual property and technologies;
- make milestone, royalty, or other payments due under any license or collaboration agreements;
- obtain, maintain, protect, and enforce our intellectual property portfolio, including intellectual property obtained through license agreements;
- maintain and potentially expand our facilities and infrastructure to support our continued research and development, operations and any planned commercialization efforts in the future;
- defend against any litigation, including but not limited to any patent disputes, employment matters, product liability claims or other lawsuits related to our products, our marketing, advertising, or labeling, or our clinical research;
- support potential international commercial expansion of our products;
- continue to engage the medical community and others to drive awareness and adoption of multi cancer early detection (“MCED”) testing; and
- meet the requirements and demands of being a public company.

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, NHS England decided to wait for the final results from the NHS-Galleri Trial, a trial designed to inform implementation of the Galleri test as a national screening program (if recommended by the UK National Screening Committee), before determining whether to implement the Galleri test in NHS, rather than rely on certain results of an early analysis from the first screening test (the prevalent screening round) in the NHS-Galleri Trial to begin a two-year commercial pilot in England. It is possible that the final results will be unsuitable, 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. FDA has granted breakthrough device designation for Galleri. We plan to complete a PMA submission for an 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 it plans 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. The phase-in of medical device requirements to LDTs, including the potential requirement for FDA marketing authorization, will be costly and time-consuming, and if we fail to comply with such requirements, or if we cannot ultimately obtain marketing authorization for our LDTs where required, our business will be substantially harmed

Moreover, FDA and other regulators may require that we generate additional clinical data to support such clearance, approval, or certification, which could result in delays, increased costs, or other limitations or negative impact 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." Our stakeholders include certain third parties, including telemedicine and phlebotomy providers, couriers, storage and data collection management providers, and ordering and results delivery providers, among others, which we refer to as patient-facing service providers. Other important third parties are clinical study providers and collaborators, including contract research organizations ("CROs") and partners. Negative results experiences or outcomes, including those published by third parties, such as patient-facing service providers and other partners, that use our methylation platform, our products, or our offerings may harm our reputation, business, and growth prospects.

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 current commercial use as an LDT). With respect to Galleri, we intend to undertake one or more bridging studies to measure and evaluate concordance, performance and safety of the subsequent, enhanced version of Galleri (for which we are submitting our PMA) versus the existing version of Galleri (currently sold as an LDT), 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 enhancements. Reverting to the existing version of the test may cause delays in our PMA submission timeline. 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.

Finally, generating the clinical data necessary to validate and support the launch of our products as LDTs and enhanced versions of products and to subsequently obtain regulatory clearance, approval, or certification, or coverage and reimbursement, is time-consuming and carries with it the risk of not yielding the desired results. The performance achieved in published studies may not be replicated in later studies that may be required to obtain or maintain premarket clearance, approval, or certification, or coverage and reimbursement. Limited results from earlier-stage studies may not predict results from studies in larger numbers of participants or participants drawn from different populations. Unfavorable results from ongoing or future clinical studies could result in delays in, modifications to, or abandonment of ongoing or future clinical studies, or abandonment of a product development program, or may delay, limit, or prevent regulatory clearances, approvals, or certifications, or coverage and reimbursement of our products.

The clinical study process is lengthy and expensive with uncertain outcomes. We have encountered delays and may encounter future delays in, or unexpected data from, our clinical studies, and may therefore be unable to complete our clinical studies on the timelines we expect, if at all, which could materially and adversely impact our ability to launch our products and seek regulatory clearance or approval, or coverage and reimbursement.

Clinical testing is expensive, time-consuming, and subject to uncertainty. Initiating and completing clinical studies necessary to validate and market our products, and to support regulatory authorizations or certifications and coverage and reimbursement, will be time-consuming and expensive and the outcomes are inherently uncertain. Clinical studies must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements and regulations, and are subject to oversight by governmental agencies and institutional review boards ("IRBs") or ethics committees at the medical institutions where the clinical studies are conducted.

The results of our development efforts and clinical studies of our products conducted to date and ongoing or future studies of our current or future products may not be predictive of the results of later clinical studies, and interim results of a clinical study do not necessarily predict final results. Our interpretation of data and results from our clinical studies do not ensure that we will achieve similar or favorable results in future clinical studies. In addition, clinical data are often susceptible to various interpretations, analyses, and methodological limitations, and many companies that have believed their products performed satisfactorily in earlier clinical studies have nonetheless failed to replicate results in later clinical studies. Products in later future clinical studies may fail to show the desired safety and efficacy despite having success in previous clinical studies.

In addition, we cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all, or within the anticipated budget. The timely completion of clinical studies in accordance with their protocols and applicable requirements depends, among other things, on our ability to enroll a sufficient number of participants who remain in the study until its conclusion. Many of our clinical studies require enrolling a large number of asymptomatic participants (i.e., individuals without symptoms of cancer) who may not see value in enrollment. Additionally, we may encounter delays as a result of the administrative complexities in managing and recruiting for studies of this scope and size. If we are unable to recruit sufficient participants for our clinical studies, including our Real-world Evidence to Advance Multi-Cancer Early Detection Health Equity ("REACH/Galleri-Medicare") study, or if we are unable to maintain sufficient participation of enrolled participants to maintain

statistical power for our endpoints, our product development, commercialization activities, and our ability to seek regulatory clearance or approval for our products could be delayed, require modification, or be prevented.

For example, our PMA submission for Galleri requires clinical data, including certain data from our ongoing PATHFINDER 2 study, which we are conducting under an FDA-approved Investigational Device Exemption ("IDE") application. We may encounter difficulties enrolling or maintaining a sufficient number of participants in our current or future studies, including our PATHFINDER 2 study and the NHS-Galleri study. Delays in our studies would cause us to delay completion of our PMA submission for Galleri, which would negatively impact our business, financial condition, results of operations, and growth prospects.

Further, FDA may require that we conduct additional studies or expand the enrollment of completed or ongoing studies to support our PMA, which would add significant time delay to our PMA submission, which would negatively impact our business, financial condition, results of operations, and growth prospects,

The initiation and completion of clinical studies may be prevented, delayed, or halted for numerous reasons, including as a result of the following:

- the inability to generate sufficient data to support the initiation or continuation of clinical studies;
- the inability to rely on previously-collected data on earlier versions of our products, such as Galleri, in support of the launch or submission for marketing authorization (or certification) of the later or enhanced versions of our products, including Galleri, or our other products and future products;
- the requirement to submit an IDE or comparable foreign application to the FDA or comparable foreign regulatory authorities, which must become effective prior to commencing certain human clinical studies of medical devices, and which the FDA or comparable foreign regulatory authorities may disapprove;
- delays caused by participants withdrawing from clinical studies or failing to return for follow-up or by institutions failing to submit data, including follow-up data, to us;
- delays or failure in reaching a consensus or agreement, if required, with regulatory agencies on study design or feedback from regulatory agencies necessitating changes to ongoing or planned clinical study design;
- delays or failure in reaching agreement on acceptable terms with CROs, service providers, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays or failure in obtaining any required IRB approval or ethics committee approval for our clinical study sites;
- delays in amending, or the inability to amend, our IRB- or ethics committee-approved protocols at clinical study sites when necessary or desired;
- difficulty or delays in collaborating with sites, institutions, and investigators;
- failure by us, investigators, sites, or participants to comply with the applicable study protocol or applicable regulatory requirements and standards for data collection, reporting, records maintenance, or data integrity;
- failure by us or any CROs or other third parties to adhere to clinical study requirements, including the applicable protocol;
- failure to perform in accordance with good clinical practice ("GCP") and good laboratory practice ("GLP") requirements, and/or other applicable regulations and requirements of the FDA or other applicable governmental authorities; failure to comply with applicable data privacy and security laws, including laws related to processing of special categories of personal data clinical studies such as the European

Union's ("EU") General Data Protection Regulation ("EU GDPR") or United Kingdom's General Data Protection Regulation and the Data Protection Act 2018 ("UK GDPR") (the UK GDPR and EU GDPR together referred to as the "GDPR");

- challenges caused by transferring personal information or biological samples from the EU, United Kingdom, or other countries to our systems or facilities in the United States for processing;
- failure of our products and future products to achieve acceptable performance metrics, such as sensitivity, specificity, positive predictive value, and/or safety endpoints;
- unacceptable safety findings, including findings related to the risk, such as higher likelihood, of false positive test results (which could lead to unnecessary confirmatory testing, such as biopsy, or anxiety) or false negative test results (which could lead to foregoing standard of care screening, a delay in diagnosis or disease progression);
- termination or suspension of a study or site by us or the data safety monitoring board (or independent data monitoring committee), suspension or termination of a study or site by an IRB, ethics committee, or institution, or clinical hold or termination of a study or site by a regulatory authority, including the FDA;
- our inability to collaborate with clinical investigators, including if they are disqualified, terminated, suspended, or change affiliated institutions;
- adverse inspections of our clinical study sites or results by any applicable regulatory authority, including the FDA, NHS, or United Kingdom Medicines and Healthcare products Regulatory Agency;
- changes in statutory or regulatory requirements or guidance, or clinical guidelines, that require amending existing or designing new clinical protocols, obtaining new IRB or ethics committee approvals, modifying our clinical studies, modifying our consent process or obtaining additional consent from study participants, or altering the pathway to clearance, approval, or certification of our products and future products;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional clinical studies;
- the cost of clinical studies of our products and future products being greater than we anticipate;
- destruction or compromise of, or other inability to access or receive, clinical study samples processed, stored, managed, or otherwise in the control of a clinical site or other third party;
- determination that data from research conducted outside the United States, including the NHS-Galleri Trail, does not meet the FDA's requirements for submission and support of a marketing authorization or future clinical study IDE application, for example because the foreign data are not applicable to the U.S. population and U.S. medical practice, the studies have been performed by clinical investigators of unsuitable competence, or the FDA cannot validate the data through an on-site inspection or other appropriate means;
- clinical studies of our products and future products producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical studies or abandon development programs; and
- lack of adequate funding.

Any such delays could adversely affect the costs, timing, or successful completion of our clinical studies. Moreover, we depend on our collaborators and on medical and clinical institutions and CROs to conduct our clinical studies in compliance with applicable GCP and other regulatory requirements, and while we have agreements governing their committed activities, we have limited influence over their actual performance. To the extent we, our collaborators or the CROs fail to enroll participants for our clinical studies, fail to conduct the study

according to applicable GCP or other regulatory requirements, or are delayed for a significant time in the execution of studies, including achieving full enrollment, we may be affected by increased costs, program delays, enforcement actions, or a determination that the data are unusable for regulatory or product development purposes. In addition, clinical studies that are conducted in countries outside the United States may subject us to further delays and expenses.

Any inability to initiate or complete clinical studies successfully could result in additional costs to us, slow down or prevent our product development and receipt of positive reimbursement coverage decisions, or impair our ability to generate revenue. Delays in initiating or completing our planned clinical studies could also allow third parties to bring products to market sooner than expected, which could impair our ability to successfully commercialize our products and future products, if launched, and may harm our business, financial condition, results of operations, and growth prospects. In addition, many of the factors that may cause, or lead to, a delay in initiation or completion of clinical studies may also ultimately lead to the delay or the narrowing or denial of any regulatory clearance, approval, or certification we may seek with respect to our products and future products. Delays in the initiation or completion of any clinical study of our products or future products in development, such as Galleri or our precision oncology portfolio, or seeking broad coverage and reimbursement, will increase our costs, slow down or jeopardize our product development and regulatory clearance, approval, or certification process, and delay or potentially jeopardize broad adoption of our products and future products and their ability to generate revenue.

Our commercial products may fail to achieve the degree of market acceptance necessary for commercial success.

The commercial success of any of our marketed products, including Galleri and our precision oncology portfolio, or future products will depend on the degree of market acceptance by consumers, including self- insured employers, health systems, healthcare providers, life insurance companies, patients, and, over the longer- term, third-party payors. The degree of market acceptance of our products will depend on a number of factors, including:

- the performance, validation, and clinical utility of such products as demonstrated in clinical studies, from real-world use, and published in peer-reviewed journals;
- our ability to demonstrate the clinical validation and utility of our products and their potential advantages to the medical community;
- the ability of our products to demonstrate comparable or non-inferior performance in real-world intended use populations as in clinical studies;
- the willingness of consumers, including self-insured employers, health systems, healthcare providers, life insurance companies, patients, and others in the medical community to utilize our products;
- the willingness of commercial third-party payors and government payors to cover and reimburse our products, the scope and amount of which will affect an individual's or entity's willingness or ability to pay for our products and likely heavily influence healthcare providers' decisions to recommend our products;
- willingness of providers, patients, and others to learn about our products, and establish a sense of understanding and confidence in the use of our products;
- with respect to Galleri, which was launched as an LDT in the United States for use in an asymptomatic population, the concern that the product could lead to unnecessary medical screening procedures or a high false positive rate and the associated costs of unnecessary workups resulting from false positives;
- the belief of providers, patients, and others that the use of Galleri in its intended use population is clinically appropriate, and not restricting its use to a narrower intended population;
- the introduction or market acceptance of future third-party products, including the expansion of the capabilities of existing products and tests that are reimbursed;

- the ability of our partners and our employees and contractors to ensure the safety and privacy of our patient data;

- publicity (adverse or positive) concerning our products or operations (including third-party partners, patient-facing service providers, vendors, or suppliers) or future third-party products, including adverse publicity resulting from the use of our products or offerings by third parties, including partners; and

- the strength of our marketing and distribution support and patient-facing service providers.

The failure of our products, once introduced, to be listed in physician guidelines or of our studies to produce favorable and consistent results or to be published in peer-reviewed journals could limit the adoption of our products. In addition, healthcare providers and third-party payors, including the Centers for Medicare and Medicaid Services ("CMS"), may rely on physician guidelines issued by industry groups, medical societies, and other key organizations, such as the United States Preventive Services Task Force ("USPSTF"), an independent, volunteer panel of experts in the field of prevention, evidence-based medicine and primary care, before utilizing or reimbursing the cost of any diagnostic or screening test. Although we have a number of clinical studies underway designed to evaluate the clinical validity of Galleri, our product is not yet, and may never be, listed in any such guidelines, even if approved by the FDA.

Further, if our products or the technology underlying them do not receive sufficient favorable exposure in peer-reviewed publications, the rate of physician and market acceptance of our products and positive reimbursement coverage decisions for our products could be negatively affected. The publication of clinical data in peer-reviewed journals is a crucial step in commercializing and helping obtain reimbursement for products, and our inability to control when, if ever, results are published, if positive, may delay or limit our ability to derive sufficient revenues from any product that is developed using data from a clinical study.

Additionally, we believe that FDA approval for Galleri may provide clinical and regulatory credibility and validation in the view of providers, third-party payors, and others, and our failure to achieve FDA approval, at all or within our anticipated timelines, could limit adoption of Galleri, even if we continue to publish data on its clinical validity and utility in peer-reviewed journals. Our PMA submission and a potential subsequent rejection or material delay, including a requirement by the FDA to conduct additional studies or expand the enrollment of completed or ongoing studies, may reflect negatively on Galleri and the ongoing and planned clinical studies used to support our PMA submission, which could lead healthcare providers, payors, and others to lose confidence in the utility or benefit of Galleri and our other products and future products.

Failure to achieve broad market acceptance of our products would materially harm our business, financial condition, and results of operations.

We may not be able to generate sufficient revenue to offset our ongoing operating expenses and achieve and maintain profitability, and it may be difficult for us to offset the costs of our royalties, including the high single-digit royalty that we will be required to pay to Illumina in perpetuity or our royalties payable to the Chinese University of Hong Kong.

Our ability to generate future revenue growth from product sales and achieve profitability depends on our ability to continue commercializing our products. We completed our first sale of Galleri in mid-2021 and as of June 30, 2024 we have sold more than 215,000 Galleri tests through our existing market channels. We also launched our precision oncology portfolio in 2023, which comprises a research use only ("RUO") offering, and have partnered with several biopharmaceutical companies to deploy this offering. While we are continuing to support our precision oncology portfolio following the Restructuring Plan, we may not be able to generate sufficient revenues to offset the costs of offering these products or achieve or maintain profitability on these products, and revenues from precision oncology may not be a significant source of our overall revenue in the future. We cannot assure you that we will successfully be able to launch any future products as planned, if at all, and our failure to do so may prevent us from generating increased revenue. Furthermore, even if we are able to launch future products in a timely manner, we may not be able to generate sufficient revenue to offset our costs

and achieve profitability. Our ability to generate future revenue growth from product sales depends heavily on our success in:

- continuing clinical development, validation, and demonstration of the clinical utility of our products and future products and continuing to improve product performance and expand product features over time;
- seeking, obtaining, and maintaining marketing authorizations or certifications that may be necessary or desired for any versions of Galleri and any future products that we develop;
- launching and commercializing our products by maintaining and expanding our sales force, marketing, medical affairs, and distribution infrastructure, and collaborating with commercialization partners;
- investing in and enhancing our proprietary methylation platform, and enhancing later versions of our existing and future products and offerings;
- obtaining market acceptance by consumers, including self-insured employers, health systems, healthcare providers, life insurance companies, patients, and third-party payors;
- establishing and maintaining supply and manufacturing relationships with third parties that can timely and consistently provide adequate, in both amount and quality, products and services to support clinical development and the market demand for Galleri, our precision oncology portfolio, and, if launched, future versions of Galleri or other future products;
- achieving adequate coverage and reimbursement from government healthcare programs, health insurance organizations, and other third-party payors for products that we launch;
- achieving sufficient efficiencies and cost management strategies in our laboratory, supply chain, and elsewhere to maintain an appropriate cost of goods sold to offer our products at an acceptable price in a pre-reimbursement environment;
- addressing any technological and market developments;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter and maintaining such existing or future arrangements;
- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, know-how, and trademarks;
- the potential cost of and delays in product development as a result of any regulatory oversight applicable to our existing and future products and offerings;
- defending against third-party interference, invalidation, or infringement claims, if any; and
- attracting, hiring, and retaining qualified personnel.

We anticipate incurring significant costs to continue commercializing our products. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies, or notified bodies to delay the launch of any new products, narrow or change our intended use or product claims, and modify or expand our clinical studies or to perform additional clinical studies, either pre- or post-approval (or certification), in addition to those that we currently anticipate. Additionally, it may be difficult for us to offset the costs of the high-single-digit royalty that we will be required to pay under our agreement with Illumina in perpetuity. For more information, see “Business,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Material Cash Requirements,” and “Certain Relationships and Related Party Transactions— Agreements with Illumina” in the Information Statement and “Management’s Discussion and Analysis of Financial Condition and Results of Operations--Minimum Royalties” in this Quarterly Report on Form 10-Q.

Under the terms of our license agreements with the Chinese University of Hong Kong, we are also required to pay a low single-digit royalty on net sales of our products that use the technology we license from Chinese University of Hong Kong, subject to minimum annual guarantees. Our payment obligations with respect to each license for each product containing any licensed technology extends until the expiration or termination of such license, which shall be the later of a low double-digit number of years from our payment of the license issue fee or expiration of the last-to-expire licensed patent. Although certain provisions in our agreement with Illumina allow us to reduce our royalty to Illumina by up to a low single-digit percentage due to third party royalties actually paid, such as our royalty payment to Chinese University of Hong Kong, our obligation to pay this royalty on our net sales could reduce our gross margins and increase our expenses. See the section titled "Business—Intellectual Property—License Agreements with the Chinese University of Hong Kong" in the Information Statement and "Management's Discussion and Analysis of Financial Condition and Results of Operations--Minimum Royalties" in this Quarterly Report on Form 10-Q.

We will need to generate significant additional revenue to achieve and maintain profitability and will need to obtain additional funding to continue operations. Even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. We may never be able to generate sufficient revenue to achieve or maintain profitability and our recent and historical growth should not be considered indicative of our future performance. If we do not achieve or maintain profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives, either of which could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

A substantial majority of our revenue is generated from sales of Galleri and we are highly dependent on it for our success.

