Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

As confidentially submitted to the Securities and Exchange Commission on March 8, 2024 as Amendment No. 2 to the initial confidential submission. This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

File No.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Amendment No. 2
to
Form 10

GENERAL FORM
FOR REGISTRATION OF SECURITIES
Pursuant to Section 12(b) or (g) of
the Securities Exchange Act of 1934

GRAIL, LLC
to be converted as described herein into a corporation named

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)**

Registrant's telephone number, including area code:
(833) 694-2553

Copies to:

Illumina, Inc.	**Cravath, Swaine & Moore LLP**	**GRAIL, Inc.**	**Latham & Watkins LLP**
5200 Illumina Way	**Worldwide Plaza**	**1525 O'Brien Drive**	**355 South Grand Avenue, Suite 100**
San Diego, CA 92122	**825 Eighth Avenue**	**Menlo Park, California**	**Los Angeles, California 90071**
(858) 202-4500	**New York, New York 10019**	**(833) 694-2553**	**(213) 485-1234**
Attn: Charles E. Dadswell,	**(212) 474-1000**	**Attn: Abram Barth,**	**Attn: W. Alex Voxman**
General Counsel and Secretary	**Attn: Andrew J. Pitts**	**General Counsel**	**Andrew Clark**
	Ting S. Chen		**Ross McAloon**
	Daniel J. Cerqueira		**Alexa Berlin**

Securities to be registered pursuant to Section 12(b) of the Act:

Title of Each Class to be so Registered	**Name of Each Exchange on Which Each Class is to be Registered**
Common stock, par value $0.001 per share	**The Nasdaq Stock Market LLC**

Securities to be registered pursuant to Section 12(g) of the Act: None.

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 checkmark 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. ☒

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EXPLANATORY NOTE

GRAIL, LLC, the registrant whose name appears on the cover of this Form 10 registration statement, is a Delaware limited liability company. Prior to the completion of the Spin-Off, GRAIL, LLC will be converted into a Delaware corporation and will be renamed GRAIL, Inc. References to "GRAIL" in this Form 10 registration statement are to GRAIL, LLC prior to the effective time of such conversion and to GRAIL, Inc. on and after the effective time of such conversion.

GRAIL is a wholly owned subsidiary of Illumina, Inc. ("Illumina"). On August 18, 2021, Illumina acquired GRAIL. The acquisition is subject to ongoing legal proceedings and, on September 6, 2022, the European Commission adopted an order prohibiting Illumina's acquisition of GRAIL. On October 12, 2023, the European Commission adopted a decision requiring Illumina to divest GRAIL and imposing transitional measures providing that GRAIL must be held and operated separately and independently from Illumina.

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GRAIL, LLC
Information Required in Registration Statement
Cross-Reference Sheet Between the Information Statement and Items of Form 10

This Registration Statement on Form 10 incorporates by reference information contained in our Information Statement filed as Exhibit 99.1 to this Form 10. For your convenience, we have provided below a cross-reference sheet identifying where the items required by Form 10 can be found in the Information Statement.

Item No.	Caption	Location in Information Statement
1.	Business	See "Summary," "Risk Factors," "Cautionary Statement Concerning Forward-Looking Statements," "The Spin-Off," "Business," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Where You Can Find More Information"
1A.	Risk Factors	See "Summary," "Risk Factors," and "Cautionary Statement Concerning Forward-Looking Statements"
2.	Financial Information	See "Summary," "Risk Factors," "Capitalization," "Selected Historical Financial Data," "Unaudited Pro Forma Condensed Consolidated Financial Information," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Index to Consolidated Financial Statements"
3.	Properties	See "Business—Properties"
4.	Security Ownership of Certain Beneficial Owners and Management	See "Security Ownership of Certain Beneficial Owners and Management"
5.	Directors and Executive Officers	See "Management"
6.	Executive Compensation	See "Management" and "Executive Compensation"
7.	Certain Relationships and Related Transactions, and Director Independence	See "Risk Factors," "The Spin-Off," "Management," and "Certain Relationships and Related Party Transactions"
8.	Legal Proceedings	See "Business—Legal Proceedings"
9.	Market Price of and Dividends on the Registrant's Common Equity and Related Stockholder Matters	See "Summary," "The Spin-Off," "Dividend Policy," "Security Ownership of Certain Beneficial Owners and Management," and "Description of Our Capital Stock"
10.	Recent Sales of Unregistered Securities	See "Description of Our Capital Stock"
11.	Description of Registrant's Securities to be Registered	See "Description of Our Capital Stock"

Item No.	Caption	Location in Information Statement
12.	Indemnification of Directors and Officers	See "Description of Our Capital Stock" and "Certain Relationships and Related Party Transactions—Agreements with Illumina—Separation and Distribution Agreement"
13.	Financial Statements and Supplementary Data	See "Summary," "Selected Historical Financial Data," "Unaudited Pro Forma Condensed Consolidated Financial Information," and "Index to Consolidated Financial Statements" and the consolidated financial statements referenced therein
14.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	Not applicable
15.	Financial Statements and Exhibits	(a) Consolidated Financial Statements See "Unaudited Pro Forma Consolidated Condensed Financial Information" and "Index to Consolidated Financial Statements" and the consolidated financial statements referenced therein (b) Exhibits See below

The following documents are filed as exhibits hereto:

Exhibit Number	Exhibit Description
2.1	Form of Separation and Distribution Agreement between GRAIL, LLC and Illumina, Inc.*
3.1	Form of Certificate of Incorporation of GRAIL, Inc.*
3.2	Form of Bylaws of GRAIL, Inc.*
10.1	Form of Tax Matters Agreement between GRAIL, LLC and Illumina, Inc.*
10.2	Form of Stockholder and Registration Rights Agreement between GRAIL, LLC and Illumina, Inc.*
10.3	Agreement and Plan of Merger, dated as of September 20, 2020, among Illumina, Inc., SDG Ops, Inc., SDG Ops, LLC and GRAIL, Inc.†
10.4	Amendment to the Agreement and Plan of Merger, dated as of September 20, 2020, among Illumina, Inc., SDG Ops, Inc., SDG Ops, LLC and GRAIL, Inc., dated as of February 4, 2021†
10.5	Amended and Restated Supply and Commercialization Agreement, dated as of February 28, 2017, by and between Illumina, Inc. and GRAIL, Inc., as amended on September 27, 2017 and on August 18, 2021*
10.6	Third Amendment to the Amended and Restated Supply and Commercialization Agreement, dated as of , by and between Illumina, Inc. and GRAIL, LLC.*
10.7	Form of 2024 Incentive Award Plan+*
10.8	Form of Long-term Incentive Award Agreement+*
10.9	Form of Indemnification Agreement between GRAIL, LLC and each of its directors and executive officers+*
10.10	Form of Change of Control and Severance Agreement between GRAIL, LLC and each of its executive officers+*
10.11	Form of 2024 Employee Stock Purchase Plan+*
10.12	Employment Offer Letter, between GRAIL, LLC and Robert Ragusa, dated October 14, 2021+*
10.13	Letter Agreement, between GRAIL, Inc. and Aaron Freidin, dated July 5, 2018+*
10.14	Employment Offer Letter, between GRAIL, Inc. and Josh Ofman, dated May 13, 2019+*
10.15	License Agreement by and between The Chinese University of Hong Kong and Cirina Limited (No. TC1510005), dated as of April 7, 2016, as amended May 29, 2017*
10.16	License Agreement by and between The Chinese University of Hong Kong and Cirina Limited (No. TC1510006), dated as of April 7, 2016, as amended May 29, 2017*
10.17	License Agreement by and between The Chinese University of Hong Kong and Cirina Limited (No. TC1711655), dated as of May 29, 2017*
10.18	License Agreement by and between The Chinese University of Hong Kong and Cirina Limited (No. TC1711656), dated as of May 29, 2017*
10.19	License Agreement by and between The Chinese University of Hong Kong and Cirina Limited (No. TC1711657), dated as of May 29, 2017*
10.20	Lease by and between MENLO PREHC I, LLC, MENLO PREPI I, LLC, TPI Investors 9, LLC and GRAIL, Inc., dated as of May 5, 2016*
10.21	First Amendment to Lease among MENLO PREHC I, LLC, MENLO PREPI I, LLC, TPI Investors 9, LLC and GRAIL, Inc., dated as of June 8, 2017*
10.22	Lease Agreement by and between PP Office Owner 1, L.P. and GRAIL, Inc., dated as of June 4, 2020*
21.1	List of subsidiaries of GRAIL, Inc.†
99.1	Preliminary Information Statement of GRAIL, LLC, subject to completion, dated March 8, 2024

* To be filed by amendment.
\+ Indicates management contract or compensatory plan.
† Previously filed.

SIGNATURE

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant has duly caused this Registration Statement on Form 10 to be signed on its behalf by the undersigned, thereunto duly authorized.

GRAIL, LLC

By: _____
Name:
Title:

Dated:

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

Exhibit 99.1

Information contained herein is subject to completion or amendment. A Registration Statement on Form 10 relating to these securities has been confidentially submitted with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended.

PRELIMINARY AND SUBJECT TO COMPLETION, DATED , 2024

INFORMATION STATEMENT

GRAIL, LLC

1525 O'Brien Drive
Menlo Park, California 94025

Common Stock
(par value $0.001)

We are sending you this Information Statement in connection with Illumina, Inc.'s partial spin-off of its wholly owned subsidiary, GRAIL, LLC, or "GRAIL." GRAIL must be held and operated separately and independently from Illumina pursuant to the transitional measures ordered by the European Commission, following the prohibition of Illumina's acquisition of GRAIL on September 6, 2022. Prior to the completion of the spin-off, GRAIL will be converted into a Delaware corporation and will be renamed GRAIL, Inc. To effect the spin-off, Illumina, Inc., or "Illumina," will distribute at least 85.5% of the shares of GRAIL's common stock owned by Illumina as of the close of business on , 2024, which is the record date for the distribution, on a pro rata basis to the holders of Illumina common stock. Immediately after the distribution becomes effective, Illumina may retain up to 14.5% of GRAIL's common stock.

We intend that the distribution of GRAIL common stock will be tax-free to Illumina stockholders for U.S. federal income tax purposes, except for cash that stockholders receive in lieu of fractional shares and subject to the discussion below under "The Spin-Off—Material U.S. Federal Income Tax Consequences of the Spin-Off—Consequences to Holders of Illumina Common Stock." You should consult your own tax advisor as to the tax consequences of the distribution to you, including potential tax consequences under state, local and non-U.S. tax laws.

If you are a record holder of Illumina common stock as of the record date, for every share[s] of Illumina common stock you hold on that date, you will be entitled to receive share[s] of GRAIL common stock. Illumina will distribute the shares of GRAIL common stock in book-entry form, which means that we will not issue physical stock certificates. The distribution agent will not distribute any fractional shares of GRAIL common stock. Instead, the distribution agent will aggregate fractional shares into whole shares, sell the whole shares in the open market at prevailing market prices and distribute the aggregate cash proceeds of the sales, net of brokerage fees and other costs, pro rata to each holder (net of any required withholding for taxes applicable to each holder) who would otherwise have been entitled to receive a fractional share in the distribution. As discussed in the section entitled "The Spin-Off—Trading Prior to the Distribution Date" beginning on page 107 of this Information Statement, if you sell your Illumina common stock in the "regular-way" market after the record date and on or before the distribution date, you also will be selling your right to receive shares of GRAIL common stock in connection with the distribution.