We began selling Galleri in the United States in mid-2021. Sales of Galleri accounted for a substantial majority of our revenue to date and we expect that such sales will continue to account for the substantial majority of our revenue for the foreseeable future. Our ability to execute our growth strategy and become profitable will therefore depend upon the adoption of Galleri as a widely used MCED test. Continued adoption and use of Galleri will depend on several factors discussed in these risk factors, including, among others, the prices we charge for our tests, the scope of coverage and amount of reimbursement available from third-party payors, including managed care organizations, private health insurers, and government healthcare programs, such as Medicare and Medicaid in the United States and similar programs in other countries, the availability of clinical and real-world data that supports the value and impact of our tests, and the extent to which our tests receive FDA authorization or a USPSTF grade A or B recommendation. We cannot assure you that Galleri will continue to maintain or gain market acceptance, and any failure to do so would harm our business and results of operations.

One of the key elements of our strategy is to expand access to our tests by pursuing coverage and reimbursement from third-party payors, both private and government payors. If our products do not receive adequate coverage and reimbursement, if at all, from third-party payors, our ability to expand access to our products beyond our existing sales channels will be limited and our overall commercial success will be limited.

We have established private reimbursement for Galleri from a number of third-party payors in the United States, but do not currently have broader coverage and reimbursement by government healthcare programs, such as Medicare. A key element of our strategy is to expand access to our tests by pursuing broad coverage and reimbursement by third-party payors, including government payors. Coverage and reimbursement by third-party payors, including managed care organizations, private health insurers, and government healthcare programs, such as Medicare and Medicaid in the United States and similar programs in other countries, for early detection tests we offer or are planning to offer, can be limited and uncertain. Healthcare providers may not order our products unless third-party payors cover and provide adequate reimbursement rates for a substantial portion of the price of our products. If we are not able to obtain adequate coverage and an acceptable level of reimbursement for our products from third-party payors, there could be a greater co-insurance or co-payment obligation for any individual for whom a test is ordered. The individual may be forced to pay the entire cost of a test out-of-pocket, which could dissuade physicians from ordering our products and, if ordered, could result in delay in or decreased likelihood of our collection of payment. We believe our revenue and revenue growth will depend on our success in achieving coverage and adequate reimbursement for our products from third-party payors.

Medicare is the single largest U.S. payor and a particularly important payor for many cancer-related laboratory services given the demographics of the Medicare population. Traditional fee-for-service Medicare generally does not cover screening tests, which are considered preventive services, that are performed in the absence of signs or symptoms of illness or injury, unless there is a statutory provision that explicitly authorizes coverage of the test. The Medicare Improvements for Patients and Providers Act of 2008 authorizes the CMS to cover additional preventive services that are not expressly covered by the statute if the service is (a) reasonable and necessary for the prevention or early detection of an illness or disability, (b) recommended with a grade of A or B by the USPSTF, and (c) appropriate for Medicare beneficiaries under Part A or Part B. CMS establishes coverage through a national coverage determination ("NCD") process, which generally requires, or is significantly more likely following, FDA approval. In its discretion, the USPSTF generally waits for FDA authorization before it considers undertaking reviews of novel technology. Galleri and certain other future products could be considered screening tests under Medicare and, accordingly, are and may not be eligible for traditional Medicare fee-for-service coverage and reimbursement unless we pursue substantial additional measures, including, but not limited to, securing FDA authorization of Galleri and other future products, followed by obtaining a grade A or B recommendation from the USPSTF, in an effort to enable CMS to issue an NCD. Medicare coverage can also be changed by statute, and another possible pathway for Medicare reimbursement would be to amend the Medicare statute to cover MCED testing. This process would generally require new legislation to expressly authorize CMS to cover FDA-approved early cancer screening and detection tests. We are working with stakeholders to advance and shape the public reimbursement landscape to reflect that additional scope of coverage. However, even if we are successful in obtaining an NCD on the basis of the new reimbursement landscape envisioned by this legislation, we intend to seek a USPSTF grade for Galleri. If we receive an NCD for Galleri or our other products and subsequently receive a USPSTF grade lower than A or B, it is possible that CMS would rescind the NCD. Further, such legislation may never be enacted, may be significantly delayed in being enacted, or may be enacted in a different form, including narrower or less favorable terms, any of which could have a material adverse effect on our business, financial condition, results of operations, and growth prospects. Any of these efforts, individually and together, require significant investments and resources, and may ultimately be unsuccessful or may take several years, if at all, to achieve.

If the USPSTF does not recommend any of our products with a grade of A or B, CMS declines to initiate an NCD, CMS decides to rescind a prior NCD, or the decision regarding an NCD is negative, the impacted product would not be eligible for fee-for-service Medicare coverage in the absence of a new statutory provision providing for coverage. Even if the USPSTF were to recommend Galleri or other products we are developing, the USPSTF review process and the ensuing NCD process by CMS could take several years to complete, and coverage for our products would be delayed while review is ongoing. The Affordable Care Act ("ACA") mandates that many private insurance plans cover, among other preventive health services, evidence-based items or services recommended by USPSTF with a grade of A or B, with certain prohibitions on cost-sharing requirements. Accordingly, if USPSTF does not recommend use of Galleri or other products we are developing or requires a substantial amount of time to review such products, our business and results of our operations would be harmed. Coverage and adequate reimbursement under Medicare are also uncertain as discussed further in "Business— Government Regulations—Coverage and Reimbursement" in the Information Statement. DAC is intended to be a diagnostic aid, and we believe it could be eligible, with current or additional clinical study data, for Medicare coverage and reimbursement in the next several years, although there can be no assurances that we will be successful in obtaining such coverage, if and when DAC is launched.

If eligible for reimbursement, laboratory tests including ours are generally classified for reimbursement purposes under CMS's Healthcare Common Procedure Coding System ("HCPCS") and the American Medical Association's ("AMA") Current Procedural Terminology ("CPT") coding systems. We and payors must use those coding systems to bill and pay for our diagnostic tests, respectively. These HCPCS and CPT codes are associated with the particular product or service that is provided to the individual. Accordingly, without a HCPCS or CPT code applicable to our products, the submission of claims would be a significant challenge. Once CMS creates an HCPCS code or the AMA establishes a CPT code, CMS establishes payment rates and coverage rules under traditional Medicare, and private payors establish rates and coverage rules independently. Under Medicare, payment for laboratory tests is generally made under the Clinical Laboratory Fee Schedule ("CLFS") with payment amounts assigned to specific HCPCS and CPT codes. In addition, effective January 1, 2018, a new Medicare payment methodology went into effect for clinical laboratory tests, under which laboratory-reported private payor rates are used to establish Medicare payment rates for tests reimbursed via the Medicare Clinical Laboratory Fee Schedule. The new methodology implements Section 216 of the Protecting Access to Medicare Act of 2014

("PAMA") and requires laboratories that meet certain requirements related to volume and type of Medicare revenues to report to CMS their private payor payment rates for each test they perform, the volume of tests paid at each rate, and the HCPCS code associated with the test. CMS uses the reported information to set the payment rate for each test at the weighted median private payor rate. Most affected tests are revalued every three years. A series of legislative amendments delayed the next PAMA reporting period to January 1, 2024 through March 31, 2024, which will cover the original data collection period of January 1, 2019 through June 30, 2019. New CLFS rates for clinical diagnostic laboratory tests ("CDLTs") will be established based on that data beginning in 2025, subject to phase-in limits. As a result, Medicare payment rates determined by data reported in 2017 will continue through December 31, 2024. In addition, under PAMA, as amended, the payment reduction cap will be 15% per test per year in each of the years 2024 through 2026. PAMA also authorized the adoption of new, temporary billing codes and unique test identifiers for FDA-cleared or approved tests, as well as advanced diagnostic laboratory tests ("ADLTs"). The AMA's CPT Editorial Panel approved a proposal to create a new section of billing codes called Proprietary Laboratory Analyses ("PLA") codes, to facilitate implementation of this section of PAMA. The full impact of the PAMA rate-setting methodology and its applicability to our products remains uncertain at this time.

Coverage and reimbursement by a third-party payor may depend on a number of factors, including a payor's determination that a product is appropriate, medically necessary, and cost-effective. Each payor will make its own decision as to whether to establish a policy or enter into a contract to cover our products and the amount it will reimburse for such products. Any determination by a payor to cover and the amount for which it will reimburse our products would likely be made on an indication-by-indication basis. For example, we may face additional scrutiny in obtaining coverage and reimbursement from third-party payors given the additional costs of further diagnostic workup in the event the test is deployed at scale, as a result of the false positive rate. As a result, obtaining approvals from third-party payors to cover our products and establishing adequate coding recognition and reimbursement levels is an unpredictable, challenging, time-consuming, and costly process and we may never be successful. If third-party payors do not provide adequate coverage and reimbursement for our products, our ability to succeed commercially will be limited.

Even if we establish relationships with payors to provide our products at negotiated rates, such agreements would not obligate any healthcare providers to order our products or guarantee that we would receive reimbursement for our products from these or any other payors at adequate levels. Thus, these payor relationships may not result in acceptable levels of coverage and reimbursement for our products, including Galleri and any current or future products, including future versions of Galleri or DAC. We believe it may take several years to achieve coverage and adequate reimbursement with a majority of third-party payors, including with those payors offering negotiated rates. In addition, we cannot predict whether, under what circumstances, or at what payment levels payors will cover and reimburse our products. Although we do not expect Galleri to have Medicare or other broad third-party coverage or reimbursement in the near term, we will continue to market our product to health systems, large self-insured employers, life insurance providers, physician directed channels, health plans, and additional at-risk groups such as first responders, including firefighters. If we fail to establish and maintain coverage and reimbursement for our products, our ability to expand access to our products, generate increased revenue, and grow our test volume and customer base will be limited and our overall commercial success and growth prospects will be limited.

We may be unable to develop and commercialize new products, including enhanced versions of current products.

Though we are reducing investment in the development of products beyond Galleri as part of the Restructuring Plan, including DAC and our precision oncology portfolio, we are continuing research and development of our proprietary methylation platform and our large clinical and genomic datasets to develop enhanced versions of Galleri. In the future, we may determine to invest further in new product development. The commercialization of any new products, including enhanced versions of current products, will require the completion of certain clinical development activities, regulatory activities, and the expenditure of additional cash resources. We cannot assure you that we can successfully complete these activities for any such products. For example, to the extent an enhanced version of an existing product is developed, we intend to undertake one or more bridging studies to measure and evaluate concordance, performance and safety of the subsequent, enhanced version of our product versus the existing product, 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 of any such subsequent, enhanced version of our products.

We cannot ensure that we will generate sufficient revenue from products that we successfully commercialize or otherwise mitigate the risks associated with our business to raise enough capital to develop and commercialize new products. In addition, once our development efforts for a product are completed, commercialization efforts, including allocation of resources necessary to comply with applicable laws and regulations, will require significant expenditures. Any failure to develop, obtain necessary marketing authorizations for, or commercialize new products, and meet and continue compliance with applicable laws and regulations, could have a material adverse effect on our ability to implement our strategy and grow our business.

If similar third-party products are developed and do not perform as intended or cause harm or injury to patients, the market for our products could be impaired.

Many companies are attempting to develop competing cancer detection tests and technologies focused on improving cancer care with early cancer detection tests and post-diagnostic products. If any of these tests do not perform to expectations or cause harm or injury to patients, it may result in lower clinical and consumer confidence in early cancer detection and precision medicine in general, which could potentially adversely affect confidence in our products. As a result, the failure of any competing products to perform as expected could significantly adversely affect public perception about cancer detection tests generally, including our products, and could significantly impair our reputation and operating results.

If we fail to obtain additional financing, we may be unable to expand our commercialization efforts with respect to Galleri and any other products that we successfully develop and commercialize, or to develop additional products.

Our operations have required substantial amounts of cash since inception. To date, we have financed our operations primarily through the sale of equity securities and capital contributions from Illumina and, to a lesser extent, revenue derived from Galleri sales and precision oncology portfolio revenue. Our product development and clinical study activities are expensive, and we expect to continue to spend substantial amounts as we expand our commercialization efforts with respect to Galleri, including pursuing broader coverage and reimbursement, continue to enhance our core technology platform, broaden the applications of our technology platform, and develop new products in the future. In addition, obtaining any necessary or desirable regulatory approvals, clearances, or certifications, as well as coverage and reimbursement, for our products will require substantial additional funding.

As of June 30, 2024, we had $958.8 million in cash and cash equivalents. We believe that our existing cash and cash equivalents, together with the funding obligations of Illumina required by the EC Divestment Decision (as defined in the section titled “The Spin-Off—Background” in the Information Statement), will be sufficient to fund our projected operations for at least the next 12 months. Our estimate as to how long we expect our existing cash, cash equivalents, and funding obligations from Illumina to be available to fund our operations is based on assumptions that may prove to be inaccurate, and we could use our available capital resources sooner than we currently expect. In addition, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may need to raise additional funds sooner than we anticipate.

We will require additional capital to expand the commercialization of Galleri and our precision oncology portfolio, and for the development and commercialization of future products. Our future capital requirements depend on many additional factors, including:

- the cost of development and commercialization activities for our products, including Galleri and our precision oncology portfolio and our future products, including marketing, sales, and distribution costs;

- the cost related to continued scaling operations to support demand for our products, including the cost of operating our laboratory in Durham, North Carolina;

- the timing of, and the costs involved in, obtaining any required or desired regulatory approvals, clearances, or certifications for our products;
- the timing, scope, progress, results, and costs of developing additional products and conducting clinical studies;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending, and enforcing patent and other intellectual property rights and claims, including litigation costs and the outcome of such litigation;
- the timing and amount of sales of our products and collection of related receivables;
- the extent to which our products are eligible for coverage and reimbursement from third-party payors;
- the emergence of new technologies, products, or services and other adverse market developments; and
- other potential adverse developments.

Additional capital may not be available when we need it, on terms acceptable to us or at all. We have no committed source of additional capital, other than the funds to be committed by Illumina as described above. Furthermore, any additional capital raised through the sale of equity or equity-linked securities will dilute stockholders' ownership interests in us, may require stockholder approval, may have an adverse effect on the price of our common stock, and holders of these securities may have rights, preferences or privileges senior to those of our then-existing stockholders. Debt financing, if available, may include restrictive covenants that could limit how we conduct our business and limit our ability to further raise capital, and if available, may be available only on undesirable terms, particularly as we would borrow as an independent company and not a subsidiary of Illumina. If adequate capital is not available to us on a timely basis, we may be required to significantly delay, scale back, or discontinue the commercialization of our products or research and development programs, or be unable to continue or expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition, results of operations, and growth prospects and cause the price of our common stock to decline.

As a result of the Spin-Off, we are subject to a number of limitations and risks that may impact our ability to obtain additional financing. For example, certain restrictions under the Tax Matters Agreement limit our ability to obtain additional financing, including offerings of common stock, or otherwise require that we undertake certain procedures with Illumina. In addition, certain terms of the Spin-Off may impact our ability to successfully obtain financing on favorable terms or at all. For example, in connection with the Spin-Off, Illumina provided us with disposal funding in the amount of $932.3 million in accordance of the Separation and Distribution Agreement, subject to a clawback feature in the event that the Company (i) consummates 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 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, in each case prior to the 15-month anniversary of the Distribution Date. If the Company consummates a transaction described in the foregoing clause (i) prior to the 15-month anniversary of the Distribution Date, the Company must return to Illumina a cash amount calculated by reference to the number of months which have elapsed since June 24, 2024 at the time of the public announcement of the event giving rise to such transaction. If the Company consummates a transaction described in the foregoing clause (ii) prior to the 15-month anniversary of the Distribution Date, the Company must return to Illumina a cash amount equal to the payments made by the Company in connection with such transaction up to an aggregate maximum amount equal to the amount of the initial disposal funding subject to a clawback feature in the event of a change in control, or the Company (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, prior to September 24, 2025. If these clawback features are triggered, we must return to Illumina the aggregate amount of payments to equity holders as a result of or in connection with such a transaction. Additionally, in connection with certain change of control transactions prior to September 24, 2025, we must return to Illumina a

cash amount calculated by reference to the number of months which have elapsed since June 24, 2024 at the time of the public announcement of the event giving rise to the change of control. These restrictions under these agreements may impact our ability to obtain additional financing when needed, if at all, and, if we are required to repay any disposal funds to Illumina under the clawback provision, our cash balance will be reduced and we may have greater need for additional financing.

If our products result in direct or indirect participant or patient harm or injury, we could be subject to significant reputational and liability risks.

Our success will depend on the market's confidence that our products, including Galleri and, if successfully developed and launched, enhanced versions of Galleri, and our precision oncology portfolio can provide reliable, high-quality results. We believe that participants, patients, customers, physicians, and regulators are likely to be sensitive to errors in the use of our products or failure of our products to perform as described, and there can be no guarantee that our products will meet expectations. Galleri is intended to be used to detect a cancer signal in individuals, but its results are not intended to be diagnostic. If a cancer signal is detected, the product is used to localize the origin of the cancer signal; a "cancer signal detected" test result must be followed up by appropriate diagnostic workup. Because the product cannot detect all cancer signals, and may not detect signals for all cancer types, a negative test does not rule out the presence of cancer. Additionally, an individual undergoing unnecessary diagnostic tests on the basis of a false positive result or an erroneous cancer signal origin result could expose us to significant liability and reputational risks. Similarly, an individual who receives a cancer diagnosis shortly following a "no cancer signal detected" test result may create negative publicity about our product, which would discourage adoption. Performance failures could establish a negative perception of our products among physicians, patients, customers, and regulators, jeopardize our ability to successfully commercialize our products, impair our ability to obtain marketing authorizations or secure favorable coverage and reimbursement, or otherwise result in reputational harm or enforcement action or inquiry by a regulatory body. These risks may be more pronounced for certain applications in our precision oncology portfolio, such as companion diagnostic development, as our products would be directly involved with the choice to use certain treatments in a particular case. In addition, we may be subject to legal claims arising from any errors in the use, manufacture, design, labeling, marketing, or performance of our products, including false positive or false negative results. If our products result in direct or indirect participant or patient harm or injury, we could be subject to significant reputational and liability risks, and our reputation, business, financial condition, results of operations, and growth prospects could be materially adversely affected.

We rely on Illumina as a sole supplier for our next-generation sequencers and associated reagents, Madison Industries ("Madison") (who acquired our blood collection tube manufacturer, Streck, Inc., in 2023) as a sole supplier of our blood collection tubes, and Twist Bioscience Corporation ("Twist") as a sole supplier of our DNA panels. Additionally, we rely on a limited number of suppliers for some of our laboratory instruments and reagents, and we may not be able to immediately find replacements if necessary.

We rely on Illumina as the sole supplier of the next-generation sequencers and associated Illumina-supplied reagents we use to perform our genomic tests and as the sole provider of servicing, including maintenance and repair services for these sequencers. Additionally, as a part of the Spin-Off, Illumina distributed 85.5% of its holdings of the Company to its shareholders but remained a significant shareholder through its retention of 14.5% of our outstanding shares immediately following the Spin-Off and we are party to a number of agreements with Illumina entered into in connection with the Spin-Off. Any disruption or interruption in Illumina's operations or breach of our supply-related agreements would impact our supply chain and laboratory operations. We also rely on Madison as the sole supplier of our blood collection tubes and Twist as the sole supplier of our DNA panels. We rely on other vendors as sole suppliers, although we believe we are less reliant on their offerings than the vendors named above. A disruption or interruption in supply from these vendors could delay our ability to continue laboratory operations, and develop and commercialize any other future products. Any such disruption or interruption in supply, quality, or servicing would adversely affect our commercial partnerships, our ability to continue supporting clinical studies and conduct new studies, our reputation, and could impact our timing for regulatory authorization and coverage and reimbursement.

Further, we are in the process of submitting a PMA for Galleri to the FDA. We may similarly seek FDA authorization for future products. For products or components supplied to us by Illumina, we have not negotiated

the use of all of their products in any product we intend to submit for an FDA marketing authorization. We are cooperating with Madison to obtain FDA clearance or approval for their blood collection tubes for use with our products. In some cases, use of these third-party products in any FDA-cleared or approved product we may seek to commercialize will be conditioned on these suppliers having obtained FDA clearance or approval for their products for the uses of those third-party products as intended with ours. Before we pursue approval for our products that incorporate or use materials supplied to us by these suppliers, we will need to negotiate and execute agreements with these parties and in some cases may need to ensure these products have obtained the requisite clearances or approvals for the intended uses with our products. Any failures or delays in negotiating agreements with our suppliers on reasonable terms, or their inability to obtain any required clearances or approvals, may increase our costs or delay or prevent us from obtaining approval of, and thus successfully commercializing, our products.

Moreover, products supplied to us for use in our LDT products may be currently available to us as RUO products, which means, among other things, that the third-party supplier intends for the products not to be used for clinical use and that the products must be labeled "For Research Use Only. Not for use in diagnostic procedures." If the FDA were to take enforcement action against us or our suppliers for our use of RUO products in connection with our products and future products that we intend to use for clinical purposes, including our launch of LDTs, such action could require us to seek alternative suppliers and thus materially and adversely affect our ability to provide such products to our customers and could significantly increase our costs of conducting business. Products for FDA-approved or cleared *in vitro* diagnostic use generally have significantly higher costs than LDT uses, which, in turn, are more costly than products intended for RUO.

Our current suppliers, including Illumina, Madison, or Twist, may also discontinue or substantially change the specification of products that we utilize or intend to utilize in our products and future products. While we believe other suppliers exist that are capable of supplying and servicing the equipment and materials necessary for our products and laboratory operations, including certain instruments, components, consumables, and reagents, qualifying, contracting with, validating, and transitioning to any such new suppliers could temporarily result in interruptions in or otherwise affect our ability to manufacture and commercialize products or the performance specifications of our laboratory operations and sample processing or, if we receive FDA authorization for our current or future products, could require that we revalidate such products or submit such changes for regulatory authorization by the FDA. For example, we have used, currently use and expect to continue to use Madison blood collection tubes for all of our prior, ongoing, and planned clinical studies that support product development and validation. It may be difficult to engage with another supplier who can provide the same products and with the same quality and availability as Madison, which could significantly delay our clinical studies and ability to process tests, and materially adversely impact our business. In addition, we purchase certain products on a purchase order basis and cannot guarantee a consistent source of supply. The use of equipment or materials provided by a replacement supplier could require us to alter our laboratory operations and sample collection and processing and related procedures. In the case of attempting to obtain an alternative supplier for Illumina, Madison, or Twist, replacement instruments and associated reagents, tubes, and panels that meet our quality control and performance requirements may not be immediately available. If we encounter delays or difficulties in securing, reconfiguring or revalidating the equipment, reagents, and other materials that we require for our tests, laboratory operations and sample collection and processing, we would likely face significant delays in ongoing clinical studies or conducting new studies, commercializing our products and our reputation, business, financial condition, results of operations, and growth prospects would be adversely affected.

If our facilities become inoperable, our ability to provide our products will be significantly impaired and our business will be harmed.

We currently perform all research and development, and conduct commercial testing work, for our products, including Galleri, in our laboratories located in Menlo Park, California and Durham, North Carolina. We also have offices in Washington D.C. and the United Kingdom, which is important to our international operations. The facilities may be harmed, rendered inoperable by physical damage or otherwise become partially or completely unusable due to fire, floods, earthquakes, power loss, telecommunications failures, break-ins, accidents, pandemics, and similar events, which may render it difficult or impossible for us to provide our products for some period of time. Our laboratories and the equipment we use to perform our research and development or commercialization work could be unavailable or costly and time-consuming to repair or replace. It would be difficult, time-consuming, and expensive to rebuild our facilities, particularly in light of the licensure, permits, and

accreditation requirements for clinical laboratories like ours. For example, the development and commercial test processing activities for Galleri, and future potential commercial launch of future products, are dependent on the operation of our Durham, North Carolina laboratory, which received Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certification to perform high-complexity training, and College of American Pathologists ("CAP") accreditation. A disruption at this facility could materially adversely impact our business and operations. Although we carry insurance for damage to our properties and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

Our operations and business are materially dependent on various third parties, including information technology, sample collection, processing, transfer facilities, and other patient-facing service providers, a of which could experience disruption, failure, or interruption.

We depend on third parties for information technology, telecommunication systems, the collection, processing, transport, and storage of sample, and other patient-facing services. Any disruption in these services or operations could materially adversely harm our business and operations.

We depend on information technology and telecommunications systems, including those provided by third parties and their vendors, for significant elements of our operations, such as our laboratory information management systems, including test validation, specimen tracking, and quality control; personal information collection, storage, maintenance, and transmission; our report production systems; and our billing and reimbursement, research and development, scientific, and medical data analysis; and general administrative activities. In connection with becoming a public company, we expect to expand and strengthen a number of enterprise software systems that affect a broad range of business processes and functions, including, for example, systems handling human resources, financial controls and reporting, customer relationship management, regulatory compliance, security controls, and other infrastructure operations. These expansions may prove more difficult than we expect and could cause disruptions in our operations or additional expense. Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts, and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive events. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business, reputation, results of operation, financial condition, and growth prospects.

Our business also depends on our ability to reliably sequence blood samples that we collect, which are transported to our Menlo Park or Durham facility for analysis. Within the United Kingdom, our samples are initially collected, processed, frozen, and stored at several off-site facilities. Any disruption to the operations of these facilities could compromise the integrity of our samples and impede our ability to access and accurately sequence the data. For example, Event Marketing Solutions Ltd ("EMS") is responsible for collection of our NHS-Galleri Trial samples and ships those samples to UK Biocentre Ltd ("UKBC") for, among other things, receipt, storage, and management. If any natural or man-made disaster, accident, or break-in were to affect the UKBC facility or EMS' collection or shipping operations, our NHS-Galleri samples could be lost, destroyed, compromised, or otherwise adversely affected. In addition, we maintain samples from our clinical studies for several years. It is possible that the long-term stability of these samples may not be maintained with the passage of time, which could negatively impact our ability to use such samples to validate our products. Further, interruptions in collection, processing, freezing, or transportation of samples performed by patient-facing service providers and other third parties, whether due to labor disruptions, bad weather, natural disaster, terrorist acts, threats, or for other reasons could adversely affect the samples and our ability to process the samples in a timely manner, which could negatively affect our ongoing research studies and harm our business. This is particularly true for transport of our samples, which generally must be delivered to our facilities for processing within seven days of blood draw.

We also depend on third-party telemedicine providers for certain referrals and follow up services with patients. Third-party phlebotomists also provide patient-facing services in collecting samples and shipping samples to our facilities for processing. If these telemedicine or phlebotomist vendors fail to perform services, or if services are performed poorly or perceived to be performed poorly, we may suffer reputational harm, need to replace a provider, limit our ability to reach patients, result in loss of samples, failure to receive samples in a timely manner, insufficient quality of samples, or other harms.

Finally, the facilities of any of our third-party collaborators, consultants, contractors, vendors, suppliers, and service providers could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, tornadoes, hurricanes, fires, extreme weather conditions, medical epidemics, pandemics, and other natural or man-made disasters or business interruptions. In addition, they may be affected by government shutdowns, changes to applicable laws, regulations, and policies, or funding shortages. The occurrence of any of these business disruptions could seriously harm their ability to complete their contracted services to us, which may adversely impact our operations and financial condition.

Failure of, or defects in, our machine learning algorithms, artificial intelligence, and cloud-based computing infrastructure, including interruptions of service through our key provider, Amazon Web Services, or increased regulation in the machine learning or artificial intelligence space, could impair our ability to process our data, develop products, or provide test results, and harm our business and results of operations.

We depend on technology systems for significant elements of our business operations. These technology systems support a variety of functions, including manufacturing operations, laboratory operations, data analysis, quality control, partner service and support, billing, research and development activities, and scientific and general administrative activities. The design, development, maintenance, and operation of our technology over time is expensive and complex, and may involve unforeseen difficulties including performance problems, undetected defects, or errors. Overcoming technical obstacles and correcting defects or errors could prove to be impossible or impracticable, and the costs incurred may be substantial and adversely affect our results of operations. Additionally, regulation in the machine learning and artificial intelligence space is constantly evolving and limitations placed on the use of data, including personal information, health data, or genetic/ genomic data in such systems may make it difficult for us to continue using our machine learning algorithms. If our technology does not function reliably, fails to meet expectations in terms of performance, or cannot be fully utilized due to increasing regulation, including regulation by the FDA or comparable regulatory authorities of artificial intelligence or medical device software, we may be unable to provide, or our customers may stop using, our products.We expect that increased investment will be required in the future to continuously improve our use of AI technologies. As with many technological innovations, there are significant risks involved in developing, maintaining and deploying these technologies and there can be no assurance that the usage of or our investments in such technologies will always enhance our products or services or be beneficial to our business, including our efficiency or profitability.

In Europe, on July 12, 2024, the EU Artificial Intelligence Act (the “EU AI Act”) was published in the EU Official Journal, and establishes a comprehensive, risk-based governance framework for AI in the EU market. The EU AI Act enters into force on August 2, 2024, and the majority of the substantive requirements will apply from August 2, 2026. The EU AI Act applies to companies that develop, use and/or provide AI in the EU and includes requirements around transparency, conformity assessments and monitoring, risk assessments, human oversight, security, accuracy, general purpose AI and foundation models, and imposes significant fines for breaches which may amount up to 7% of an undertaking’s worldwide annual turnover. The EU AI Act and its future interpretation and application may affect our use of AI technologies and our ability to provide, improve or commercialize our services, require additional compliance measures and changes to our operations and processes, result in increased compliance costs and potential increases in civil claims against us, and could adversely affect our business, operations and financial condition. It is also possible that further laws and regulations will be adopted in the United States and in other non-U.S. jurisdictions, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit our ability to use AI technologies for our business, or require us to change the way we use AI technologies. For example, Colorado passed the Colorado Artificial Intelligence Act and Utah passed the Utah Artificial Intelligence Policy Act, both of which will have implications on the ways that businesses can use AI technologies.

We currently host all of our data on, and conduct a significant portion of our data analysis through, Amazon Web Services (“AWS”) cloud-based hosting facilities. In addition, certain functions of our laboratory operations and business functions use or leverage AWS. Any technical problems or outages that may arise in connection with AWS, including its data center hosting facilities, could result in operational disruption, loss of data or delayed or ineffective data processing. A variety of factors, including infrastructure changes, human or software errors, viruses, malware, security attacks, fraud, spikes in customer usage, or denial of service issues could cause interruptions in our service. Such service interruptions may reduce or inhibit our ability to provide our products, process tests, operate our laboratory, delay our clinical studies, and damage our relationships with our customers.

We could also be exposed to potential lawsuits, liability claims, reputational impact, or regulatory actions, for example if AWS experienced a data privacy breach. If we were required to transfer to another service provider, including the transfer of data to an alternative hosting provider, the transfer and acclimation to the new provider could result in significant business delays and require additional resources.

If we are unable to scale our operations successfully to support demand for our products, our business could suffer.

As and to the extent test volumes grow, we may need to ramp up laboratory capacity, including increasing the processing of Galleri in our Durham, North Carolina facility. This could include the eventual transition of operations from 18 hours of operation seven days a week to 24 hours of operation seven days a week. While we have heavily invested in our scalability, including by expanding our Durham facility laboratory capacity, further buildout of our Durham facility may be needed, as well as further new infrastructure, data processing capabilities, customer service, billing and systems processes, and expanding our internal quality assurance program and information technology to support testing on a larger scale. We will also need additional equipment, and certified and licensed laboratory personnel to process higher volumes of tests. Our ability to hire personnel to scale would be more challenging if 24/7 operations are implemented and we will require night shift work. We may face difficulties increasing the scale of our operations, including implementing changes in infrastructure or programs or acquiring additional equipment or personnel, as well as any additional regulatory, licensing, permitting, or certificate obligations that need to be met at the local, state, or federal level. As we refine our products, develop additional products, and enhance existing products, we may need to bring new equipment on-line, comply with additional applicable laws and regulations, implement new systems, technology, controls and procedures, and hire personnel with different qualifications, licenses, or certifications.

The value of Galleri, our precision oncology portfolio, and any future products will depend, in part, on our ability to perform tests and return results to providers on a timely basis and at an appropriate quality standard, and on our reputation for such timeliness and quality. Failure to implement necessary procedures, to transition to new equipment or processes, or to hire the appropriate, qualified personnel could result in higher costs of processing, longer turnaround times or an inability to meet market demand. There can be no assurance that we will be able to perform tests on a timely basis at a level consistent with demand, that we will be able to maintain the quality of our test results as we scale our commercial operations, or that we will be successful in responding to the growing complexity of our laboratory operations, including the related data analysis requirements.

We may also experience difficulties scaling in international markets in which we are required under law or contract, or decide to, construct and operate a laboratory in that market. For example, we may be required or decide to build and operate a laboratory in the United Kingdom if and when we have a commercial presence in that country. This may be challenging due to significant startup costs, difficulty recruiting, and lack of familiarity with the local jurisdiction, among other reasons. If we are unable to build and operate laboratories internationally, our ability to expand internationally may be limited, and have a negative impact on our business and results of operations.

In addition, our growth may place a significant strain on our management, operating and financial systems, research and development, and our sales, marketing, and administrative resources. As a result of our growth, our operating costs may escalate even faster than planned, and some of our internal systems may need to be enhanced or replaced. If we cannot effectively manage our expanding operations and our costs, we may not be able to grow successfully or we may grow at a slower pace, and our business could be adversely affected.

Our business and results of operations will suffer if we fail to perform effectively.

There are market participants in the cancer detection space both in the United States and abroad, including Adela, Inc., DELFI Diagnostics, Inc., Exact Sciences Corporation, Exai Bio, Inc., Freenome Inc., Guardant Health, Inc., and Harbinger Health within the United States and AnchorDx, Anpac Bio-Medical Science Co., Ltd., Burning Rock Biotech Limited, Datar Cancer Genetics, Elypta AB, Gene Solutions JSC, Singlera Genomics, Inc. and Seekin, Inc. outside of the United States, among others, that have stated that they are attempting to develop tests designed to detect certain types of cancer, including some that will use cell free DNA (“cfDNA”) analyses. The precision oncology market includes companies such as Roche/Foundation Medicine, Inc., Natera, Inc., Guardant, Inc., Tempus AI, Inc., Invitae Corp., NeoGenomics Laboratories, Personalis, Inc., Twist Bioscience Corp. and

Adaptive Biotechnologies Corp., among others. These companies have or may have greater financial, technical, and other resources, such as larger research and development staff, well-established marketing and sales forces, existing integrated systems connected to health practices' electronic health or medical records to facilitate product ordering and results delivery, or may operate in jurisdictions where lower standards of evidence are required to bring products to market. These companies may succeed in developing, acquiring, or licensing, on an exclusive basis or otherwise, tests or services that are more effective, have higher performance, or are less costly than our products. In addition, established medical technology, biotechnology, or pharmaceutical companies may invest to accelerate discovery and development of tests that could make our products less successful than we anticipate. For example, large and long-tenured healthcare, life sciences, or technology companies may initiate research and development of MCED and bring significant resources and disruption to the cancer detection space.

Our ability to perform successfully will depend largely on our ability to:

- successfully expand commercialization efforts for our products;
- demonstrate compelling advantages in the performance and convenience of our products, including on a cost efficient basis;
- achieve market acceptance of our products by healthcare providers and patients, including through our reputation;
- achieve adequate coverage and reimbursement by third-party payors for our products;
- differentiate our product from future tests and products of and third parties;
- attract qualified scientific, data science, clinical development, product development, and commercial personnel;
- obtain, maintain, defend, and enforce patent and other proprietary protection as necessary for our products;
- obtain and maintain any necessary or desirable marketing authorizations or certifications from regulators in the United States and other jurisdictions, and notified bodies;
- integrate product ordering and results delivery into practices' electronic health or medical records systems;
- successfully collaborate with institutions in the discovery, development, and commercialization of our products; and
- successfully expand our operations and implement a successful sales and marketing strategy to support commercialization.

We may not be able to perform effectively if we are unable to accomplish one or more of these or similar objectives.

If we cannot maintain our current collaborations or partnerships and enter into new collaborations or partnerships in a timely manner and on acceptable terms, our efforts to develop and commercialize our products could be delayed or adversely affected.

We rely, and expect to continue to rely, on collaborative partners to help us develop our products and enhance our research and development efforts. For example, we have collaborated with pharmaceutical companies, research institutions, and academic centers. Additionally, our RUO offering has formed the basis of biopharmaceutical partnerships with several leading oncology companies. These partnerships leverage our RUO offering to test applications of biomarkers with the goal of optimizing the use of therapeutic interventions. Partnerships may also include development of customized applications to support clinical studies and companion

diagnostic development and commercialization. Our reliance on certain of these third parties reduces our control over our product development activities.

If any of our collaborators or partners were to breach or terminate their agreements with us or otherwise fail to conduct the contracted activities successfully and in a timely manner, the research and development activities of certain of our products could be delayed or terminated. Further, our collaborators or partners may fail to properly protect our intellectual property rights, may infringe the intellectual property rights of third parties, may misappropriate our trade secrets, or may use our proprietary information or others' in such a way as to expose us to litigation and potential liability. Disagreements or disputes with our collaborators or partners, including disagreements over proprietary rights, funding, or contract interpretation, might cause delays or termination of the research, development or commercialization of our products, might lead to additional responsibilities for us with respect to these products or activities or might result in litigation or arbitration, any of which would divert management attention and resources and be time-consuming and expensive. We may not be able to renew our current agreements with collaborators or partners or negotiate additional collaboration or partnership agreements on acceptable terms, if at all, and these collaborations and partnerships may not be successful. Any transition from a current collaborator to a new collaborator could be costly and result in significant product development delays.

From time to time, we expect to engage in discussions with potential development and/or commercial collaborators that may or may not lead to collaborations. However, we cannot guarantee that any discussions will result in development or commercial collaborations. Further, once news of discussions regarding possible collaborations are known in the general public, regardless of whether the news is accurate, failure to announce a collaboration agreement, or the entity's announcement of a collaboration with an entity other than us, could result in adverse speculation about us, our products, or our technology, resulting in harm to our reputation and our business. In addition, establishing collaborations is difficult, time-consuming and may require our significant financial investment. Potential collaborators may elect not to work with us based on their assessment of our financial, regulatory, or intellectual property position. Even if we establish new collaborations, they may not result in the successful development or commercialization of our products or technology.

We will need to grow the size and capabilities of our organization to support scale over time, and we may experience difficulties in managing this growth. If we are unable to maintain and expand sales and marketing capabilities in particular, we may not be successful in increasing sales of Galleri or commercializing new products over the long term.

As of June 30, 2024, we had approximately 1,370 employees, substantially all of whom were full- time Following implementation of the Restructuring Plan, our headcount will be reduced. As our development plans and strategies develop, and as we continue our operation as a public company, we may require a significant number of additional managerial, operational, financial, and other personnel. Moreover, despite our progress made in driving commercial implementation to date, we may not be able to market, sell, or distribute Galleri, or any future products that we may develop and commercialize, effectively enough to support our planned growth. Although the Restructuring Plan will result in a lower number of employees and a focus on Galleri-related activities, we may nevertheless need to continue to grow our operations to achieve our goals.

Factors that may inhibit our efforts to commercialize any of our products include:

- our inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel;
- the inability of sales personnel to generate an adequate numbers of customers, including healthcare systems and healthcare providers, to use our products;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of gross margin and profitability;
- our inability to effectively market to, collaborate with, and secure coverage and reimbursement from third-party payors;

- our failure to comply with applicable regulatory requirements governing the sale, marketing, reimbursement, and commercialization of our products; and

- unforeseen costs and expenses associated with maintaining a commercialization organization.

Future growth will impose significant added responsibilities on members of management besides those related to our efforts to commercialize, which will include: managing our internal development efforts effectively, including creating compliant programs and processes, such as a compliant laboratory and manufacturing quality system, and managing the regulatory requirements for our products, while complying with our contractual obligations to contractors and other third parties, including patient-facing service providers; expanding our operational, financial and management controls, reporting systems, and procedures; and managing the increasing complexity associated with a larger organization and expanded operations.