We expect that the distribution will be effective as of , New York City time, on , 2024. Immediately after the distribution becomes effective, GRAIL will be an independent, publicly traded company.

Illumina's stockholders are not required to vote on or take any other action in connection with the spin-off. We are not asking you for a proxy, and request that you do not send us a proxy. Illumina's stockholders will not be required to pay any consideration for the shares of GRAIL common stock they receive in the spin-off, and they will not be required to surrender or exchange their common stock of Illumina or take any other action in connection with the spin-off.

Illumina currently owns all outstanding shares of GRAIL common stock. Accordingly, no public trading market for GRAIL common stock currently exists. We expect, however, that a limited trading market for GRAIL common stock, commonly known as a "when-issued" trading market, will develop on or shortly before the record date for the distribution, and we expect "regular-way" trading of GRAIL common stock will begin on the first trading day after the distribution date. We intend to list the GRAIL common stock on the Nasdaq Global Select Market under the ticker symbol "GRAL." Following the distribution, Illumina will continue to trade on the Nasdaq Global Select Market under the ticker symbol "ILMN."

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012.

In reviewing this Information Statement, you should carefully consider the matters described in the section entitled "Risk Factors" beginning on page 30 of this Information Statement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this Information Statement is truthful or complete. Any representation to the contrary is a criminal offense.

This Information Statement is not an offer to sell, or a solicitation of an offer to buy, any securities.

The date of this Information Statement is , 2024.

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INDUSTRY AND MARKET DATA

Unless otherwise indicated, information contained in this Information Statement concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity, and market size, is based on information from various sources on assumptions that we have made that are based on such information and other, similar sources and on our knowledge of, and expectations about, the markets for our products. This information involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. While we believe the market position, market opportunity, and market size information included in this Information Statement is generally reliable, such information is inherently imprecise. In addition, projections, assumptions, and estimates of our future performance and the future performance of the industry in which we operate is necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section entitled "Risk Factors" and elsewhere in this Information Statement. These and other factors could cause results to differ materially from those expressed in the estimates made by independent third parties and by us.

TRADEMARKS AND COPYRIGHTS

"GRAIL," the GRAIL logos, "Galleri" and other trade names, trademarks or service marks of GRAIL appearing in this Information Statement are the property of GRAIL. GRAIL also owns or has the rights to copyrights that protect the content of its products. Other trade names, trademarks, service marks or copyrights appearing in this Information Statement are the property of their respective holders. Solely for convenience, trade names, trademarks, service marks, and copyrights referred to in this Information Statement appear without the ®, ™, SM, and © symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trade names, trademarks, service marks, and copyrights.

BASIS OF FINANCIAL PRESENTATION

Illumina acquired the common stock of GRAIL that it did not own and completed its acquisition of GRAIL on August 18, 2021. Our consolidated balance sheets as of December 31, 2023 and January 1, 2023, and our consolidated statements of operations, comprehensive loss, and cash flows for the period from January 2, 2022 to January 1, 2023, the period from January 2, 2023 to December 31, 2023, and the period from August 19, 2021 to January 2, 2022 (the "Successor") reflect the new basis of accounting established in connection with the acquisition of GRAIL on August 18, 2021 and for the period from January 1, 2021 to August 18, 2021 (the "Predecessor") reflect the predecessor activity of GRAIL prior to the acquisition. A black line distinguishes the periods before and after the acquisition of GRAIL because these periods are not comparable.

Prior to the acquisition, we had a fiscal year end of December 31, which we will revert back to upon the closing of the Spin-Off. Illumina, and, by proxy, us following the acquisition and prior to the Spin-Off, use a 52-53 week fiscal year-end calendar that ends on the Sunday closest to the quarter-end, so the exact year-end date may change from year to year. In this Information Statement when we discuss our financial results:

- references to 2023 refer to the fiscal year ended December 31, 2023, which was 52 weeks;
- references to 2022 refer to the fiscal year ended January 1, 2023, which was 52 weeks; and
- references to 2021 refer either to the Predecessor period from January 1, 2021 to August 18, 2021 (the "2021 predecessor period"), or the Successor period from August 19, 2021 to January 2, 2022 (the "2021 successor period").

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SUMMARY

This summary highlights selected information from this Information Statement and provides an overview of our company, our separation from Illumina and Illumina's distribution of our common stock to its stockholders. For a more complete understanding of our business and the spin-off, you should read the entire Information Statement carefully, particularly the discussion of "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operation" beginning on pages 30 and 176, respectively, of this Information Statement, and our historical consolidated financial statements and the notes to those financial statements appearing elsewhere in this Information Statement.

In this Information Statement, unless the context otherwise requires:

- "GRAIL," "we," "our," and "us" refer to GRAIL, LLC and its consolidated subsidiaries prior to the effective time of its conversion to a corporation and to GRAIL, Inc. and its consolidated subsidiaries on and after the effective time of such conversion;
- "Illumina" refers to Illumina, Inc. and its consolidated subsidiaries other than, for all periods following the Spin-Off (as defined below), GRAIL;
- the "Distribution" refers to the transaction in which Illumina will distribute to its stockholders at least 85.5% of the shares of our common stock owned by Illumina;
- the "Distribution Date" refers to the date on which the Distribution occurs; and
- the "Spin-Off" refers to the transaction in which we will be separated from Illumina.

Our Company

Our mission is to detect cancer early, when it can be cured.