Our future financial performance and our ability to commercialize our products will depend, in part, on our ability to effectively manage any future growth. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to manage these growth activities. Our ability to successfully manage our expected growth is uncertain given the fact that we have been in operation as a company only since 2016, and have grown significantly in recent years.

If we are not able to effectively expand our organization by hiring new employees, we may not be able to successfully implement the tasks necessary to commercialize our products, which would have a negative impact on our business and results of operations.

We are highly dependent on our key personnel. If we are not successful in attracting, motivating, and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to perform in the biotechnology industry depends upon our ability to attract, motivate, and retain highly qualified personnel. We are highly dependent on our executive management team and our scientific, medical, technological, and engineering personnel. The loss of the services provided by any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements in a timely manner, could result in delays in commercialization of our products and harm our business. The risk of losing our executive officers, key employees and scientific and medical advisors may increase in connection with the Restructuring Plan.

We are headquartered in Menlo Park, California, a region in which many other healthcare companies, technology companies, and academic and research institutions are headquartered. In addition, we operate a laboratory facility in Durham, North Carolina, where there is also demand for skilled personnel, especially engineering and laboratory personnel. Competition for personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We expect that we may need to recruit talent from outside of these regions, and doing so may be costly and difficult.

To induce valuable employees to join or remain at our company, in addition to salary and periodic cash incentives, we have generally granted Cash-Based Equity Awards that vest over time. The value to employees of these grants that vest over time may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with certain key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. If we are unable to attract and incentivize highly qualified personnel on acceptable terms in a timely manner, or at all, our business and results of operations may suffer.

Our business is subject to economic, political, regulatory, and other risks associated with international operations.

Our business is subject to risks associated with conducting business internationally. For example, some of our suppliers and parties with whom we have collaborative relationships are located outside the United States,

including in the United Kingdom and Israel. 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;
- 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 geo-political actions, including war and terrorism, such as recent conflicts in the Middle East, pandemics, or natural disasters, 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 would impact our business or operations, but the uncertainty surrounding these matters could create difficulties in our efforts to partner with certain healthcare providers, suppliers, and insurance carriers. Moreover, future operational expansion into other geographies will subject us to additional political and regulatory regimes that will require us to invest 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, could 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.

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. We are also subject to a number of risks relating to regulations and legal compliance. For additional information, see "—Risks Relating to Regulation and Legal Compliance.".

Our information technology systems, or those used by our third-party collaborators or other contractors or consultants, may fail or suffer security breaches or cyberattacks.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store, and transmit large amounts of confidential information, including intellectual property, proprietary business information, personal, financial, and health information of patients and personal and financial information of our employees and contractors. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information.

Despite the implementation of security and back-up measures, our information technology systems as well as those of our third-party collaborators, consultants, contractors, suppliers, and service providers, may be vulnerable to attack, damage, or interruption from physical or electronic break-ins, computer viruses, malware, malicious code, ransomware, denial or degradation of service, hacking, phishing attacks, and other cyber-attacks, natural disasters, terrorism, war, telecommunication and electrical failures, instructions and attacks from sophisticated nation-state and nation-state-supported actors (including advanced persistent threat intrusions), or other disruptive incidents that could result in unauthorized access to, use or disclosure of, corruption of, or loss of sensitive, and/ or proprietary data, including personal information, protected health information, and other sensitive information, and could subject us to significant liabilities and regulatory and enforcement actions, and reputational damage. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased and evolved. If we or our third-party vendors were to experience a significant cybersecurity breach of our or their information technology systems or data, the costs associated with the investigation, remediation, and potential notification of the breach to counter-parties and data subjects could be material, in addition to any money required to resolve a ransomware attack. For example, laws in the European Economic Area ("EEA"), the United Kingdom, and all 50 U.S. states may require businesses to notify regulators within specific timeframes that a breach affecting personal information has occurred and/or to provide notice to individuals whose personal information has been impacted as a result of such breach. Complying with such numerous and complex regulations in the event of a data security breach would be expensive and difficult, and failure to comply could subject us to regulatory scrutiny and additional liability. In addition, our remediation efforts may not be successful. In connection with the Restructuring Plan, we may decide to reduce the number of employees or amount of resources dedicated to these matters. Even if we do allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could nevertheless suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss, or the loss of or damage to intellectual property or other proprietary information.

Companies with whom we engage in data sharing, including our service providers, are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident, or security breach to date, we may nonetheless be a target of such an attack, and if such an event were to occur and cause interruptions in our operations, or any of our third-party collaborators' operations, it could result in a material disruption of our development programs, reputation, and business operations whether due to a loss, corruption, or unauthorized disclosure of our trade secrets, personal

information, financial information, health information, or other proprietary or sensitive information, or other similar disruptions. For example, the loss of clinical study data from completed or ongoing clinical studies could result in delays in any regulatory clearance, approval, or certification efforts and significantly increase our costs to recover or reproduce the data, and subsequently commercialize our products. If we or our third-party collaborators, consultants, contractors, suppliers, or service providers were to suffer an attack or breach, for example, that resulted in the unauthorized access to or use or disclosure of personal or health information, we may have to notify physicians, patients, partners, collaborators, government authorities, and the media, and may be subject to investigations, civil penalties, administrative and enforcement actions, and litigation, any of which could harm our business and reputation. Likewise, we rely on our third-party research institution collaborators and other third parties to conduct clinical studies, and similar events relating to their computer systems could also have a material adverse effect on our business. It could also expose us to risks, including an inability to provide our services and fulfill contractual demands, and could cause management distraction and the obligation to devote significant financial and other resources to mitigate such problems, which would increase our future information security costs, including through organizational changes, deploying additional personnel, reinforcing administrative, physical, and technical safeguards, further training of employees, changing third-party vendor control practices, and engaging third-party subject matter experts and consultants and reduce the demand for our technology and services. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate or unauthorized access to or disclosure or use of confidential, proprietary, or other sensitive, personal, or health information, we could incur liability, we could be exposed to the risk of litigation, our market position could be harmed, we could suffer reputational harm, and the development and commercialization of our products could be delayed. Furthermore, federal, state, and international laws and regulations can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties, fines, and significant legal liability, if our information technology security efforts fail or if there are material findings regarding data security or data integrity deficiencies by us or our critical partners, vendors, or suppliers.

Attacks on information technology systems are increasing in their frequency, levels of persistence, sophistication, and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security incidents that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

Our insurance policies may not be adequate to compensate us for the potential losses arising from such disruptions, failure, or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and defending a suit, regardless of its merit, could be costly, divert management attention, and harm our reputation.

If we are sued for product or professional liability, we could face substantial liabilities that exceed our resources and insurance coverage.

Actual or perceived errors resulting from laboratory or reporting errors, false positive or false negative test results, or the manufacture, design, marketing, or labeling of our products, could subject us to product liability or professional liability claims. A product liability or professional liability claim against us could result in substantial damages and be costly and time-consuming to defend. These risks may be more pronounced for certain applications in our precision oncology portfolio, such as companion diagnostic development, as our products would be directly involved with the choice to use certain treatments in a particular case. Although we maintain liability insurance, including for errors and omissions, our insurance may not fully protect us from the financial impact of defending against these types of claims or any judgments, fines, or settlement costs arising out of any such claims. Any liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any liability lawsuit could damage our reputation or force us to suspend sales of our products. The occurrence of any of these events could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

Our quarterly results of operations may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our results of operations to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- our ability to successfully develop, market, and sell our products, including Galleri and our future products, such as our precision oncology portfolio and DAC, if and when launched;
- changes in strategic focus or priorities;
- the prices at which we are able to sell our products;
- the impact of market developments or our response thereto;
- disruptions in our business due to manufacturing, supply, security breaches, outages, or other issues;
- the cost of performing next-generation sequencing;
- the extent to which our products are deemed eligible or ineligible for coverage and reimbursement from third-party payors;
- changes in coverage and reimbursement or in reimbursement-related laws directly affecting our business;
- our ability to obtain regulatory approval for our products, and the degree of impact of those approvals on perceptions of our products and market demand;
- regulatory developments affecting our products or any future competing products;
- timing of investments in our laboratories and other infrastructure;
- timing of expenditures in connection with our clinical studies;
- the success of our international expansion efforts; and
- non-routine cash and non-cash expenses and write-offs, whether associated with acquisitions, restructuring activities, litigation, investigations, or otherwise.

If our quarterly results of operations fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our results of operations, which could be caused by any number of factors including seasonality of prescribing our products, may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Acquisitions or other strategic transactions may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We have in the past engaged in and may in the future engage in acquisitions and strategic partnerships, including licensing or acquiring complementary intellectual property rights, technologies, or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;

- the issuance of our equity securities that would result in dilution to our stockholders;
- assimilation of operations, intellectual property, and products of an acquired company;
- difficulties associated with integrating new personnel;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such an acquisition or strategic partnership;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing or future products and regulatory approvals or certifications, and the validity and enforceability of their intellectual property;
- inability to consummate acquisitions on which we spend a significant amount of time and resources;
- possible write-offs or impairment charges relating to acquired businesses; and
- our inability to generate revenue from acquired intellectual property, technology, or tests sufficient to meet our objectives or offset the associated transaction costs.

In addition, as our strategy evolves, we may opt to discontinue, deprioritize, or dispose of assets, technologies, or acquired businesses.

We have and may continue to become subject to securities class action lawsuits, investigations initiated by regulators and law firms, and derivative or other similar litigation, any or all of which, individually or in the aggregate, could have a material adverse effect on our business, financial condition and results of operations.

We have and may continue to become subject to securities class action lawsuits, investigations initiated by regulators and law firms, and derivative or other similar litigation that can be expensive, divert management attention and human and financial capital to less productive uses and result in potential reputational damage. These lawsuits, claims and investigations may related to regulatory or other matters, privacy, intellectual property, and/or employment matters, or any other aspect of our business.

For example, since the acquisition of our business by Illumina in 2021, the acquisition has been subject to various legal challenges, including by the FTC and the European Commission. At the time of the acquisition, Illumina executed binding commitments pursuant to which Illumina held GRAIL separately during the European Commission's review of the acquisition (the "Hold Separate Commitments"). Pursuant to such Hold Separate Commitments and the various orders of the European Commission related to its review of the acquisition, we and Illumina operated as independent legal entities that transact at arms' length. As a result, we have been a party, together with Illumina and as a separate party, to a number of regulatory and administrative proceedings regarding the acquisition, including ongoing proceedings and proceedings in which we have filed separate appeals. In addition, we have intervened in certain procedures in support of Illumina. We may become or remain party to various proceedings, including certain administrative and litigation proceedings related the matters referred to above. For example, as certain provisions of the European Commission's divestment decision continue to apply to GRAIL after the Spin-Off, we expect to continue to have continued interactions with the European Commission. We also expected to remain involved as a separate party from Illumina in a number of ongoing court proceedings. 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 is cooperating with the SEC in this investigation.

In addition, our acquisition by Illumina and subsequent litigation resulted in (i) the announcement of an investigation by the SEC and others by law firms of possible securities law violations; and (ii) the filing of three securities class actions in the United States District Court for the Southern District of California: Kangas v. Illumina, Inc. et al., Roy v. Illumina, Inc. et al., and 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 their 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 Exchange Act and SEC Rule 10b-5 in connection with Illumina's acquisition of GRAIL. Illumina's response is due August 20, 2024. We deny the allegations in the complaints and intend to vigorously defend the litigation. See *Note 9 — Legal And Regulatory Proceedings* for additional details. In the event that any of the matters described above result in one or more adverse judgments or settlements, we may experience an adverse impact on our financial condition, results of operations or stock price.

Lawsuits and other proceedings have in the past and may in the future result in us incurring significant expenses in settlement and litigation costs. Any negative outcome from any such lawsuits or claims could result in payments of substantial monetary damages or fines, or undesirable changes to our products or business practices and, accordingly, our business, results of operations, financial condition, or prospects could be adversely affected. There can be no assurances that a favorable final outcome will be obtained in any or all instances, and defending any lawsuit, even unmerited claims, is costly and can impose a significant burden on management and employees. Any litigation to which we are a party may result in an onerous or unfavorable judgment that may not be reversed upon appeal or in payments of substantial monetary damages or fines, or we may decide to settle lawsuits on similarly unfavorable terms, which could adversely affect our business, results of operations, financial condition, and prospects.

Risks Relating to Regulation and Legal Compliance

We have launched Galleri as a laboratory developed test ("LDT") in the United States. The FDA recently finalized a regulation pursuant to which it plans 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. The phase-in of medical device requirements to LDTs, including the potential requirement for FDA marketing authorization, will be costly and time-consuming, and if we fail to comply with such requirements, or if we cannot ultimately obtain marketing authorization for our LDTs where required, 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 LDTs are classified by the FDA as medical devices and the FDA has asserted statutory authority to ensure that medical devices, including LDTs, are safe and effective for their intended uses, 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.

The FDA has for a number of years stated its intention to modify its enforcement discretion policy with respect to LDTs and impose applicable medical device requirements to LDTs more broadly. Most recently, the FDA proposed an amendment to its regulations in October 2023 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 final rule, which would involve a phase-in of medical device requirements to these products over this time period. The FDA issued this final rule on May 6, 2024, which will 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, potentially, including the potential requirement for FDA marketing authorization.

In connection with the final rule, the FDA established certain new, targeted enforcement discretion policies, including, among others, for LDTs marketed as of the date of publication of the 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, the FDA intends 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 final rule's publication, although such products must still comply with certain other FDA requirements, including registration and listing, 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 final rule's publication date, this enforcement discretion policy will no longer apply and the FDA intends to enforce all applicable FDA requirements (including premarket review and marketing authorization requirements) consistent with the phase-in policy. In addition, for LDTs that receive approval from NY CLEP, FDA intends not to enforce marketing authorization requirements when these requirements are phased in more generally at either three and a half or four years following the date of publication of the final rule. However, these tests will 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 are phased in more generally.

Notwithstanding these new targeted enforcement discretion policies, depending on the kinds of future changes we make to our currently-marketed LDT or any NY CLEP-approved LDT we offer, we may become subject to the application of the phase-in of all FDA medical device requirements (including the need to seek and obtain marketing authorization) at the time that those medical device requirements are phased in more generally. If we are unable to comply with the phase-in of medical device requirements applicable to our LDTs over the phase-in period, we may be required to cease marketing any products that we market as LDTs. In addition, efforts by the FDA to actively regulate 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 LDTs and may take enforcement action against us and/or require premarket review and marketing authorizations, even before the deadline for phasing in medical device requirements to 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, may 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 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 the VALID Act or any other or similar legislative proposals (including any proposals that would, in contrast, reduce FDA oversight of LDTs) will be passed by Congress or signed into law by the President. Depending on the approach adopted under any potential legislation, 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.

As the FDA begins to phase out its policy of enforcement discretion for LDTs as recently described in its final rule subjecting LDTs to affirmative medical device regulation, or if it asserts that our LDTs are not eligible for application of its new, targeted enforcement discretion policies, or if Congress enacts legislation such as the VALID Act to subject LDTs to affirmative FDA oversight as IVCTs, we may be required to obtain marketing authorization for our LDT products from the FDA prior to initially launching our future products or may be required to cease marketing any commercially marketed products that are marketed as LDTs until such marketing authorization is obtained or the applications are submitted. There can be no assurance that we will be able to obtain such marketing authorization 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 will be adequate to support continued adoption of and reimbursement for our products. Even if our products are allowed to remain on the market prior to any required marketing authorization, demand or reimbursement for our products may decline if there is uncertainty about our products, if we are required by the FDA to label our products as investigational, or if the FDA limits the labeling claims we are permitted to make for our products. As a result, we could experience significantly increased development costs and a delay in generating additional revenue from our products, or from other future products now in development, which could reduce our revenues or increase our costs and adversely affect our business, results of operations, financial condition, or growth prospects.

The regulatory clearance, approval, or certification processes of the FDA and comparable foreign regulatory authorities or notified bodies 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.

We have not yet obtained FDA clearance or approval for any of our products or products in development. We are in the process of seeking PMA approval from the FDA for Galleri, while we market Galleri as an LDT. We may also seek FDA approval or clearance for other products in the future. The time required and ability to obtain clearance or approval by the FDA and comparable foreign regulatory authorities is unpredictable, typically takes several years following the commencement of clinical studies, and depends upon numerous factors, including the type, complexity, and novelty of our products and future products. In addition, policies, laws, regulations, or the type and amount of clinical data necessary to gain clearance or approval may change during the course of a test's clinical development and may vary among jurisdictions, which may cause delays in the clearance or approval of, or the decision not to approve, an application. Regulatory authorities have substantial discretion in the premarket review process and may refuse to accept any application, decide that all or part of our data are unusable or insufficient for clearance or approval, require additional clinical or other data, including analytical validation data, determine that our manufacturing and quality systems are insufficient or in violation of applicable requirements, or determine that our clinical research program is insufficient or in violation of applicable good clinical practice or other requirements related to research compliance, human subject protections, or data integrity. Even if we believe our data are sufficient to support marketing authorization, regulatory authorities may disagree, or may require the generation and submission of additional data or analyses, which could significantly delay or preclude marketing authorization.

Before a new medical device can be marketed in the United States, a company must first submit an application for and receive 510(k) clearance pursuant to a premarket notification submitted under Section 510(k) of the FDCA, approval of a PMA application, or grant of a de novo classification request from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device

must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the process of obtaining PMA approval, which we are pursuing for Galleri, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, analytical validation, pre-clinical, clinical trial, manufacturing, and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. In the de novo classification process, a manufacturer whose novel device under the FDCA would otherwise be automatically classified as Class III and require the submission and approval of a PMA prior to marketing is able to request down-classification of the device to Class I or Class II on the basis that the device presents a low or moderate risk. If the FDA grants the de novo classification request, the applicant will receive authorization to market the device. This device type may be used subsequently as a predicate device for future 510(k) submissions.

The PMA approval, 510(k) clearance and de novo classification processes can be expensive, lengthy and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can take longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA, including if an Advisory Committee is needed to evaluate a novel technology, which could occur for the review of a PMA for Galleri. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, a device may not obtain marketing authorization by the FDA. Any delay or failure to obtain necessary regulatory marketing authorizations could harm our business. Furthermore, even if we are granted such marketing authorizations, they may include significant limitations on the indicated uses for the test, which may limit the potential commercial market for the test.

In the United States, any modification to a product for which we receive clearance or approval may require us to submit a new 510(k) notification and obtain clearance, to submit a PMA and obtain FDA approval, or to submit a de novo request prior to implementing the change. For example, any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, generally requires a new 510(k) clearance or other marketing authorization. The FDA requires every manufacturer to make such determinations in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with a manufacturer's decisions regarding whether new clearances or approvals are necessary. If we obtain clearances or approvals from the FDA, we may make modifications or add additional features in the future that we believe do not require a new 510(k) clearance, de novo request or approval of a PMA application or supplement. If the FDA disagrees with our determination and requires us to seek new marketing authorizations for the modifications for which we have concluded that new marketing authorizations are unnecessary, we may be required to cease marketing and/or to recall the modified product until we obtain such marketing authorization, and we may be subject to significant regulatory fines or penalties. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our business.

In addition, we are or may become subject to new laws, regulations, and industry standards concerning medical devices proposed and enacted in various foreign jurisdictions. The EU regulatory landscape concerning IVDs recently evolved. On May 26, 2022, the EU In Vitro Diagnostic Medical Devices Regulation ("EU IVDR") entered into force, which repeals and replaces the EU In Vitro Diagnostic Medical Devices Directive ("EU IVDD"). Subject to the transitional provisions (i.e., a tiered system extending the grace period for many devices (depending on their risk classification) before they have to be fully compliant with the EU IVDR) and in order to sell our products in the EU member states, our products must comply with the general safety and performance requirements of the EU IVDR. Compliance with these requirements is a prerequisite to be able to affix the European Conformity ("CE") mark to our products, without which they cannot be sold or marketed in the EU. All medical devices placed on the market in the EU must meet the general safety and performance requirements laid down in Annex I to the EU IVDR including the requirement that a medical device must be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and - where applicable - other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are

compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. To demonstrate compliance with the general safety and performance requirements, manufacturers must undergo a conformity assessment procedure, which varies according to the type of in vitro diagnostic medical device and its (risk) classification. A conformity assessment procedure generally requires the intervention of a notified body. The notified body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. If satisfied that the relevant product conforms to the relevant general safety and performance requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU.