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 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, which can help guide next steps for diagnosis, and yield high positive predictive values and low false positive rates, all from a simple blood draw. We launched Galleri in the United States in mid-2021. As of December 31, 2023, we have sold more than 150,000 commercial tests and established over 100 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.

Cancer is a major public health crisis. It is the second leading cause of death both in the United States and worldwide. Most cancers that result in death are diagnosed too late, in advanced stages when they are most challenging to treat. We estimate that more than 60% of cancer deaths result from cancers that have no recommended screening guidelines. In the United States, we consider standard of care screening for cancer to consist of the grade A and B recommendations published by the United States Preventive Services Task Force ("USPSTF"), which currently recommend broad population screening for only four types of cancer using single-cancer screening tests (breast, cervical, colorectal, and lung cancer), and prostate cancer screening, which is USPSTF grade C and is widely implemented in the United States. Grade A and B recommendations are services

that USPSTF most highly recommends for preventative care and that have a high or moderate net benefit for patients. Grade C recommendations are services that USPSTF recommends selectively offering or providing to patients based on individual circumstances and that have a moderate certainty of a small net benefit for patients. According to data in the American Cancer Society's *Cancer Facts & Figures 2024*, cancers for which there are grade A and B recommendations published by the USPSTF (breast, cervical, colorectal, and lung cancer) are expected to result in approximately 225,000 deaths out of approximately 612,000 cancer-related deaths in the United States in 2024, and prostate cancer is expected to resulted in approximately 35,000 additional deaths. We believe that expanding upon these current guidelines to screen individuals for many types of cancer with a single test represents a significant opportunity to reduce cancer mortality and the cost of cancer care. In 2021, we published modeling data in *Cancer Epidemiology, Biomarkers & Prevention* (Cancer Epidemiol Biomarkers Prev. 2021; 30:460–8) that estimated the potential impact of MCED testing on mortality reduction based on test performance in our CCGA-2 study and using 2006 to 2015 data from the Surveillance, Epidemiology, and End Results Program of the U.S. National Cancer Institute ("SEER") for ages 50-79. Based on this model, we estimate that by adding Galleri to the five standard of care single-cancer screening tests (breast, cervical, colorectal, lung cancer, and prostate), there is potential to detect many more cancers at an earlier stage, which could translate into the potential to avert approximately 100,000 deaths per year in the United States as measured by five-year survival. In addition, an analysis published in *Data* (Data. 2017; 2(30):2–16) estimated that diagnosing cancer early could result in $26 billion in annual cost-savings in the United States.

We designed Galleri to detect cancer early. If cancer is detected early, it is more amenable to curative treatment. Galleri works by detecting DNA fragments shed into the bloodstream by tumor cells. In cancerous cells, methylation, a natural biological process that determines which sections of DNA to turn on or off and that drives tissue differentiation, becomes abnormal. As a result, DNA from cancer has specific methylation patterns that can be used to both identify a general cancer signal and localize that signal to a specific organ or tissue type. In our CCGA study, Galleri identified a shared cancer signal across more than 50 types of cancer, often at an early stage. If a cancer signal is detected, Galleri can accurately predict the tissue type or organ associated with the cancer signal (the cancer signal origin). In our PATHFINDER study, Galleri correctly predicted the first or second cancer signal origins in 22 of 25 participants with a cancer diagnosis following a cancer signal detected (positive) test result (*i.e.*, participants with true positive test results), demonstrating a high cancer signal origin prediction accuracy of 88%. Test results are then used by healthcare providers to guide follow-up diagnostic testing.

As an early proponent of MCED testing, we have established strong relationships within the cancer and primary care community, including through partnerships with academic and community medical centers, key opinion leaders, and governmental policy and advocacy partners. We have shared evidence supporting our MCED testing at renowned medical conferences, such as the American Association of Cancer Research ("AACR"), American Society of Clinical Oncology ("ASCO"), European Society of Medical Oncology ("ESMO"), and American Academy of Family Physicians ("AAFP"). We have also published results from our studies in leading scientific and medical journals, including *The Lancet*, *Nature*, *Nature Medicine*, *Cancer Cell*, and *The Lancet Oncology*. Our industry leadership has been recognized with multiple national high profile accolades, including being acknowledged by *Time Magazine* as one of the Best Inventions of 2022 and *The Atlantic* as one of the top breakthroughs of 2022, and being named in *Fast Company* World Changing Ideas of 2022 and in the *Fortune* Change the World List in 2023.

To support broad access for Galleri in the United States, we plan to complete a premarket approval application ("PMA") submission with the U.S. Food and Drug Administration (the "FDA") in . We seek to use data from the NHS-Galleri Trial, together with data from our PATHFINDER 2 study, as well as supplemental data from other clinical studies, to support our planned PMA submission for Galleri in the United States. We believe that FDA approval could unlock broad coverage by large commercial payors in the United States. 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. We are working with stakeholders to advance and shape the public reimbursement landscape to cover MCED screening for FDA-approved MCED tests. Galleri has not been approved or cleared by the FDA and obtaining PMA approval can take several years from the time a premarket application is submitted. 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. Following FDA approval, we also expect to pursue inclusion of Galleri in the USPSTF's guideline recommendation, although such inclusion is not certain even with FDA approval. In the United Kingdom, we are working with NHS England to complete our NHS-Galleri Trial. Subject to results of an early analysis from the first screening test (the prevalent screening round) representing one year of results out of the three-year trial period, the NHS may commence phased commercial implementation in England, beginning with a two-year pilot, and with the potential for further expansion subject to final results from the trial. We believe our work with the NHS and the 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.