If we fail to comply with applicable laws and regulations, we would be unable to affix the CE mark to our products, which would prevent us from selling them within the EU. The aforementioned EU rules are generally applicable in the EEA (which consists of the 27 EU member states plus Iceland, Norway and Liechtenstein). Non-compliance with the above requirements would also prevent us from selling our products in these three countries.

Following Brexit, EU laws such as the EU IVDR do not apply directly in Great Britain, however under the terms of the Protocol on Ireland/Northern Ireland, the EU IVDR does apply in Northern Ireland. Consequently, there are currently different regulations in place in Great Britain as compared to both Northern Ireland and the EU, respectively. Ongoing compliance with both sets of regulatory requirements may result in increased costs for our business.

Furthermore, the U.K. government is currently drafting amendments to the U.K. MDR which is likely to result in further changes to the Great Britain regulations in the near future. For example, subject to transitional periods for validly certified devices, the new Great Britain regulations are expected to require IVDs placed on the Great Britain market to be “UKCA” certified by a U.K. Approved Body in order to be lawfully placed on the market. The U.K. government has stated that the core elements of the new regime are likely to apply from July 1, 2025 but that IVDs in compliance with either the EU IVDD or EU IVDR can continue to be placed on the Great Britain market until the sooner of certificate expiration or June 30, 2030; understanding and ensuring compliance with any new requirements is likely to lead to further complexity and increased costs to our business. If there is insufficient U.K. approved body capacity, there is a risk that our product certification could be delayed which might impact our ability to market products in Great Britain after the respective transition periods.

It is currently unclear to what extent the U.K. government will seek to align its regulations with the EU. The EU laws that have been transposed into U.K. law through secondary legislation remain applicable in Great Britain, however the U.K. government is expected to introduce changes to the applicable requirements in Great Britain and the full extent of these changes remains uncertain and may cause additional cost to our business.

Significant political and economic uncertainty remains about how much the relationship between the United Kingdom and EU will differ as a result of the U.K.’s withdrawal. These developments, or the perception that any related developments could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these factors could depress economic activity and restrict our access to capital, which could have a material adverse effect on our business, financial condition, and results of operations and reduce the price of our common stock.

The FDA, other regulators or notified bodies can delay, limit, or deny clearance, approval, or certification of a product for many reasons, including but not limited to the following:

- the FDA, comparable foreign regulatory authorities or notified bodies may disagree with the design, implementation, or results of, or interpretation of the data from, our clinical studies;

- the FDA, comparable foreign regulatory authorities or notified bodies may determine that our product has not been shown to be safe and effective or substantially equivalent to a predicate device, or has other characteristics that preclude us from obtaining marketing authorization or certification, or prevent or limit its commercial use (for example, a narrowed indication for use claim);

- the population studied in the clinical program may not be sufficiently broad, generalizable, or representative of the intended target population of our product to assure effectiveness and safety in the population for which we seek approval, clearance, or certification;

- the FDA, comparable foreign regulatory authorities or notified bodies may disagree with our interpretation of data from clinical studies or may fail to accept data from clinical studies (or clinical sites), including if we fail to establish the integrity of our data;

- the FDA, comparable foreign regulatory authorities or notified bodies may determine that our clinical studies otherwise fail to comply with applicable regulations, including good clinical practice requirements;

- serious or unexpected adverse effects or other performance issues are identified with our existing or future products;

- the FDA, comparable foreign regulatory authorities or notified bodies may determine that our manufacturing or quality system fails to comply with applicable regulations or otherwise fails to meet the standards necessary to support approval or certification; and

- the approval (or certification) policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval or certification.

We are engaged in ongoing discussions with the FDA regarding the clinical studies and data that will be needed to support a successful PMA for a multi-cancer test for our planned indications, based on the designs of our current and planned clinical studies. There can be no assurance that our existing or future products for which we may seek clearance, approval, or certification will be approved, cleared, or certified by the FDA, a comparable foreign regulatory authority or a notified body on a timely basis, if at all. If our products or future products receive clearance, approval, or certification but there is uncertainty about such products among providers or payors, reimbursement may be adversely affected and we may not be able to sell our products. Compliance with FDA or comparable foreign regulations will require substantial costs, and subject us to heightened scrutiny by regulators and substantial penalties for failure to comply with such requirements or the inability to market our products, if and when cleared, approved, or certified. The lengthy and unpredictable clearance, approval, and certification processes, as well as the unpredictability of the results of our clinical studies, may result in our failing to obtain regulatory clearance, approval, or certification to market our products, which would significantly harm our business, results of operations, reputation, and prospects.

Regulatory approval by the FDA or other regulatory authorities is limited to those specific indications and conditions for which approval has been granted, and we may be subject to substantial fines, criminal penalties, injunctions or other enforcement actions if we are determined to be promoting the use of our products for unapproved or "off-label" uses, or in a manner inconsistent with the approved labeling, resulting in damage to our reputation and business.

We must comply with requirements concerning advertising and promotion for any product candidates for which we obtain marketing approval from the FDA. When the FDA or other regulatory authorities issue regulatory approval for a product, the regulatory approval is limited to those specific uses and indications for which a product is approved.

There can be no assurance that labeling claims will be consistent with our anticipated claims or current claims or marketing statements, including with respect to Galleri as an LDT and its current marketing as an MCED test in its intended use population, or adequate to support adoption of, or reimbursement for, our products. If the approved, cleared, or certified indication or other labeling claims the FDA or a comparable foreign regulatory authority or notified body allows us to make are more limited than we expect, or are more limited than current claims made with respect to Galleri, our business, prospects, and growth may be adversely affected and we may be limited in our ability to sell, or unable to sell, our products. If we are not able to obtain FDA approval for desired uses or indications for our current and future products, we may not market or promote them for those indications and uses, and our business, financial condition, results of operations, stock price and prospects could be materially harmed. We also must sufficiently substantiate any claims that we make for any products, including

claims comparing those products to other companies' products, and must abide by the FDA's strict requirements regarding the content of promotion and advertising.

Our multi-cancer detection tests are a new approach to cancer screening, which present a number of novel and complex issues for FDA review. Because the FDA has never cleared or approved a multi-cancer detection test, we cannot provide assurances regarding what information we will need to submit to obtain approval of a PMA from the FDA for a proposed intended use, or if we will be able to obtain such approval on a timely basis or at all.

Our multi-cancer detection tests represent a new approach to cancer screening, and obtaining FDA approval for Galleri presents a number of novel issues. The FDA has never granted marketing authorization for a multi-cancer detection test. Additionally, in March 2020, the FDA held a public workshop to discuss the clinical, scientific, and regulatory challenges associated with circulating tumor DNA cancer screening tests, and we expect the FDA to continue to gather input from a variety of industry, academic, and clinical stakeholders to inform its thinking on how to assess these types of tests, including potentially convening an Advisory Committee meeting during review of a PMA for Galleri (or another company's PMA for a multi-cancer early detection test, should it precede ours). In fact, the FDA on November 29, 2023, the FDA held a meeting of the Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee to discuss and make recommendations on the design of multi-cancer detection in vitro diagnostic devices (tests) as well as potential study designs and study outcomes of interest that could inform the assessment of the probable benefits and risks of multi-cancer detection screening tests. The FDA stated that the committee's discussion and recommendations from this meeting will help inform future FDA regulatory efforts for these novel tests. As such, the FDA requirements that will govern multi-cancer detection 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 we cannot provide assurances what information we will need to submit to obtain approval of a PMA from the FDA for a proposed intended use.

We continue to work with the FDA to regarding the data we must provide the FDA to support our PMA submission for a multi-cancer detection test based on a proposed intended use. As part of our ongoing discussions, the FDA has provided feedback regarding how it plans to assess the safety and effectiveness of Galleri based on potential intended use statements. In addition, we have made pre-submissions to the FDA detailing the clinical and analytical studies intended to support our PMA submission for Galleri, including related to limit of detection, reproducibility, repeatability and other analytical validation studies. Subsequent to these pre-submissions, we met with the FDA and the FDA provided written and verbal feedback, documented in minutes, evaluating the use and size of certain of our proposed studies in our PMA submission and requesting or suggesting changes to certain of our proposed studies. While we plan to continue discussions with the FDA, including regarding the FDA's feedback, requests and suggestions to date, the FDA may raise additional questions or request additional information in connection with the submission of a marketing application.

Given the novel nature and complexity of our multi-cancer detection tests, and the fact that the FDA has never granted marketing authorization for a multi-cancer detection test, we cannot be certain whether we will receive FDA approval for Galleri and we cannot provide assurances that the studies we have conducted, are currently conducting, or plan to conduct, will be sufficient to provide the data that the FDA requires to support a proposed intended use. For example, we plan on providing evidence from our PATHFINDER 2 study and NHS-Galleri Trial to support a PMA as our pivotal study data, as well as supplemental data from other clinical studies, and certain clinical data in the post-approval setting. We may be required to conduct additional studies or expand the enrollment of completed or ongoing studies to support our PMA, as the study design and enrollment continue to be discussed with the FDA recommendation. The FDA may require us to perform new analyses of our clinical data. These and other efforts that we may be required to, undertake could delay the submission of our PMA or delay or prevent approval, lead to a more limited intended use statement or approved labeling, and/or lead to significant post-approval limitations or restrictions, if approval is obtained at all. If the FDA ultimately determines that the data we plan to submit in our PMA are insufficient to support approval, our PMA submission could be delayed. Further, if the FDA ultimately determines upon review of our PMA that the data we submit are insufficient to support approval, and that we need to generate more data from additional patients, we may not receive approval and may need to resubmit a PMA following completion of additional clinical studies.

Our use and disclosure of personal information, including individually identifiable health information, and biologic samples and related data are subject to federal, state and foreign privacy and security

regulations. Data privacy rules are evolving and new legislation concerning privacy and data use may limit our ability to use such data and specimens. Our actual or perceived failure to comply with privacy and security requirements or to adequately secure such information could result in significant liability, administrative or governmental penalties, and/or reputational harm and, in turn, substantial harm to our business, financial condition and results of operations.

The global data protection landscape is rapidly evolving and we and our partners are or may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address data privacy and security). Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer, use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, consents and authorizations, our internal or publicly facing policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, results of operation, and financial condition.

We receive, store, process and use personal information as part of our business and as our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, numerous state and federal laws and regulations govern the collection, dissemination, use, disclosure, privacy, confidentiality, security, availability and integrity of personal information, including health related information. We are a covered entity under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, and the regulations that implement both laws (collectively, "HIPAA"). HIPAA establishes, among other things, a set of national privacy and security standards relating to the privacy, security, transmission, and breach reporting of individually identifiable health information, by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, the business associates with whom such covered entities contract for services that involve creating, receiving, maintaining, or transmitting protected health information, and the subcontractors of such business associates. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA.

HIPAA requires covered entities and business associates to develop and maintain policies with respect to the protection of, use and disclosure of protected health information ("PHI"), including the adoption of administrative, physical and technical safeguards to protect such information, and certain notification requirements in the event of a breach of unsecured PHI. Additionally, under HIPAA, covered entities must report breaches of unsecured PHI to affected individuals without unreasonable delay, not to exceed 60 days following discovery of the breach by a covered entity or its agents. Notification also must be made to the U.S. Department of Health and Human Services Office for Civil Rights ("OCR") and, in certain circumstances involving large breaches, to the media. Business associates must report breaches of unsecured PHI to covered entities within 60 days of discovery of the breach by the business associate or its agents. A non-permitted use or disclosure of PHI is presumed to be a breach under HIPAA unless the covered entity or business associate establishes that there is a low probability the information has been compromised consistent with requirements enumerated in HIPAA.

Entities that are found to be in violation of HIPAA as the result of a breach of unsecured PHI, a complaint about privacy practices or an audit by the U.S. Department of Health and Human Services ("HHS"), may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. HIPAA also authorizes state Attorneys General to file suit on behalf of their residents. Courts may award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI.

Certain states have also adopted comparable privacy and security laws and regulations which govern the privacy, processing and protection of health-related and other personal information, such as the California Confidentiality of Medical Information Act; these laws are not preempted by HIPAA to the extent that they are more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act ("CCPA"), which went into effect on January 1, 2020, creates individual privacy rights for California consumers and increases privacy and security obligations on entities handling certain personal information. The CCPA provides for fines and penalties for violations, as well as a private right of action for data breaches that is expected to increase the likelihood of, and risks associated with, data breach litigation. Further, the California Privacy Rights Act ("CPRA") generally went into effect on January 1, 2023, and significantly amends the CCPA. It imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may also be required. Although there are limited exemptions for certain health-related data, including clinical trial data and protected health information subject to HIPAA, the CCPA (including as amended by CPRA) may increase our compliance costs and potential liability. Other states have passed or are considering similar privacy laws and the federal government may seek to enact a similar federal privacy law, reflecting a trend toward more stringent privacy legislation in the United States.

We also expect that there will continue to be new laws, regulations and industry standards concerning privacy, data protection and information security proposed and enacted in various jurisdictions. For example, Washington State has enacted a broadly applicable law to protect the privacy of personal health information known as the "My Health My Data Act," which generally requires affirmative consent for the collection, use, or sharing of any "consumer health data." Consumer health data is defined to include personal information that is linked or reasonably linkable to a consumer and that identifies a consumer's past, present, or future physical or mental health status; consumer health data also includes information that is derived or extrapolated from non-health information, such as algorithms and machine learning. Other states, including Connecticut and Nevada, have also passed consumer health data laws, and given the increased focus on the use of health data by entities that are not subject to HIPAA, additional states are expected to pass consumer health privacy laws. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. We could be adversely affected if HIPAA, the CCPA (including as amended by CPRA) and other state or federal legislation or regulations applicable to GRAIL require changes in our business practices, our use, receipt, or transfer of health information, or our privacy policies, or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively affect our business, financial condition and results of operations.

The Federal Trade Commission ("FTC") also has authority to initiate enforcement actions against entities that mislead customers about HIPAA compliance, make deceptive statements about privacy and data sharing in privacy policies, fail to limit third-party use of personal health information, fail to implement policies to protect personal health information or engage in other unfair practices that harm customers or that may violate Section 5 of the Federal Trade Commission Act ("FTC Act"). Even when HIPAA does not apply, according to the FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of the FTC Act. The FTC also expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Personal health information is considered sensitive data that merits stronger safeguards.

We strive to comply with applicable laws, regulations, policies and other legal obligations relating to privacy, data protection and information security. However, the various regulatory frameworks for privacy and data protection are, and are likely to remain, uncertain for the foreseeable future, and it is possible that these or other actual or alleged obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other rules and subject our business practices to uncertainty.

In addition, the actual or perceived compromise of, lax oversight of, irresponsible or unauthorized use of, or unauthorized access to or release of, patient data or information by GRAIL, our partners, suppliers, contractors,

consultants, or vendors, could erode provider, patient, and customer confidence, which could impact our business, financial condition, and results of operations.

We seek to utilize biological samples and data from participants in accordance with applicable law, IRB stipulations, and participant permissions (through consent forms and HIPAA authorizations). If we are unable or significantly restricted in using participant samples and data for secondary research purposes, our ability to develop additional products and/or improve or refine existing products will be limited, which may impact our business and prospects.

In addition, we are or may in the future be subject to a range of laws, regulations, and industry standards concerning privacy, data protection, and information security proposed and enacted in various foreign jurisdictions. In Europe, we are subject to the United Kingdom General Data Protection Regulation and the Data Protection Act 2018 ("UK GDPR") and the EU General Data Protection Regulation ("EU GDPR") (the UK GDPR and EU GDPR together referred to as the "GDPR"). The GDPR imposes a comprehensive data privacy compliance regime including: maintaining a record of data processing; providing detailed disclosures about how personal information is collected and processed (in a concise, intelligible and easily accessible form); demonstrating that appropriate legal bases are in place to justify data processing activities; complying with rights for data subjects in regard to their personal information (including data access, erasure (the right to be "forgotten") and portability); ensuring appropriate safeguards are in place where personal information is transferred out of the EEA and the UK; and complying with the principal of accountability and the obligation to demonstrate compliance through policies, procedures, training and audit. The applicability of the specific requirements depends on whether an organization acts as controller or processor.

Some of the personal information we process, for example in respect of clinical trial participants, is special category data under the GDPR, and subject to additional compliance obligations and to local law derogations. We may be subject to diverging requirements under national UK laws and EU member state laws, such as the legal basis we can rely on when processing health data of clinical trial participants as controller or the roles, responsibilities and liabilities as between CROs. As these laws develop, we may need to make operational changes to adapt to these diverging rules, which could increase our costs and adversely affect our business. Further, the regulatory landscape of data and digital laws in the UK and EU is under constant development, and in the future we may be required to adapt our processes, or change the way we engage with health data (for example, if proposed legislation such as the Data Governance Act and the Data Act is enacted and applies to our operations).

Among other requirements, the GDPR regulates the transfer of personal information outside of the EEA and the UK. Case law from the Court of Justice of the European Union ("CJEU") states that reliance on the standard contractual clauses-a standard form of contract approved by the European Commission as an adequate personal information transfer mechanism-alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On October 7, 2022, President Biden signed an Executive Order on 'Enhancing Safeguards for United States Intelligence Activities' which introduced new redress mechanisms and binding safeguards to address the concerns raised by the CJEU in relation to data transfers from the EEA to the United States and which formed the basis of the new EU-US Data Privacy Framework ("DPF"), as released on December 13, 2022. The European Commission adopted its Adequacy Decision in relation to the DPF on July 10, 2023, rendering the DPF effective as an EU GDPR transfer mechanism to United States entities self- certified under the DPF. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a UK GDPR data transfer mechanism to United States entities self-certified under the UK Extension to the DPF. We currently rely on the EU standard contractual clauses, the UK Addendum to the EU standard contractual clauses, and the UK International Data Transfer Agreement, as relevant, to transfer personal information outside the EEA and the UK, including to the United States, with respect to both intragroup and third-party transfers. We expect the existing legal complexity and uncertainty regarding international transfers of personal information to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, we could suffer additional costs, complaints and/or regulatory investigations or fines; we may have to stop using certain tools and vendors and make certain operational changes, including to implement other/revised relevant documentation for data transfers within required time frames; and/or it could

otherwise affect the manner in which we provide our services, and could adversely affect our business, operations and financial condition.

Penalties and fines for failure to comply with the GDPR are significant, including fines of up to €20 million/ £17.5 million or 4% of a noncompliant company's global turnover for the preceding year, whichever is higher. Since we are subject to the supervision of relevant data protection authorities under both the UK GDPR and the EU GDPR, we could be fined under each of those regimes independently in respect of the same non-compliance. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business. Noncompliance with applicable foreign privacy laws, such as the GDPR, would also adversely affect public perception of GRAIL's data stewardship practices and policies, which could impair our business and prospects with other foreign health systems and governments.

If we or our partners fail to comply with federal, state, and foreign laboratory and other applicable licensing and registration requirements, we could be prevented from performing our tests or experience disruptions to our business.

CLIA is a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of disease, or impairment of, or the assessment of the health of, human beings. CLIA regulations require, among other things, clinical laboratories to obtain a certificate and mandate specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, test management, and quality assurance. CLIA certification is also required for us to be eligible to bill state and federal healthcare programs, if such reimbursement is otherwise available, as well as many third-party payors, for our products. To renew these certifications, we are and will be subject to routine surveys and inspections. Moreover, CLIA inspectors may make random or "for cause" inspections of our clinical laboratories.

We hold CLIA certificates from CMS for our laboratories in Menlo Park, California and Durham, North Carolina to conduct high complexity testing, subject to inspection to determine compliance with the CLIA regulations. We also hold CAP accreditations for our Menlo Park and Durham facilities. While we have completed validation studies for the version of Galleri currently marketed as an LDT, we are continuing our validation efforts for the version of Galleri that we intend to submit for PMA approval. We may not successfully complete such validation. Certain product additions to our test menu require notification to the regulatory and accrediting bodies that regulate our laboratories (e.g., CMS, the California Department of Public Health Laboratory Field Services ("CALFS") and CAP) that we are adding a new specialty to our assay offerings. At their discretion, any regulatory or accrediting body may come on-site to inspect our laboratories at any time. Any failure to pass inspections, maintain our CLIA certificates, CAP accreditation, or state licenses, or add new validated products to our laboratory assay offerings could significantly harm our business, results of operations, and prospects.