Since our founding, we have undertaken a rigorous approach to identify in a blood sample the most informative markers of cancer through what we believe is the largest clinical program in genomic medicine to date. We are collecting population-scale clinical data from more than 385,000 participants across nine clinical studies, with more than 21,000 of these participants included in the studies that supported the development and launch of Galleri, and over 165,000 individuals enrolled and an additional approximately 60,000 anticipated to be enrolled in interventional studies (NHS-Galleri and PATHFINDER 2, which support our PMA submission, and the first-of-its kind Galleri-Medicare real-world study). These studies include our foundational case-control CCGA study to develop and validate our MCED technology, multiple large-scale observational studies in asymptomatic individuals, and multiple large-scale interventional studies in intended use populations. Our interventional studies include our NHS-Galleri Trial, which is the first and largest randomized controlled trial of an MCED test, and which enrolled more than 140,000 individuals in just over 10 months. These studies also include our initiation of the Real-world Evidence to Advance multi-Cancer early detection Health equity ("REACH") interventional study. This first-of-its kind real-world "Galleri-Medicare" study will further evaluate the clinical impact of the Galleri multi-cancer early detection test among Medicare beneficiaries, including racial and ethnic minorities, and seniors from historically underserved communities. Through these studies and our ongoing collection of real-world data, we have built what we believe is an unprecedented longitudinal dataset of high quality, linked clinical and genomic data. We believe our clinical studies, including our early discovery work, have demonstrated robust and reproducible test performance. Notably, data from our interventional PATHFINDER study, including positive predictive value ("PPV"), cancer signal original prediction accuracy, and specificity, were generally consistent with data from our case-control CCGA study, which is evidence supporting the generalizability and robustness of Galleri in an interventional study involving analysis of returned Galleri results on clinical diagnostic and care pathways, outside of the foundational case-control context. Specifically, the 43% positive predictive value ("PPV") achieved in the study is similar to our previously published modeled PPV of 44% based on test performance in our CCGA study extrapolated to a potential representative population aged 50-79 based on 2016 to 2017 SEER data. We extrapolated the CCGA-based modeled PPV to a representative population due to the limitations of measuring PPV in a case controlled study with enrichment of cancer cases in the sample set, whereas the PATHFINDER study was performed in an intended use population and PPV was measured directly. We expect to continue to report ongoing and long-term follow-up clinical data from these studies over many years.

Based on our extensive discovery work, we believe that a targeted methylation approach, which entails interrogating specific methylation sites within a genome to assess methylation patterns and which serves as the technological basis for our Galleri test, is the best approach for detecting a cancer signal and identifying a cancer signal origin. In our head-to-head analyses we compared multiple different classifiers that were trained to detect a cancer signal and predict the cancer signal origin, and which were independently validated. We found that interrogating methylation patterns yielded significantly better results for cancer detection (based on sensitivity,

cancer signal origin prediction accuracy, and clinical limit of detection (a measure of the how much signal must exist in order to be detected)) than was observed by interrogating mutations (changes in a DNA sequence), chromosomal alterations (changes to the structure or number of chromosomes, which are strands of genetic material), fragment lengths (differences in length of DNA fragments), and other genomic features, either alone or in combination. In contrast to well-established cancer mutations that only affect a handful of genomic locations, there are nearly 30 million methylation sites across the human genome, making them a ubiquitous and rich signal for cancer detection. After comprehensive analysis of whole-genome methylation patterns in connection with our CCGA study, we discovered highly informative and low-noise methylation sites for cancer signal and cancer signal origin detection. Highly informative sites are likely to have abnormal methylation patterns resulting from cancer, and low-noise sites are less likely to be subject to confounding signals from biological noise resulting from confounding conditions (such as aging, inflammatory conditions) and circulating DNA from non-cancerous cells. This discovery led to our development of a targeted methylation approach. Our targeted methylation approach can detect lower levels of cancer signal in blood compared to the other approaches we examined, enabling early cancer detection in asymptomatic individuals more efficiently compared to whole-genome methylation. Our targeted methylation assay had a clinical limit of detection of approximately 150 parts per million, which was significantly lower than other approaches we assessed. For additional information, see "Business—Methylation Technology Platform."

Our proprietary targeted methylation platform, as well as our growing body of clinical and real-world data, have provided us with unique insights into cancer biology that enable development of products beyond asymptomatic screening. We are leveraging our proprietary platform for additional applications, including:

- *Precision oncology portfolio:* We are developing our precision oncology portfolio and launched our research use only ("RUO") targeted methylation platform with customizable classifiers in 2023. We have partnered with a number of leading oncology therapeutics companies to test applications of biomarkers with the goal of optimizing the use of therapeutic interventions. Some of our partnerships also include development of customized applications to support clinical studies and companion diagnostic development and commercialization. Potential applications for our technology in a precision oncology setting include pre-treatment prognosis, post-treatment prognosis or minimal residual disease ("MRD"), biomarker discovery, detection of recurrence, and clinical monitoring. We believe the research and clinical development settings represent significant opportunities with biopharmaceutical companies given the large number of ongoing oncology studies and the significant need to identify residual disease or recurrence early and help inform treatment decisions. In addition to companion diagnostic opportunities, we believe that our methylation platform could enable standalone clinical products and support patient care across the cancer care continuum.
- *Diagnostic aid for cancer test*: We are developing our diagnostic aid for cancer ("DAC") test to accelerate diagnostic resolution for patients with non-specific signs and symptoms, but with a clinical suspicion of cancer. Through a simple blood test, DAC is designed to provide physicians with a powerful decision-making tool to aid diagnosis, achieve resolution more quickly, and avoid unnecessary workups. Symptomatic detection of cancer is a significant unmet need; we estimate that approximately 16 million patients in the United States present with non-specific signs and symptoms each year. Data from our SYMPLIFY study published in *The Lancet Oncology* showed that, in a symptomatic patient population, our methylation technology was able to detect many cancer types and accurately identify where the cancer signal origin was located in the body. In our SYMPLIFY study, our technology correctly predicted the first or second cancer signal origins in 214 of 237 participants with a cancer diagnosis following a cancer signal detected (positive) test result (*i.e.*, participants with true positive test results), demonstrating a high cancer signal origin prediction accuracy of 90%. Product development efforts are ongoing, and we currently consider the launch of our DAC test as a medium- to longer-term objective, subject to a number of factors, including determining the requirements for reimbursement in the United States.

We believe these products and other future products in development have the potential to reach additional customers and may result in additional patient care solutions across the cancer care continuum.

Our Strengths

We believe our continued growth will be driven by the following strengths:

- **Our clinically-validated, commercially available, MCED test, Galleri.** Galleri is a commercially available MCED test that is setting the standard for multi-cancer early detection. We believe Galleri is clinically validated based on the results of its clinical studies completed to date. From a simple blood draw, Galleri can detect a cancer signal shared by over 50 types of cancer, over 45 of which do not have recommended screening guidelines. We believe Galleri enables the early detection of cancer in asymptomatic individuals by screening for multiple types of cancer, and in clinical studies has demonstrated a high positive predictive value ("PPV") and a low false positive rate, and an ability to predict the location of the suspected cancer with high accuracy (88%), which can help guide an efficient diagnostic evaluation. Further, as Galleri relies on a blood draw, the test can be integrated into existing care pathways, such as annual health checks, which can enable wide scale implementation and increase access to cancer screening, thus helping to address well-known disparities in cancer care. Our industry leadership in MCED testing has been recognized with multiple national high profile accolades, including being acknowledged by *Time Magazine* as one of the Best Inventions of 2022 and *The Atlantic* as one of the top breakthroughs of 2022, and being named in *Fast Company* World Changing Ideas of 2022 and in the *Fortune* Change the World List in 2023.
- **Our established commercial leadership is driving the development of a significant market.** The commercial opportunity for Galleri is significant, with more than 300 million individuals globally over the age of 50 (our intended use population), including more than 100 million individuals in the United States. We launched Galleri in the United States in mid-2021. As of December 31, 2023, we have sold more than 150,000 commercial tests and established over 100 commercial partnerships, including leading healthcare systems, employers, payors, and life insurance providers. In this real-world setting, Galleri is detecting deadly cancers in early stages. As an early proponent of MCED testing, we have established strong relationships within the cancer and primary care community, including through partnerships with academic and community medical centers, key opinion leaders, and governmental policy and advocacy partners. Our partnership with the NHS presents an opportunity to drive further adoption of Galleri, including by payors and health systems around the world. Subject to the results of an early analysis from the first screening test (the prevalent screening round) in the NHS-Galleri Trial, the NHS may commence phased commercial implementation in England, beginning with a two-year pilot, and with the potential for further expansion subject to final results from the trial. Our commercial leadership is further supported by our high-capacity laboratories to enable population screening volumes.
- **Clinical validation through unprecedented clinical studies and real-world experience.** We designed and executed what we believe is the largest clinical program in genomic medicine to date. We are collecting population-scale clinical data from more than 385,000 participants across nine clinical studies, with more than 21,000 of these participants included in the studies that supported the development and launch of Galleri, and over 165,000 individuals enrolled and an additional approximately 60,000 anticipated to be enrolled in interventional studies (NHS-Galleri and PATHFINDER 2, which support our PMA submission, and the first-of-its kind Galleri-Medicare real-world study). These studies include our foundational case-control CCGA study to develop and validate our MCED technology, multiple large-scale observational studies in asymptomatic individuals, and multiple large-scale interventional studies. Our interventional studies include our NHS-Galleri Trial, which is the first and largest randomized controlled trial of an MCED test, and which enrolled more

than 140,000 individuals in just over 10 months. Through these studies and our ongoing collection of real-world data, we have built what we believe is an unprecedented longitudinal dataset of high quality, linked clinical and genomic data. We believe our clinical studies, including our early discovery work, have demonstrated robust and reproducible test performance. Notably, data, including PPV, cancer signal original prediction accuracy, and specificity, from our interventional PATHFINDER study, which involved analysis of diagnostic and care pathways outside of the case-control context, were generally consistent with data from our case-control CCGA study, which is evidence supporting the generalizability and robustness of Galleri. Together with our partners at leading community and academic medical centers in the United States and United Kingdom, we expect to continue to report ongoing and long-term follow-up clinical data from these studies over many years.

- **Our highly-differentiated methylation platform, which enables product opportunities across the cancer care continuum.** We have taken a scientifically rigorous approach to develop a deep and comprehensive understanding of cancer biology. We built an atlas to characterize the landscape of cell-free nucleic acids ("cfDNA") across a broad and diverse population and in individuals with and without cancer. We then used this atlas and other data to train our machine learning algorithms to recognize methylation patterns indicative of cancer and accurately predict the cancer signal origin. These efforts supported the development of our proprietary methylation platform on which Galleri is based, and which we will continue to leverage to advance a number of clinical applications across the cancer care continuum. For example, we developed and launched our post-diagnosis RUO offering and are working closely with biopharmaceutical companies to develop products and services to optimize treatment once a cancer has been diagnosed. Potential applications for our technology in a post-diagnosis setting include pre-treatment prognosis, post-treatment prognosis or MRD, biomarker discovery, detection of recurrence, and clinical monitoring. We are also developing our DAC test to enable faster diagnosis and care for patients presenting with non-specific symptoms that are suspicious for cancer.
- **Our intellectual property portfolio.** We own or license exclusive worldwide commercial rights to intellectual property covering Galleri and our products in development. Specifically, as of December 31, 2023, we have exclusive licenses to more than 470 granted patents globally, and own or co-own more than 120 issued patents, with more than 800 pending patent applications (licensed, owned, or co-owned) covering methylation and other technologies. In addition, our patents, trade secrets, and know-how provide broad intellectual property coverage for our products, including chemistry, bioinformatics, and machine learning algorithms used in Galleri and our product development pipeline. Our exclusively licensed patents will begin to expire in 2027. Our owned or co-owned patents will begin to expire in 2037.
- **Our highly experienced and multidisciplinary team.** Since our founding, we have built an entrepreneurial culture driven to improve outcomes for cancer patients. We are led by a multidisciplinary team with extensive experience across biotechnology, life sciences, public health, genomics, computer science, data science, biostatistics, clinical development, medical affairs, government and regulatory affairs, quality assurance, and laboratory and commercial operations. We believe this confluence of talent from multiple disciplines has enabled us to make significant progress in improving cancer care and will enable us to remain at the forefront of our industry.