In addition to obtaining federal certification for a laboratory under CLIA, we are also required to obtain and maintain state licenses to conduct testing in our laboratories. We have obtained a Clinical Laboratory Certificate of Deemed Status from the State of California Department of Public Health for our Menlo Park facility. The California licensure law establishes standards for the day-to-day operation of a clinical laboratory, including the training and skills required of personnel and quality control. In addition, California law mandates proficiency testing, which involves testing of specimens that have been specifically prepared for the laboratory. Further, if we test specimens originating from other states and return patient-specific results, our clinical laboratory must satisfy such states' licensure laws as well to the extent that such laws regulate out-of-state laboratories that test specimens originating in such states. For example, to be able to receive specimens originating from New York, we must maintain a New York State Department of Health clinical laboratory permit and obtain approval of Galleri, which we achieved. Research testing, however, does not require licensure if patient-specific results are not generated and/or returned for diagnostic purposes. We have obtained New York State Department of Health clinical laboratory permits for our Menlo Park facility and our Durham facility, which authorize us to accept and generate for diagnosis or treatment purposes patient-specific results on specimens originating from New York at the applicable facility, as well as having obtained New York State Department of Health approval to offer Galleri to residents of the State of New York. Applicable New York laws and regulations establish standards for day-to-day operation of a clinical laboratory, including training and skill levels required of laboratory personnel, physical requirements of a facility, equipment, and validation and quality control. There can be no assurance that we will be able to maintain New York clinical laboratory permits or approval of Galleri, or maintain licenses or permits from

any other states where we are required to be licensed or hold a permit. Failure to maintain such licenses or permits could expose us to fines and other penalties, or limit our potential testing population.

In connection with CLIA certification and state laboratory licensing and permitting, we remain subject to a number of risks in the event of noncompliance. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure or permitting, or our failure to renew or maintain a CLIA certificate, a state license or permit, or accreditation (including CAP), could have a material adverse effect on our business and reputation as certain actions are public. CMS also has the authority to impose a wide range of sanctions, including suspension, limitation, or revocation of the CLIA certification, termination of Medicare and Medicaid participation, civil money penalties, and a bar on the ownership or operation of a CLIA-certified laboratory by any owners or operators of the deficient laboratory. If we fail to obtain any required state licensure, or lose CLIA certification, CAP accreditation, or licensure, we would not be able to operate our clinical laboratories and offer our products in full or in particular states, which would adversely impact our business and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

In addition to state laboratory licensing laws, we may also be subject to state registration and/or licensing requirements that apply to companies that manufacture medical devices. Certain states require such registrations or licenses before the products are commercialized, including while manufacturers are evaluating the devices in clinical studies. Violations of these laws may result in the denial, suspension, or revocation of the registration or license, as well as other fines and penalties, including imprisonment.

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. 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, 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 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.

Any product for which we obtain a regulatory certificate, permit, license, clearance, or approval will be subject to extensive ongoing regulatory requirements, and we may be subject to penalties if we or our partners fail to comply with regulatory requirements or if we experience unanticipated problems with our products.

Any product for which we obtain a regulatory certificate, permit or license from a local, state, federal, or foreign regulatory authority, or notified body, or clearance or approval from the FDA or other comparable regulators, along with the manufacturing processes, post-market surveillance, labeling, packaging, advertising, and promotion, distribution, storage, import, export, reporting, and recordkeeping for such product, will be subject to continued regulatory review, oversight, requirements, and periodic inspections by the FDA and comparable foreign regulatory authorities, as well as our laboratory processes and practices will be subject to continued review, oversight, requirements, and inspections by CMS, CALFS, and CAP. These requirements include submissions of safety and other post-marketing information and reports; registration and listing requirements; requirements relating to quality control, quality assurance, and corresponding maintenance of records and documents; requirements relating to recalls, removals, and corrections; and requirements relating to product labeling, advertising and promotion, and recordkeeping. The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA and comparable foreign regulatory authorities enforce regulatory requirements through, among other means, periodic unannounced inspections. We do not know whether we will be found compliant in connection with any future regulatory inspections.

Regulatory clearance, approval, or certification of a test or device may be subject to limitations by the regulatory body or notified body as to the indicated uses for which the product may be marketed or to other conditions of clearance, approval, or certification. In addition, clearance, approval, or certification may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the test or device. After clearance, approval, or certification, discovery of problems with our product, suppliers, vendors, or contract manufacturers, or manufacturing processes (including software validation), and/or failure to comply with regulatory requirements, may result in actions such as:

- restrictions on operations of our laboratories;
- restrictions on manufacturing processes;
- restrictions on marketing of a product;
- Untitled or Warning letters;
- withdrawal or recall of the product from the market or seizure of the product;
- refusal to approve applications or supplements to approved applications that we may submit;
- fines, restitution or disgorgement of profits or revenue;
- suspension, limitation or withdrawal of regulatory approvals, clearances, or certifications;
- exclusion from participation in U.S. federal or state healthcare programs, such as Medicare and Medicaid;
- safety communications;

- refusal to permit the import or export of our product;
- injunctions; or
- imposition of civil or criminal penalties.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and results of operations.

In addition, the FDA may change its clearance or approval policies, adopt additional regulations or revise existing regulations, or take other actions. For example, on February 23, 2024, the FDA issued a final rule to amend the Quality System Regulation ("QSR"), which establishes current good manufacturing practice requirements for medical devices, to align more closely with the International Organization for Standardization standards. Specifically, this final rule, which the FDA expects to go into effect on February 2, 2026, replaces the QSR with the Quality Management System Regulation ("QMSR"), and among other things, incorporates by reference the quality management system requirements of ISO 13485:2016. Although the FDA has stated that the standards contained in ISO 13485:2016 are substantially similar to those set forth in the QSR, it is unclear the extent to which this final rule, one effective, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise create market pressure that may negatively affect our business. If we are unable to comply with the QMSR, once effective, or with any other changes in the laws or regulations enforced by the FDA or comparable regulatory authorities, we may be subject to adverse actions of the FDA which may result in any of the sanctions described above. Such changes may also occur in foreign jurisdictions where we intend to market our products or future products. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain clearances or approvals, increase the costs of compliance or restrict our ability to maintain any clearances or approvals we have obtained.

In addition, we are or may become subject to new laws, regulations, and industry standards concerning medical devices proposed and enacted in various foreign jurisdictions. The EU regulatory landscape concerning IVDs recently evolved. On May 26, 2022, the EU IVDR became applicable, and repealed and replaced the EU IVDD. Unlike directives, which must be implemented into the national laws of the EU member states, regulations are directly applicable (i.e., without the need for adoption of EU member state laws implementing them) in all EU member states and are intended to eliminate current differences in the regulation of medical devices among EU member states. The EU IVDR, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EU for in vitro diagnostic medical devices and ensure a high level of safety and health while supporting innovation.

These modifications may have an effect on the way we intend to develop our business in the EU and the EEA. For example, as a result of the transition towards the new regime, notified body review times have lengthened, and product introductions could be delayed or canceled, which could adversely affect our ability to grow our business.

For any of our products that are approved or cleared by the FDA, we will be required to report to the FDA certain information about adverse medical events or malfunctions, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition, results of operations, and growth prospects. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

For products for which we obtain FDA clearance or approval or that are otherwise subject to affirmative FDA oversight, we will be subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the

product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance or approval, seizure of our products or delay in clearance or approval of future products. Similar risks exist in foreign jurisdictions.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA or comparable foreign regulatory authorities may require, or we may decide, that we will need to obtain new clearances, approvals, or certifications for the device before we may market or distribute the corrected device. Seeking such clearances, approvals, or certifications may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA or comparable foreign regulatory authorities warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

To obtain and maintain FDA approvals or clearances, our products will need to be manufactured in accordance with federal and state regulations, and we could be forced to recall our devices or terminate production if we or our partners fail to comply with these regulations.

For the FDA to approve or clear a medical device marketing application, the methods used in, and the facilities used for, the manufacture of our products must comply with the FDA's QSR, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices. Furthermore, to obtain FDA clearance or approval, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Similar state regulations and various laws and regulations of foreign countries governing manufacturing also apply to our products.

Our third-party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the availability of our products or a delay in obtaining FDA authorization of our marketing application. In addition, the FDA issued a final rule to amend the QSR, which establishes current good manufacturing practice requirements for medical devices, to align more closely with the International Organization for Standardization standards. Specifically, this final rule, which the FDA expects to go into effect on February 2, 2026, replaces the QSR with the Quality Management System Regulation ("QMSR"), and among other things, incorporates by reference the quality management system requirements of ISO 13485:2016. Although the FDA has stated that the standards contained in ISO 13485:2016 are substantially similar to those set forth in the QSR, it is unclear the extent to which this final rule, once effective, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise create market pressure that may negatively affect our business. If we or our third party manufacturers are unable to comply with the QMSR, once effective, or with any other applicable FDA requirements or if we or a third party manufacturer later discovers

previously unknown problems with our products or manufacturing processes, these could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's refusal to grant pending or future clearances or approvals for our products; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us, our suppliers, or our employees.

Any of these actions could significantly and negatively affect supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and experience reduced sales and increased costs.

The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Any marketing authorization or certification we may receive or obtain for our products by the FDA, comparable foreign regulatory authorities, or notified bodies will include specified indications for use and approved (or certified) labeling. Upon receipt of FDA authorization, or certification, we will continue to train our marketing personnel and direct sales force to not promote our authorized (or certified) tests for uses outside of FDA-authorized (or certified) indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our products off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products off-label, which could harm our reputation in the marketplace among physicians and patients.

If, after FDA authorization or certification, the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

In addition, physicians may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our devices are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. As described above, product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.

Misleading, untruthful, or unsubstantiated labeling, advertising, marketing, or promotional practices could cause significant harm to our business, operations, and financial conditions. The FTC has instituted enforcement actions against certain healthcare testing companies for making false or misleading advertising claims and for failing to adequately substantiate claims made in advertising. These enforcement actions may result in warning letters, consent decrees, and the payment of civil penalties and/or restitution by the companies involved. Should the FTC determine that our claims are false or misleading or unsubstantiated, we could be subject to FTC enforcement action and may face significant penalties which may result in a material adverse effect on our reputation, business, financial condition, results of operations, and growth prospects.

The labeling, advertising, marketing, and promotional practices of GRAIL related to our products is governed by numerous state and federal regulators, including the FDA and the FTC, as well as subject to third-party claims. Any statements related to our products that could be construed as misleading, untruthful, or unsubstantiated, could subject GRAIL to regulatory enforcement action, third-party lawsuits, or plaintiffs' complaints. Any of these actions could significantly and negatively affect our reputation, expose us to liability claims, and we could lose customers and experience reduced sales and increased costs.

Healthcare reform and data protection measures, including legislation reforming the U.S. healthcare system, could cause significant harm to our business, operations and financial condition.

Healthcare systems are subject to ongoing reform in the United States and abroad. For example, in the United States, the Affordable Care Act ("ACA") made a number of substantial changes to the way healthcare is financed both by governmental and private insurers. The ACA, among other things, included provisions governing enrollment in federal and state healthcare programs, reimbursement matters, and fraud and abuse. Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. Most recently, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Other legislative changes have also been proposed and adopted in the United States since the ACA. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers, which went into effect in April 2013 and will remain in effect until 2032 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

In April 2014, Congress passed PAMA, which included substantial changes to the way in which clinical laboratory services are paid under the CLFS. Under PAMA, certain clinical laboratories are required to periodically report to CMS private payor payment rates and volumes for their tests, and laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. Medicare reimbursement for CDLTs is based on the weighted-median of the payments made by private payors for these tests, rendering private payor payment levels even more significant than in the past. As a result, future Medicare payments may fluctuate more often and become subject to the willingness of private payors to recognize the value of diagnostic tests generally and any given test individually. The impact of this payment system on rates for our tests, including any current or future tests we may develop, is uncertain. For more information, see above and the section entitled "Risks Relating to Our Business and Industry—One of the key elements of our strategy is to expand access to our tests by pursuing coverage and reimbursement from third-party payors, both private and government payors. If our products do not receive adequate coverage and reimbursement, if at all, from third-party payors, our ability to expand access to our products beyond our existing sales channels will be limited and our overall commercial success will be limited."

We cannot predict whether or when these or other recently enacted healthcare initiatives will be implemented at the federal or state level or in foreign jurisdictions or how any such legislation or regulation may affect us. For instance, the payment reductions imposed by the ACA and the changes to reimbursement amounts paid by Medicare for tests based on the procedure set forth in PAMA, could limit the prices we will be able to charge or the amount of available reimbursement for our tests, which would reduce our revenue. Additionally, these healthcare policy changes could be amended or additional healthcare initiatives could be implemented in the future.

Similar developments may occur in the EU. For instance, on December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment ("HTA") amending Directive 2011/24/EU, was adopted. While the regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once the regulation becomes applicable, it will have a phased implementation depending on the concerned products. This regulation intends to boost cooperation among EU member states in assessing health technologies, including certain high-risk medical devices, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The regulation will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

Further, the impact on our business of the expansion of the federal and state governments' role in the U.S. healthcare industry generally, including the social, governmental and other pressures to reduce healthcare costs

while expanding individual benefits, is uncertain. Any future changes or initiatives could have a materially adverse effect on our business, financial condition, results of operations and cash flows.

Obtaining and maintaining regulatory authorization of our products in one jurisdiction does not mean that we will be successful in obtaining regulatory authorization of our products in other jurisdictions.

Obtaining and maintaining regulatory authorization or certification of products in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory authorization or certification in any other jurisdiction, but a failure or delay in obtaining regulatory authorization or certification in one jurisdiction may have a negative effect on the regulatory authorization or certification process in others. For example, even if the FDA or a comparable foreign regulatory authority grants clearance or approval for our products, comparable regulatory authorities or notified bodies in foreign jurisdictions may also need to authorize or certify the products in those countries. Premarket authorization and certification processes vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional clinical studies, because clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities or notified bodies in other jurisdictions or the data may not be considered applicable to the jurisdiction's intended patient population based on demographic, medical practice, genetic, or other differences. In some cases, the price that we intend to charge for our products may also be subject to approval.

Obtaining foreign regulatory authorization or certification and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties, and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in other jurisdictions, or we fail to receive necessary or desirable marketing authorizations or certification in other jurisdictions, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

Our employees, independent contractors, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct, or other illegal activity by our employees, independent contractors, consultants, commercial partners, and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with applicable rules and regulations of the CMS, the FDA, and other comparable foreign regulatory authorities; provide true, complete and accurate information to such regulatory authorities; comply with manufacturing and clinical laboratory standards; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. For example, in June 2023, our third- party telemedicine provider experienced a software issue that resulted in erroneous test reports being delivered to patients. Since we began commercializing Galleri in the United States, our potential exposure under such laws has increased significantly, and our costs associated with compliance with such laws have, and will likely continue to, increase. In particular, research, sales, marketing, education, and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing, and other abusive practices, as well as off-label product promotion. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs, and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of participant recruitment for clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. Even if it is later determined after an action is instituted against us that we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions, and have to divert significant management resources from other matters. We expect our exposure to and costs associated with

compliance with healthcare fraud and abuse laws to increase significantly if we commercialize additional products in the future.

If we fail to comply with healthcare and other applicable laws and regulations, we could face substantial penalties and our business, reputation, and operations and financial condition could be adversely affected.

Our operations are subject to various U.S. federal and state fraud and abuse laws. In addition, the commercialization of our products outside the United States would also subject us to foreign equivalents of the healthcare laws described below, among other foreign laws. The laws that may, currently or in the future, impact our operations include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item, or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation, and many courts have interpreted that statute as being violated if merely one purpose of any arrangement is to induce referrals or purchases. In 2018, Congress enacted the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA"), which establishes an all-payor anti-kickback prohibition for, among other things, knowingly and willfully paying or offering any remuneration directly or indirectly to induce a referral of an individual to a clinical laboratory. Violations of EKRA may result in fines, imprisonment, or both, for each occurrence. The law includes a limited number of exceptions, some of which closely align with corresponding Anti-Kickback Statute exceptions and safe harbors, and others that materially differ. Currently, there is no regulation interpreting or implementing EKRA, nor any guidance released by a federal agency regarding the scope of EKRA. Accordingly, we cannot guarantee that our relationships with providers, sales representatives, or customers will not be subject to scrutiny or will withstand regulatory challenge under EKRA;

- the federal physician self-referral prohibition, commonly known as the Stark Law, which, in the absence of an applicable exception, prohibits a physician from making a referral for certain designated health services covered by the Medicare or Medicaid program, including clinical laboratory services, if the physician or an immediate family member of the physician has a financial relationship with the entity providing the designated health services. The Stark Law also prohibits the entity furnishing the designated health services from billing, presenting or causing to be presented a claim for the designated health services furnished pursuant to the prohibited referral;

- federal civil and criminal false claims laws, including the False Claims Act, which impose criminal and civil penalties, including through civil "qui tam" or "whistleblower" actions, against individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false or fraudulent. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute or Stark Law constitutes a false or fraudulent claim for purposes of the False Claims Act;

- healthcare fraud and false statements laws, which prohibit, among other things, knowingly making a false statement to improperly avoid, decrease, or conceal an obligation to pay money to the federal government. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation;

- the federal Civil Monetary Penalties Law, which, subject to certain exceptions, prohibits, among other things, the offer or transfer of remuneration, including waivers of copayments and deductible amounts (or any part thereof), to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program;

- the federal Physician Payment Sunshine Act, created under the ACA, and its implementing regulations, which require manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services under the Open Payments Program, information related to payments or other transfers of value made to physicians (as defined by statute), teaching hospitals, and other healthcare practitioners, as well as ownership and investment interests held by such physicians and their immediate family members;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection, and unfair competition laws that may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangement, as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require healthcare companies to comply with the medical device industry's voluntary compliance guidelines, the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers, and other potential referral sources or state-specific standards on financial interactions with healthcare providers; state laws that require healthcare companies to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensation, and other remuneration and items of value provided to healthcare professionals and entities; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available and lack of clear guidance, it is possible that some of our business activities could, despite our efforts to comply, be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements will comply with applicable healthcare and other applicable laws may involve substantial costs. In the future, it is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or then-existing statutes, regulations, or case law interpreting applicable fraud and abuse or other healthcare or applicable laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal, and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, labeling, handling, use, storage, transport, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources or insurance coverage. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties. If the handling, use, labeling, storage, or transport of hazardous or biohazardous materials by us or our contract manufacturers or suppliers fail to comply with applicable requirements, we could incur significant costs, be subject to civil or criminal fines and penalties, experience disruption and delays in our operations, and face destruction of any non-compliant materials, which could include clinical and biological samples.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development, and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical studies or regulatory approvals or certifications could be suspended, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Changes in funding or disruptions at the FDA, other government agencies, and notified bodies caused by funding shortages, global health concerns, government shutdowns, or other causes could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, certified, or commercialized in a timely manner or at all, or otherwise prevent those agencies and notified bodies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA, foreign regulatory agencies, and notified bodies to review and clear, approve, or certify new products or changes to existing products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's, foreign regulatory agencies', and notified bodies' ability to hire and retain key personnel and accept the payment of user fees, government shutdowns, and other events that may otherwise affect the FDA's foreign regulatory agencies' and notified bodies' ability to perform routine functions. Average review times at the FDA, foreign regulatory agencies, and notified bodies have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA, other agencies, and notified bodies may also slow the time necessary for new medical devices or modifications to cleared, approved, or certified medical devices to be reviewed and/or approved, or certified by necessary government agencies or notified bodies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, during the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates, and any resurgence of COVID-19 or emergence of new variants may lead to further inspectional delays. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA, other regulatory authorities, or notified bodies from conducting their regular activities, it could significantly impact the ability of the FDA, other regulatory authorities, or notified bodies to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

In the EU, for example, notified bodies must be officially designated to certify products and services in accordance with the EU IVDR. Only a few notified bodies have been designated so far and the COVID-19 pandemic has significantly slowed down their designation process. Without EU IVDR designation, notified bodies may not yet start certifying devices in accordance with the EU IVDR. As only a few notified bodies have been EU IVDR-designated, they are facing a heavy workload and their review times have lengthened. This situation may impact the way we are conducting or intend to conduct our business in the EU and the EEA and the ability of the applicable notified body to timely review and process our regulatory submissions and perform its audits.

Our business activities are subject to the FCPA and similar anti-bribery and anti-corruption laws.

Our business activities are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations, or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is

heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the healthcare providers who administer diagnostic tests are employed by their government, and the purchasers of diagnostics tests are government entities; therefore, our dealings with these providers and purchasers are subject to regulation under the FCPA. The SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Risks Relating to Intellectual Property

If we are unable to obtain and maintain intellectual property protection for our technology, or if the scope of the intellectual property protection we obtain is not sufficiently broad, third parties could in the future develop and commercialize technology and tests similar or identical to ours, and our ability to successfully commercialize our products may be impaired.

Our ability to perform successfully will depend in part on our ability to obtain and enforce patent protection for our products, preserve our trade secrets, and operate without infringing the proprietary rights of third parties. Filing, prosecuting, and defending patents on our products and other technologies in all countries throughout the world would be prohibitively expensive and time-consuming, and the laws of some foreign countries may not protect our rights to the same extent as the laws of the United States. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patents or patent applications at a reasonable cost or in a timely manner, or in all jurisdictions. Furthermore, in some cases, we have only filed provisional patent applications on certain aspects of our products and technologies and each of these provisional patent applications, or any future provisional patent application on certain aspects of our products and technologies, is not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of the filing date of the applicable provisional patent application. In cases where we have not obtained, or decided not to obtain, patent protection for certain of our inventions, we may not be able to prevent third parties from practicing our inventions or from selling or importing tests made using our inventions in and into the United States or other jurisdictions. As a result of our Restructuring Plan, we have determined to strategically refocus our patent portfolio, which we expect to result in filing and maintaining fewer patents in fewer jurisdictions, which could amplify these risks.

Moreover, while we have applied for patents that protect aspects of our technology in the United States and numerous other countries, we cannot assure you that our intellectual property position, including our owned and exclusively licensed pending and issued patents, will not be challenged or that all patents for which we have applied will be issued on a timely basis or at all, or that such patents will protect our technology, in whole or in part, or be issued in a form that will provide us with meaningful protection.

Although patents are presumed valid and enforceable upon issuance, a patent may be challenged as to its inventorship, scope, validity, or enforceability, and certain of our owned or exclusively in-licensed patents have been, and others in the future may be, challenged in the courts or patent offices in the United States or abroad. For example, certain of our in-licensed and owned European patents have been subject to oppositions in Europe, as described below. As a result of such challenges, our pending or future patent applications may not result in issued patents, or the scope of existing or future patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, or our issued patents may be held invalid or unenforceable. It is also possible that we may fail to identify patentable technologies in a timely fashion, which could impair our ability to obtain patent protection on such technology at all. Third parties may be able to circumvent our owned or exclusively in-licensed patents by developing similar or alternative technologies or tests in a non-infringing manner. Third parties could in the future also set up laboratories outside the countries in which we have filed patent applications in order to compete without infringing upon our intellectual property, even if they process samples from countries in which we do have patent protection. In addition, to the extent we have granted,

or may grant in the future, licenses or sublicenses of our intellectual property rights to third parties, we cannot provide any assurance that such intellectual property rights will not be used by those third parties in a manner that could compete with our business or otherwise negatively impact any competitive advantage provided by such intellectual property rights.

Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are uncertain. Given the amount of time required for the development, testing, and regulatory review of new tests, patents protecting such tests might expire before or shortly after such products are commercialized. As a result, our owned or exclusively in-licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If a third party obtains an issued patent on inventions we use in our products, that party could prevent us from using those inventions, and we may not be able to design around the third party's patents or obtain a license on commercially reasonable terms, if at all. Third-party patents or other intellectual property may exist that our current technology, manufacturing methods, products, or future methods or tests infringe or will infringe, which could result in litigation, the imposition of injunctions preventing our use of the foregoing, or require us to obtain licenses or pay royalties and/or other forms of compensation to third parties, which could be significant and could harm our results of operations.

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the U.S. Patent and Trademark Office ("USPTO") and various government patent agencies outside of the United States over the lifetime of our owned or in-licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies and to take the necessary actions to comply with other requirements to maintain such in-licensed patents during their term. In some cases, non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical tests or technology, which could have a material adverse effect on our market position.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We have agreements with Illumina and license agreements with others that provide rights to certain technologies related to assays used in our products. We may need to obtain additional licenses from others to advance our research or allow commercialization of our products or technology, either globally or in certain geographies, without infringing the intellectual property of third parties. It is possible that we may be unable to obtain such additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our technology or to develop or license replacement technology, any of which may not be feasible on a technical or commercial basis. If we are unable to obtain or maintain applicable licenses, we may be unable to commercialize certain of our products, either globally or in certain geographies, or continue to utilize our technology, which could harm our business, financial condition, results of operations, and growth prospects.

In addition, our in-licenses impose various development, diligence, commercialization, and other obligations on us, and we expect that our future license or development agreements will contain similar types of obligations. Certain of our license agreements also require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products. Despite our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements or our sublicensees may fail to fulfill their obligations to us or materially breach our related sublicense agreements, and our licensors might therefore terminate the license agreements or otherwise modify our rights under those agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements or resulting in litigation. If these in-licenses are terminated, or if the underlying patents fail to provide

the anticipated market exclusivity, other third parties may have the freedom to seek regulatory approval of, and to market, tests highly similar to ours or we may be required to cease commercialization of our products or use of our technology. Any of the foregoing could have a material adverse effect on our position, business, financial condition, results of operations, and growth prospects.

In addition, the agreements under which we currently license or otherwise obtain rights to intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations, which may lead to disputes between us and our licensor, including:

- the scope of rights granted under the license agreement;
- the extent to which our product and technology infringe on intellectual property of the licensor that is not subject to the license agreement;
- the right to sublicense patent and other rights under our collaborative development relationships;
- our diligence and other obligations under the license agreement; and
- the ownership of inventions and know-how resulting from the joint invention of intellectual property by us and our licensors and our partners.

The resolution of any contract disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and growth prospects. If we are required to engage in litigation to enforce or defend our rights under our license or development agreements, even if we are successful, such litigation could require significant financial resources, divert the attention of management and harm our business. Moreover, if disputes over intellectual property that we have licensed or otherwise obtained rights to prevent or impair our ability to maintain our current arrangements on commercially acceptable terms, or at all, we may be unable to successfully commercialize the affected product or technology, which could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

Our use of open-source software could subject our proprietary technology to unwanted open-source license conditions that could negatively impact our business.

A portion of our technology capabilities incorporates open-source software, and we may incorporate open-source software into other offerings or products in the future. If an author or other third party that distributed such open-source software to us were to allege that we had not complied with the conditions of one or more of these licenses, we could be required to remediate our open source vulnerabilities or defend against such allegations. In addition, if we combine our proprietary software with open-source software in a certain manner and make it available to others, under some open-source licenses, we could be required to license or make available the source code of our proprietary software, which could help our third parties develop products that are similar to ours and harm our business; thus, we could be required to remediate any such open source vulnerabilities.

Developments in patent law could have a negative impact on our business.

From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress, the USPTO, or applicable authorities in other jurisdictions may change the standards of patentability and any such changes could have a negative impact on our business. The scope of patent coverage available for medical diagnostics continues to evolve and uncertainty remains around the patentability of certain diagnostic-based method claims. U.S. Supreme Court and Federal Circuit decisions interpreting and/or limiting the scope of patentable subject matter under 35 U.S.C. § 101, in addition to examination guidelines from the USPTO, have made it more difficult for patentees to obtain and/or maintain patent claims in the United States that are directed to medical diagnostics, as claims to that subject matter are sometimes perceived to recite or involve laws of nature, natural phenomena, and/or natural products.

Several precedential decisions regarding patentable subject matter are of particular relevance to patents in the medical diagnostics and computer-implemented applications space. The 2012 decision in *Mayo Collaborative v. Prometheus Laboratories (Prometheus)* concerns patent claims directed to optimizing the amount of drug administered to a specific patient based on certain diagnostic measurements. The U.S. Supreme Court held that the applicable patent's claims were directed to a law of nature (i.e., a natural correlation between drug levels and efficacy or toxicity) and failed to incorporate a sufficiently inventive concept above and beyond routine and conventional method steps to allow the claimed methods of treatment to qualify as patent eligible. The 2013 decision in *Association for Molecular Pathology v. Myriad Genetics (Myriad)* concerns the patentability of isolated DNA sequences that were related to methods of diagnosing genetic predisposition to cancer. The U.S. Supreme Court held that isolated fragments of naturally occurring genetic material are not patent eligible, but non-naturally occurring fragments can be patented. The 2014 decision in *Alice Corporation Pty. Ltd. v. CLS Bank International (Alice)* concerns computer-implemented inventions. The U.S. Supreme Court held that an abstract idea could not be patented just because it is implemented on a computer, thus providing guidance on the patentability of computer-implemented applications. The 2015 decision in *Ariosa v. Sequenom* (*Sequenom*) concerns the patentability of claims directed to a method of detecting fetal DNA in a mother's serum or plasma samples. Although the U.S. Supreme Court recognized that the discovery of cell-free fetal DNA present in a mother's bloodstream was a scientific breakthrough, it held that the claims were not patent eligible since they were primarily directed to a natural phenomenon. The Federal Circuit's 2020 decision in *Illumina v. Ariosa* concerns the patentability of claims directed to preparing a fraction of DNA enriched in cell-free fetal DNA. The Federal Circuit held the claims were patent eligible and distinguished them from the claims in Sequenom as method of preparation claims, rather than diagnostic claims. The court further explained that the claimed DNA fragment size thresholds were human-engineered parameters, suggesting that claims based on natural phenomena, but not exclusively directed to such phenomena, may be patent eligible. In short, our efforts to seek patent protection for our technologies and products may be impacted by the evolving case law and guidelines/ procedures issued by the USPTO, or authorities in other jurisdictions based on such changes in the law.

We cannot fully predict the impact that the evolving case law on patentable subject matter will have on the ability to obtain or enforce patents relating to DNA, genes, genomic-related discoveries, or computer- implemented tests, including such tests that use machine learning or rely on software pipelines, in the future, as the contours of whether claims are patent eligible (or instead recite laws of nature, natural phenomena, natural products, or abstract ideas) are not clear and may take years to develop via interpretation at the USPTO and in the courts. There are many patents claiming nucleic acids and diagnostic methods based on natural correlations that issued before the court decisions summarized above and, although some of these patents may be invalid under the standards set forth in these decisions, these patents are presumed valid and enforceable until they are successfully challenged. Thus, third parties holding these patents could allege that we infringe, or request that we obtain a license under, these patents, even if these patents are not likely enforceable under current U.S. laws. Whether based on patents issued prior to or after these precedential decisions, we could be forced to defend against claims of patent infringement or obtain license rights, if available on commercially reasonable terms or at all, under these patents. In jurisdictions other than the United States, gene-related patent claims may remain valid and may be enforced against us.

Additionally, on June 1, 2023, the European Union Patent Package ("EU Patent Package") regulations were implemented with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court ("UPC") for litigation involving European patents. As a result, European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We can elect to opt out from the UPC in some of our future European patents, but doing so may preclude us from realizing the potential benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opting out under the UPC, our future European could remain under the jurisdiction of the UPC. The UPC could provide our third parties with a new forum to centrally revoke our European patents, and allow for the possibility of a third party to obtain a pan-European injunction—such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and future products and, resultantly, on our business, financial condition, prospects, and results of operations.

Further, the U.S. Congress has periodically sought to pass bills concerning subject matter eligible for patent protection. We cannot fully predict the impact that such new laws may have on our ability to obtain patent protection for our products and technologies, and our ability to operate in view of the patents controlled by third parties. These and other substantive changes to U.S. and foreign patent law could affect our susceptibility to patent infringement claims and our ability to obtain patents and, if obtained, to enforce or defend them, any of which could have a material adverse effect on our business.

Patent terms may be inadequate to protect our position on our products for an adequate amount of time.

Patents have a limited lifespan in all jurisdictions around the world. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product are obtained, once the patent life has expired for a product, we may be open to competition. Given the amount of time required for the development, testing and regulatory review of new products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing future products similar or identical to ours for a meaningful amount of time, or at all. Such an inability to exclude third parties from commercializing similar or identical products could have a material adverse impact on our reputation, business, financial condition, results of operations, and growth prospects.

Issued patents covering our products and other technologies could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States and abroad.

Third parties may challenge the validity or enforceability of our owned or in-licensed patents in court or before administrative bodies in the United States or abroad. If we or one of our licensors initiated legal proceedings against a third party to enforce a patent, the defendant could counterclaim that our asserted patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of subject matter eligibility, lack of written description, and non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a material misleading statement, during prosecution. Third parties have raised, and in the future may raise, claims challenging the validity or enforceability of our owned or in-licensed patents before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post- grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover Galleri, DAC, or our other technologies or products.

For example, in 2021, we faced an opposition in Europe with respect to European patent number EP 3 363 901 B1 in-licensed from the Fred Hutchinson Cancer Center. The opposition proceeding filed against EP 3 363 901 B1 concluded with the claims being maintained in amended form and corresponds to technology that is not currently being used in Galleri, DAC, or our precision oncology portfolio. The opponents have filed an appeal. This opposition proceeding does not affect our patents outside Europe.

If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or other technologies. Such a loss of patent protection could have a material adverse impact on our business, financial condition, results of operations, and growth prospects.

We may not be able to protect our intellectual property rights throughout the world.

Various companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement of our or any future licensors' patents or marketing of

products in violation of our proprietary rights. Certain countries outside the United States have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. As a result, a patent owner may have limited remedies in certain circumstances, which could materially diminish the value of such patent. If we or any future licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our position may be impaired, and our business, financial condition, results of operations, and growth prospects may be adversely affected. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Certain countries outside the United States also have laws that may impact a patent owner's right to claim priority or require a patent applicant to obtain a foreign filing license or first file patent applications in a foreign jurisdiction to the extent foreign nationals are involved in the development of the claimed subject matter of the resulting patent. Our pending and future patent applications may not result in patents being issued that comply with the law of each foreign jurisdiction. Pending applications and issued patents may be challenged in various jurisdictions for failure to comply with local laws, which could result in the rejection of pending applications or invalidation of issued patents. Further, the standards applied by foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our future products. While we will endeavor to try to protect our existing products and products with in development with intellectual property rights, such as patents, as appropriate, the process of obtaining patents is time consuming, expensive, and unpredictable.

In addition, geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement, or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's conflict in Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. If we are not able to protect our intellectual property rights throughout the world, our position may be impaired, and our business, financial condition, results of operations, and growth prospects may be adversely affected.

We may be subject to claims by third parties asserting that our employees or we have infringed or misappropriated intellectual property rights, or to assertions by third parties or employees claiming ownership of what we regard as our own intellectual property.

Our former, current, and future employees may have been previously employed at universities or other biotechnology, diagnostic, laboratory, technology, or pharmaceutical companies, including, for example, potential competitors and strategic partners. We train our employees not to bring or use proprietary information or technology from former employers to us or use it in their work. Although we try through such training and other measures to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we have been in the past, and in the future may be, subject to claims that an employee or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of such employee's former employer. Litigation, which would be expensive, time-consuming, a distraction to management, and uncertain of outcome, may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing or enforcing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may be breached, and we may be forced to bring claims against third parties or current or former employees, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail to prevail on any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, or be required to obtain a license, which may not be available to us on commercially reasonable terms or at all. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management, which could harm our business.

If we are unable to protect the confidentiality of our trade secrets, our business and market position would be harmed.

In addition to seeking patents for our products and other technologies, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, data, and other proprietary information, and to maintain our market position. Trade secrets and know-how can be difficult to protect. We expect some of our trade secrets and know-how to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel. This risk may be heightened when employee attrition is higher, for example in connection with the Restructuring Plan.

We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, directors, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, suppliers, service providers, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants, and remind departing employees when they leave their employment of their continuing confidentiality obligations. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite our efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. Some courts outside the United States are less willing or unwilling to protect trade secrets, and the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws within the United States. For example, in China, claims regarding infringement or misappropriation of trade secrets are more difficult to prove, and consequently plaintiffs are rarely successful in bringing these claims. If any of our trade secrets were to be lawfully obtained or independently developed by a third party, we would have no right to prevent them from using that technology or information. If any of our trade secrets were to be misappropriated by, disclosed to, or independently developed by a third party, our market position could be materially and adversely harmed.

We have and may enter into collaboration, license, contract research, and/or manufacturing relationships with contract organizations that operate in certain countries that are at heightened risk of theft of technology, data, and intellectual property through direct intrusion by private parties or foreign actors, including those affiliated with or controlled by state actors. Accordingly, our efforts to protect and enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license, and we may be at heightened risk of losing our proprietary intellectual property rights around the world, including outside of such countries, to the extent such theft or intrusion destroys the proprietary nature of our intellectual property.

Our success depends on our ability to develop and commercialize our technology without infringing, misappropriating, or otherwise violating the intellectual property of third parties. Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, and if they prevail, could block sales of our products and force us to make large damages and/or royalty payments, which could have a material adverse effect on the success of our business.

Our commercial success in part depends upon our ability, and the ability of our collaborators, to market, sell, and distribute our products and use our proprietary technologies without infringing, misappropriating, or otherwise violating the proprietary rights of third parties. There is considerable intellectual property litigation in the medical technology, biotechnology, diagnostic, and pharmaceutical industries. In addition, there is ongoing intellectual property litigation in the circulating nucleic acid analysis and cancer nucleic acid space, the outcome of which could also impact potential future litigation involving our intellectual property or our ability to commercialize our

products. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products, including interference proceedings before the USPTO and similar bodies in other jurisdictions. Third parties may assert infringement claims against us based on existing patents or patents that may be issued in the future.

If we are found to infringe, misappropriate, or otherwise violate a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing, marketing, selling, and distributing our products, or to cease using the infringing technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving third parties access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages if we are found to have willfully infringed a patent and attorneys' fees if the court finds the case to be exceptional. A finding of infringement, misappropriation, or other violation could prevent us from commercializing our products or force us to cease some of our operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Even if resolved in our favor, litigation, or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some third parties may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to perform in the marketplace.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common stock to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs, or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

We may become involved in lawsuits to protect or enforce or defend our patents, which could be expensive, time-consuming, and unsuccessful.

Third parties may infringe our patents or trademarks or misappropriate or violate our other intellectual property rights. To counter infringement, misappropriation, or unauthorized use of our intellectual property, we or any future licensors may be required to file infringement or misappropriation claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Our or any future licensors' pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents or any future licensors' patents are invalid or unenforceable, or both.

Our patents and any patents that we in-license may be challenged, narrowed, invalidated, or circumvented. If our patents are invalidated or otherwise limited or will expire prior to the commercialization of our products, other companies may be better able to develop products that could adversely affect our market position, business, financial condition, results of operations, and growth prospects.

The following are examples of litigation and other adversarial proceedings or disputes that we could become a party to involving our patents or patents licensed to us:

- we or our collaborators may initiate litigation or other proceedings against third parties to enforce our patent rights;
- third parties may initiate litigation or other proceedings seeking to invalidate patents owned by us or that are licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents licensed to us or that such patents are invalid or unenforceable;
- third parties have initiated, and in the future may initiate, oppositions, *inter partes* review, post-grant review, or reexamination proceedings challenging the validity or scope of our patent rights, requiring us or our collaborators and/or licensors to participate in such proceedings to defend the validity and scope of our patents;
- there may be a challenge or dispute regarding inventorship or ownership of patents currently identified as being owned by or licensed to us;
- at our initiation or at the initiation of a third party, the USPTO may initiate an interference between patents or patent applications owned by or licensed to us and those of third parties, requiring us or our collaborators and/or licensors to participate in an interference proceeding to determine the priority of invention, which could jeopardize our patent rights; or
- third parties may seek approval to market products similar to our future approved products prior to expiration of relevant patents owned by or licensed to us, requiring us to defend our patents, including by filing lawsuits alleging patent infringement.