Our Strategy

Key elements of our strategy include:

- **Establishing Galleri as the population multi-cancer screening standard and extending commercial leadership in large global markets.** We believe we have an unprecedented opportunity to establish a new standard of care by adding Galleri to existing single-cancer screenings, and establish

and maintain the market leading position in cancer detection. The commercial opportunity for Galleri is significant, with more than 300 million individuals globally over the age of 50, including over 100 million individuals in the United States. Our goal is to address cancer screening globally, beginning in large markets with established health systems, such as the United States and United Kingdom, and thereafter extending to other markets. We will continue to engage with key opinion leaders, healthcare providers, advocacy organizations, regulators, and payors to help drive broader scientific and commercial endorsement worldwide. In addition, we believe Galleri's performance will drive clinical outcomes and high patient and provider satisfaction that will lead to further awareness and adoption.

- **Expanding access to our products by pursuing reimbursement and coverage from payors.** Our ability to impact cancer outcomes will be accelerated in markets where we secure reimbursement for our products. 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. In the United States, we have established private reimbursement from over 80 self-insured employers and multiple payors and health systems as of December 31, 2023, but do not currently have broad coverage and reimbursement by government healthcare programs, such as Medicare. To support broad access for Galleri in the United States, we plan to complete a PMA submission with the FDA in . We seek to use data from the NHS-Galleri Trial, together with data from our PATHFINDER 2 study, as well as supplemental data from other clinical studies, to support our planned PMA submission for Galleri in the United States. We believe that FDA approval could unlock large commercial payors in the United States and we are working with stakeholders to advance and shape the public reimbursement landscape in the United States to enable coverage of FDA-approved MCED tests by Medicare. Galleri has not been approved or cleared by the FDA and obtaining PMA approval can take several years, if at all, from the time a premarket application is submitted. 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. Following FDA approval, we also expect to pursue inclusion of Galleri in the USPSTF's guideline recommendation, although such inclusion is not certain even with FDA approval. In the United Kingdom, we are working with NHS England to complete our NHS-Galleri Trial. Subject to results of an early analysis from the first screening test (the prevalent screening round) representing one year of results out of the three-year trial period, the NHS may commence phased commercial implementation in England, beginning with a two-year pilot, and with the potential for further expansion subject to final results from the trial. We believe our work with the NHS and the 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. We will continue to invest in clinical evidence generation and work with regulatory bodies and payors in our target markets to expand coverage for early cancer screening and to increase access.
- **Defining, leading, and expanding adoption of MCED.** We coined the term "multi-cancer early detection" and will continue to drive MCED as a solution to one of healthcare's most important challenges. Since our inception in 2016, we have established and maintained a leading voice regarding the early detection of multiple cancer types in peer-reviewed literature. As of December 31, 2023, we have published more than 60 manuscripts, including in high profile journals like *The Lancet*, *Nature*, *Nature Medicine*, *Cancer Cell*, and *The Lancet Oncology*. We have also presented our data in more than 20 podium and 170 poster presentations at renowned medical conferences, including AACR, ASCO, ESMO, and AAFP. We fund medical education programs for MCED and intend to continue to educate healthcare providers, as well as key opinion leaders, regulators, professional societies, and policymakers on the clinical benefits and public health impact of MCED. In addition, we believe this

market development strategy will drive adoption of our products and further awareness of the benefits of MCED testing generally.

- **Driving cutting edge science and technology to continuously improve existing products and develop new products.** Our methylation platform and extensive technological infrastructure, together with expansive ongoing data collection, will continue to drive improvements to Galleri and enable the development of additional products. Our technology has broad applicability in cancer detection and management, and findings from our SYMPLIFY study demonstrated the potential of our platform to extend beyond asymptomatic screening, into symptomatic detection. We launched our RUO offering, a part of our precision oncology portfolio, in 2023, which has formed the basis of additional biopharmaceutical partnerships to enable further discovery and execution of new development programs. In addition, these partnerships have generated findings that support expansion into precision oncology applications, including pre-and post-treatment prognosis, recurrence detection, and clinical monitoring. We continually seek to enhance the performance of our products through a comprehensive, rigorous approach to ongoing classifier training, improvement of features, and reduced processing time and cost. We will continue to improve our technologies and launch innovative products across the cancer care continuum.
- **Leveraging our existing infrastructure to enable and scale our growing business.** Over the last several years, we have made significant investments to build a scalable infrastructure capable of meeting significant demand while satisfying stringent certification parameters. Our high-capacity laboratories are accredited by the College of American Pathologists ("CAP") and certified by the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") and the New York Department of Health, which represent one of the most rigorous levels of validation required for laboratory developed tests. Our facilities are able to process a substantial number of tests per year. In addition, we engineered custom technology infrastructure and cloud-based tools to enable scalable data collection and analysis capabilities. Our ability to collect, manage, and integrate high-quality genomic and clinical data is central to our business, and our automated laboratory workflows and processes enable high volumes of tests and samples to be processed automatically with high efficiency and speed and low failure rates. As demand for our products increases, we expect to leverage the scale efficiencies of our infrastructure and platform technology, which we believe will positively impact margins over time.
- **Sustaining a patient-first corporate culture that champions diversity.** We have built a multi-disciplinary organization of leading scientists, engineers, and clinicians driven to improve outcomes for cancer patients. In our pursuit to improve cancer care and solve one of healthcare's most important challenges, we intend to grow our diversity among employees and will continue to foster an agile and inclusive environment that is a destination for world-class talent. We believe our mission, values, and leadership attributes all contribute to this vibrant and inclusive culture and serve as a powerful magnet for talent.