These lawsuits and proceedings would be costly and could affect our results of operations and divert the attention of our managerial, legal, and scientific personnel. There is a risk that a court or administrative body would decide that our owned or exclusively in-licensed patents are invalid or not infringed by a third party's activities, or that the scope of certain issued claims must be limited. An adverse outcome in a litigation or proceeding involving our owned or exclusively in-licensed patents could limit our ability to assert our patents against third parties, affect our ability to receive royalties or other licensing consideration from our licensees or sublicensees, and may curtail or preclude our ability to exclude third parties from making, using and selling similar products. We may become more susceptible to these types of lawsuits and proceedings given the proliferation of organizations pursuing intellectual property protections in the cancer detection and cfDNA space. Any of these occurrences could adversely affect our business position, business, financial condition, results of operations, and growth prospects.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

In addition, our registered or unregistered trademarks or trade names may be challenged, infringed or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we view as valuable to building name recognition among potential partners and customers in our markets of interest. At times, other third parties have adopted or may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion and/or litigation. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. We may also license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to perform effectively and our business may be adversely affected. Our efforts to enforce, protect, or defend our proprietary rights related to trademarks may be ineffective and could result in

substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations, and growth prospects.

Risks Relating to the Spin-Off

We could have an indemnification obligation to Illumina if the Distribution were determined not to qualify for non-recognition treatment for U.S. federal tax purposes.

Illumina received a private letter ruling from the IRS and a written opinion of Cravath, Swaine & Moore LLP that, subject to the limitations specified therein and the accuracy of and compliance with certain representations, warranties, and covenants, the Spin-Off will qualify for non-recognition of gain and loss under Sections 355 and 368 of the Code. Notwithstanding this ruling and opinion, if the Spin-Off were determined not to qualify for non-recognition of gain and loss under Sections 355 and 368 of the Code, we could be required, under certain circumstances, to indemnify Illumina for certain taxes and related expenses. In addition, current tax law generally creates a presumption that the Spin-Off would be taxable to Illumina, but not to holders, if we or our shareholders were to engage in transactions that result in a 50% or greater change by vote or value in the ownership of our stock during the four-year period beginning on the date that begins two years before the date of the Distribution, unless it were established that such transactions and the Distribution were not part of a plan or series of related transactions giving effect to such a change in ownership. If the Distribution were taxable to Illumina due to such a 50% or greater change in ownership of our stock, we could, under certain circumstances, be required under the Tax Matters Agreement to indemnify Illumina for some or all of the tax on such gain and related expenses. Any such indemnification obligation could materially adversely affect our business, financial condition, and results of operations.

We have agreed to numerous restrictions to preserve the non-recognition treatment of the Spin-Off, which may reduce our strategic and operating flexibility.

We agreed in the Tax Matters Agreement to certain covenants and indemnification obligations (including restrictions on share issuances, redemptions or repurchases, business combinations, sales of assets, and similar transactions) that address compliance with the intended tax treatment of the Spin-Off. Certain of these restrictions will apply for the two-year period after the Spin-Off unless Illumina obtains an opinion from counsel or a ruling from the IRS generally to the effect that a restricted action will not cause the Spin-Off or certain related transactions to fail to qualify for its intended tax treatment, or Illumina gives its consent for us to take a restricted action. These covenants and indemnification obligations may limit our ability to pursue strategic transactions or engage in new businesses or other transactions that may otherwise maximize the value of our business, and might discourage or delay a strategic transaction that our shareholders may consider favorable. These covenants also inhibit our ability to obtain financing through public offerings of our common stock or private financings with certain parties, which may materially and adversely affect our ability to raise capital and satisfy our cash needs. If we are restricted from participating in strategic or financing activities by such contractual restrictions, our business, financial condition, results of operations, and growth prospects would be adversely affected.

Our historical financial data is not necessarily representative of the results that we would have achieved if we had been a separate, publicly traded company and may not be a reliable indicator of our future results.

From August 18, 2021 until June 24, 2024, we operated as a wholly owned subsidiary of Illumina. In connection with the legal and regulatory matters described under ""Legal Proceedings" our business was held and operated separately and independently from Illumina and Illumina was required to fund our operations and development. We derived the historical financial data included in this Quarterly Report on Form 10-Q, in part, from our consolidated financial statements and accounting records prepared as a wholly owned subsidiary of Illumina, and this data does not necessarily reflect the financial condition, results of operations, or cash flows that we would have achieved as a separate, publicly traded company during the periods presented or those that we will achieve in the future. This is primarily because of the following factors:

- the historical financial data may not fully reflect the costs associated with the Spin-Off, including the costs related to being an independent public company;

- our historical financial data does not reflect our obligations under the various transitional and other agreements we will enter into with Illumina in connection with the Spin-Off;

- since Illumina acquired us in August 2021, our working capital requirements and capital for our general corporate purposes, including capital expenditures, have been satisfied by Illumina. Following the Spin-Off, we will need to rely on our cash on hand or obtain additional financing from banks, through public offerings or private placements of debt or equity securities, strategic relationships, or other arrangements, which may or may not be available or may be available only on less attractive terms than we may have received as a part of Illumina; and

- following the Spin-Off, we expect that the cost of capital for our business is higher than Illumina's cost of capital prior to the Spin-Off.

Other significant changes may occur in our cost structure, management, financing, and business operations as a result of operating as a separate, publicly traded company. As such, our historical financial data may not be indicative of our future performance as a separate, publicly traded company. For additional information about our past financial performance and the basis of presentation of our financial statements, see "," and "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Quarterly Report on Form 10-Q and our Condensed Consolidated Financial Statements and the notes thereto included in this Quarterly Report on Form 10-Q.

Our customers, prospective customers, suppliers, or other companies with whom we conduct business may conclude that our financial stability as a separate, publicly traded company is insufficient to satisfy their requirements for doing or continuing to do business with them.

Some of our customers, prospective customers, suppliers, or other companies with whom we conduct business may conclude that our financial stability as a separate, publicly traded company is insufficient to satisfy their requirements for doing or continuing to do business with them, or may require us to provide additional credit support, such as letters of credit or other financial guarantees. Any failure of parties to be satisfied with our financial stability could have a material adverse effect on our business, financial condition, results of operations, and cash flows.

Risks Relating to Our Common Stock

Prior to June 24, 2024, no market for our common stock existed and an active trading market may not be sustained after the Spin-Off. Our stock price may fluctuate significantly.

Prior to June 24, 2024, there was no public market for our common stock. Although our common stock is listed on Nasdaq, an active trading market for our common stock may not be sustained in the future. The lack of an active market may make it more difficult for shareholders to sell our shares and could lead to our share price being depressed or volatile.

We cannot predict the prices at which our common stock may trade in the future. The market price of our common stock may fluctuate widely, depending on many factors, some of which may be beyond our control, including:

- the commercial success of Galleri and the degree to which it meets the expectations for securities analysts and investors;

- the timing of launch of any future products, and the degree to which the launch and commercialization thereof meets the expectations for securities analysts and investors;

- the timing and results of clinical studies for our products;

- commencement or termination of collaborations for our product development and research programs;

- failure or discontinuation of any of our product development and research programs;

- the overall establishment of the MCED testing field and the success of future third-party tests, services, or technologies;
- results of clinical studies, or regulatory approvals (or certifications) of future diagnostic tests of third parties, or announcements about new research programs or diagnostic tests of third parties;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents, or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our research programs or clinical development programs;
- actual or anticipated changes in our estimates as to our financial results or development timelines;
- whether our financial results, forecasts, and development timelines meet the expectations of securities analysts or investors;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders, Illumina, or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems, including changes that would affect coverage and reimbursement by third-party payors;
- market conditions in the healthcare sector;
- general economic, industry, and market conditions; and
- the other factors described in this “Risk Factors” section.

Furthermore, our business profile and market capitalization may not fit the investment objectives of some Illumina shareholders and, as a result, these Illumina shareholders may sell their shares of our common stock after the Distribution. See “—Substantial sales of our common stock may occur in connection with the Spin-Off, including the disposition by Illumina of the shares of our common stock that it retains after the Spin-Off, which could cause our stock price to decline.” Low trading volume for our stock, which may occur if an active trading market does not develop, among other reasons, would amplify the effect of the above factors on our stock price volatility.

Additionally, in recent years, stock markets in general, and the market for healthcare companies in particular (including companies in the biotechnology, diagnostics, and related sectors), have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company’s securities, securities class action litigation has often been brought against that company. See “—We could be subject to securities class action litigation.”

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or securities analysts publish about us or our business. If no or few analysts commence or continue coverage of us, the trading price of our stock could decrease. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights to our technologies or our products.

We expect to seek additional capital, and may pursue fundraising paths that could include public and private equity offerings, debt financings, strategic partnerships, and alliances and licensing arrangements. We, and indirectly, our stockholders, will bear the cost of issuing and servicing securities issued in any such transactions. Because our decision to issue debt or equity securities will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any future financings. To the extent that we raise additional capital through the sale of equity or debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell, or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, we may pursue collaborations with third parties that could provide capital in the near term but limit our potential revenues or cash flows in the future. If we raise additional funds through strategic partnerships, alliances, or licensing arrangements with third parties, we may have to trade valuable rights to our technologies or our products. Certain of the foregoing transactions may require us to obtain stockholder approval, which we may not be able to obtain.

In addition, your ownership interest may be diluted in the future because of the settlement or exercise of equity-based awards that we expect to grant to our directors, officers, and other employees, including pursuant to our 2024 Equity Incentive Plan. In addition, each Cash-Based Equity Award outstanding as of the Distribution Date converted into GRAIL RSUs. We also make equity grants to certain new employees joining the Company pursuant to an inducement plan, and our compensation committee may elect to increase the number of shares available for future grant under the inducement plan without stockholder approval. We also have an Employee Stock Purchase Plan and any shares of common stock purchased pursuant to that plan will also cause dilution.

We are an emerging growth company and the information we provide shareholders may be different from information provided by other public companies, which may result in a less active trading market for our common stock and higher volatility in our stock price.

We are an “emerging growth company” as defined by the Jumpstart Our Business Startups Act of 2012. We will continue to be an emerging growth company until the earliest to occur of the following:

- the last day of the fiscal year in which our total annual gross revenues first meet or exceed $1.235 billion (as adjusted for inflation);
- the date on which we have, during the prior three-year period, issued more than $1.0 billion in non-convertible debt;
- the last day of the fiscal year in which we (i) 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 (ii) have been a reporting company under the Exchange Act for at least one year (and filed at least one annual report under the Exchange Act); or
- 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 of 1933 (the “Securities Act”).

For as long as we are an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to:

- not being required to comply with the auditor attestation requirements of the assessment of our internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act of 2002 ("SOX");
- exemption from new or revised financial accounting standards applicable to public companies until such standards are also applicable to private companies;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements, and registration statements; and
- exemptions from the requirement of holding a nonbinding advisory vote on executive compensation and shareholder approval on golden parachute compensation not previously approved.

We have chosen to take advantage of some or all of these reduced burdens. For as long as we take advantage of the reduced reporting obligations, the information we provide shareholders may be different from information provided by other public companies. In addition, it is possible that some investors will find our common stock less attractive as a result of these elections, which may result in a less active trading market for our common stock and higher volatility in our stock price.

In addition, we have elected to not take advantage of the extended transition period that allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies, which means that the financial statements we file in the future, will be subject to all new or revised accounting standards generally applicable to public companies. Our election not to take advantage of the extended transition period is irrevocable.

Substantial sales of our common stock may occur in connection with the Spin-Off, including the disposition by Illumina of the shares of our common stock that it retains after the Spin-Off, which could cause our stock price to decline.

Illumina shareholders who received shares of our common stock in the Spin-Off generally may sell those shares immediately in the public market. It is likely that some Illumina shareholders, including some of its larger shareholders, have sold or will sell their shares of our common stock received in the Spin-Off if, for reasons such as our business profile or market capitalization as an independent company, we do not fit their investment objectives, or, in the case of index funds, we are not a participant in the index in which they are investing.

Immediately following the Spin-Off on June 24, 2024, Illumina retained a 14.5% ownership interest of our common stock. In connection with the Spin-Off, we have entered into a Stockholder and Registration Rights Agreement with Illumina, pursuant to which we provide Illumina registration rights with respect to the shares of our common stock it retained following the Spin-Off. In addition, Illumina has agreed to vote any shares of our common stock that it retains in proportion to the votes cast by our other stockholders and to grant us a proxy to vote its shares of our common stock in such proportion. Pursuant to the IRS private letter ruling, Illumina expects to be required to dispose of any such shares of our common stock that it retains as soon as warranted consistent with the business reasons for the retention of such shares, but in no event later than five years after the Spin-Off. Illumina is not required to hold any retained shares for any minimum period following the Spin-Off. We are unable to predict with certainty when Illumina will dispose of a substantial number of shares of common stock. The sales of significant amounts of our common stock by Illumina or any other significant shareholders, or the perception in the market that this will occur, may decrease the market price of our common stock.

We do not expect to pay any dividends for the foreseeable future.

You should not rely on our common stock to provide dividend income. We do not anticipate that we will pay any dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, any future credit facility or debt securities may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock, and the

terms of our Separation and Distribution Agreement with Illumina entered into in connection with the Spin-Off requires us to repay portions of the disposal funding we received from Illumina in connection with the Spin-Off in the event we pay dividends.

We will incur increased costs as a result of operating as a public company. Our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. SOX Section 404, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the Listing Rules, and other applicable U.S. rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance, and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time- consuming and costly. For example, we expect that the rules and regulations applicable to us as a public company may make it more difficult and more expensive for us to obtain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to SOX Section 404, we will be required to furnish a report by our management on our internal control over financial reporting beginning with our second filing of an Annual Report on Form 10-K with the SEC after we become a public company. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with SOX Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed time frame or at all, that our internal control over financial reporting is effective as required by SOX Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Certain provisions in our Certificate of Incorporation and Bylaws and Delaware law may discourage, delay, or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Several provisions of our Certificate of Incorporation and Bylaws may discourage, delay or prevent a merger, acquisition, or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our organizational documents:

- establish that our board of directors is divided into three classes: Class I, Class II, and Class III, with each class serving staggered three-year terms;
- provide that our directors may be removed only for cause;

- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- eliminate cumulative voting in the election of directors;
- authorize our board of directors to issue shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- permit stockholders to take actions only at a duly called annual or special meeting and not by unanimous written consent;
- prohibit stockholders from calling a special meeting of stockholders;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- authorize our board of directors, by a majority vote, to amend certain provisions of the Bylaws; and
- require the affirmative vote of at least 66 2/3% or more of the outstanding shares of common stock to amend many of the provisions described above.

In addition, Section 203 of the Delaware General Corporation Law ("DGCL") prohibits a Delaware corporation from engaging in a business combination with any interested stockholder for a period of three years following the date the person became an interested stockholder, subject to certain exceptions. In general, Section 203 of the DGCL defines an "interested stockholder" as an entity or person who, together with the entity's or person's affiliates, beneficially owns, or is an affiliate of the corporation and within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation. A Delaware corporation may "opt out" of these provisions with an express provision in its certificate of incorporation. We have not opted out of Section 203 of the DGCL in our Certificate of Incorporation.

These and other provisions of our Certificate of Incorporation, Bylaws and Delaware law may discourage, delay, or prevent certain types of transactions involving an actual or a threatened acquisition or change in control of us including unsolicited takeover attempts, even though the transaction may offer our shareholders the opportunity to sell their shares of our common stock at a price above the prevailing market price.

Our Certificate of Incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or other employees.

Our Certificate of Incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any current of former directors, officers or other employees, or stockholders to us or our stockholders;
- any action asserting a claim arising pursuant to any provision of the DGCL or our amended and restated Certificate of Incorporation and Bylaws; and
- any action asserting a claim governed by the internal affairs doctrine.

However, this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, our Certificate of Incorporation also provides that unless we consent in writing to the selection of an alternative forum, the federal

district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person purchasing or otherwise acquiring or holding any interest in shares of our capital stock is deemed to have received notice of and consented to the foregoing provisions. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds more favorable for disputes with us or with our directors, officers, other employees or agents, or our other stockholders, which may discourage such lawsuits against us and such other persons. Alternatively, if a court were to find this choice of forum provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, results of operations, and financial condition.

We could be subject to additional securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us, because healthcare companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of our management's attention and resources, which could harm our business.

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

Rule 10b5-1 Trading Plans

During the quarter ended June 30, 2024, none of our directors or 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.

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 are streamlining our commercial sales forces and focusing its field-based activities on the current customers expected to be more productive and high priority opportunities. We are maintaining sales force coverage for the majority of our current Galleri volume and active prescribers. As part of this approach,we are also streamlining investments in its enterprise business, which includes our employer and life insurance businesses. Reductions in the commercial organization include management layers and commercial roles without sales responsibilities. In addition to reductions in the commercial organization, we are making reductions in medical affairs teams involved with U.S. Galleri provider engagement.

We are substantially decreasing 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 are making 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 Board's decision was based on cost-reduction initiatives intended to reduce the Company's ongoing operating expenses and maximize shareholder value.

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

In connection with the Restructuring Plan to be effected in the third and fourth quarters of 2024, we estimate that we will incur a restructuring charge in Q3 2024 in the range of approximately $18 to $23 million which consists of severance, benefits, payroll taxes, and other termination related costs, excluding an estimated net benefit in stock based compensation due to the reversal of previously recorded stock-based compensation expenses related to award cancellations. We expect the headcount reductions to enable future cost savings of approximately $120 million on an annual basis, with approximately $27 million in savings, net of severance and benefits, in 2024. We estimate that the Restructuring Plan extends our anticipated cash runway from the second half of 2026 into 2028.

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.	S-8	6/21/24	4.1	
3.2	Bylaws of GRAIL, Inc.	S-8	6/21/24	4.2	
3.3	Certificate of Conversion	8-K	6/24/24	3.3	
10.1	Tax Matters Agreement, dated June 24, 2024, between Illumina, Inc. and GRAIL, Inc.	8-K	6/24/24	10.1	
10.2	Employee Matters Agreement, dated June 24, 2024, between Illumina, Inc. and GRAIL, Inc.	8-K	6/24/24	10.2	
10.3	Stockholder and Registration Rights Agreement, dated June 24, 2024, between Illumina, Inc. and GRAIL, Inc.	8-K	6/24/24	10.3	
10.4	Fourth Amendment to the Amended and Restated Supply and Commercialization Agreement, dated June 24, 2024, by and between Illumina, Inc. and GRAIL, Inc.	8-K	6/24/24	10.4	
10.5	Form of Indemnification Agreement	10-12B/A	5/29/24	10.11	
10.6	GRAIL, Inc. 2024 Incentive Award Plan	8-K/A	7/2/24	10.1	
10.7	GRAIL, Inc. Employee Stock Purchase Plan	8-K/A	7/2/24	10.2	
10.8	Non-Employee Director Compensation Plan	8-K/A	7/2/24	10.3	
10.9	Form of Restricted Stock Unit Agreement	S-8	6/21/24	99.2	
10.10	Form of Stock Option Agreement	10-12B/A	5/29/24	10.10	
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.				X
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.				X
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.				X
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.				X
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				X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				X

+ 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.

SIGNATURE

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: August 13, 2024

By: /s/ Robert Ragusa

Robert Ragusa
Chief Executive Officer
(Principal Executive Officer)

Date: August 13, 2024

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: August 13, 2024

/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: August 13, 2024

/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 June 30, 2024, 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: August 13, 2024

/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 June 30, 2024, 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: August 13, 2024

/s/ Aaron Freidin
Aaron Freidin
Chief Financial Officer