Risk Factors

Ownership of GRAIL common stock is subject to numerous risks, including risks relating to the Spin-Off. The following list of risk factors is not exhaustive. Please read the information in the section entitled "Risk Factors" beginning on page 30 of this Information Statement for a more thorough description of these and other risks.

Risks Relating to Our Business and Industry

- 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.

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- 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 net losses were $1.5 billion, $5.4 billion, $911.5 million and $336.2 million for fiscal year 2023 (which includes $718.5 million in goodwill and intangible impairment), fiscal year 2022 (which includes $4.7 billion in goodwill impairment), the 2021 successor period, and the 2021 predecessor period, respectively, and as of December 31, 2023, we had an accumulated deficit of $7.8 billion.
- 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. This could materially and adversely affect our business, financial condition, results of operations, and growth prospects.
- 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 from third-party payors, if at all, 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 in perpetuity that we will be required to pay to Illumina 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, 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 have launched Galleri as a laboratory developed test (“LDT”), and plan to launch DAC as an LDT in the United States. If the FDA modifies its current policy of enforcement discretion on LDTs, as it has recently proposed through rulemaking, or if Congress enacts legislation that changes the current

requirements or oversight for LDTs, we may lose the ability to commercialize any LDTs unless we have obtained FDA marketing authorization, which could require us to incur substantial costs and delays.

- 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 depend on various third parties, including information technology, sample collection, processing, transfer facilities, and other patient-facing service providers. Any disruption, failure, or interruption at any of these third parties could materially adversely affect our business, results of operations, financial condition, and growth prospects.
- If we are unable to scale our operations successfully to support demand for our products, our business could suffer.
- 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, 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 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.
- If the Distribution does not qualify as a transaction that is tax-free for U.S. federal income tax purposes, Illumina and its stockholders could be subject to significant tax liability.
- 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, which could materially adversely affect our business, financial condition and results of operations.
- We intend to agree to numerous restrictions to preserve the non-recognition treatment of the Distribution, which may reduce our strategic and operating flexibility.
- We may be unable to achieve some or all of the benefits that we expect to achieve from the Spin-Off, which could materially adversely affect our business, financial condition and results of operations.
- No market for our common stock currently exists and an active trading market may not develop or 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.

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- 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 Spin-Off

Illumina acquired the common stock of GRAIL that it did not own and completed its acquisition of GRAIL on August 18, 2021 (the "Acquisition"). The Acquisition has been subject to various legal challenges, including by the U.S. Federal Trade Commission and the European Commission. Pursuant to the binding Hold Separate Commitments (as defined in the section entitled "The Spin-Off—Background" beginning on page 98 of this Information Statement) that Illumina put in place and the various orders of the European Commission related to its review of the Acquisition, Illumina and GRAIL have operated as independent legal entities that transact at arms' length and the day-to-day operation of GRAIL has remained the sole responsibility of GRAIL's management. On July 12, 2023, the European Commission adopted a final decision finding that Illumina breached the EU Merger Regulation (as defined in the section entitled "The Spin-Off—Background" beginning on page 98 of this Information Statement) by, in its view, acquiring the possibility to exert decisive influence over GRAIL and exerting such influence during the pendency of the European Commission's review. On September 26, 2023, Illumina sought the annulment of this decision. On October 12, 2023, the European Commission adopted a decision (the "EC Divestment Decision") requiring Illumina to (among other things) divest GRAIL. On December 22, 2023, Illumina sought the annulment of the EC Divestment Decision. On , the European Commission approved a divestment plan (the "Divestment Plan") submitted by Illumina pursuant to which Illumina agreed to divest GRAIL on specified terms. The EC Divestment Decision permits Illumina to retain up to a 14.5% ownership interest in GRAIL. See the section entitled "The Spin-Off—Background" beginning on page 98 of this Information Statement for more detail. On December 17, 2023, Illumina announced that it will divest GRAIL. On , 2024, Illumina announced plans for the separation of GRAIL from Illumina via the Spin-Off.

To effect the Spin-Off, Illumina will distribute at least 85.5% of the shares of GRAIL's common stock owned by Illumina to Illumina's stockholders, and GRAIL will become an independent, publicly traded company. Immediately after the Distribution becomes effective, Illumina may retain up to 14.5% of GRAIL's common stock and re-establish the royalty arrangement it previously had in place with GRAIL, which was suspended while GRAIL was owned by Illumina and will continue to be suspended until the earlier of two-and-a-half years or any earlier change of control of GRAIL, at which time royalty payments will resume.

Prior to completion of the Spin-Off, we intend to enter into a Separation and Distribution Agreement and several other agreements with Illumina related to the Spin-Off. These agreements will govern the relationship between Illumina and us after completion of the Spin-Off and allocate between Illumina and us various assets, liabilities and obligations, including tax-related assets and liabilities. See the section entitled "Certain Relationships and Related Party Transactions" beginning on page 217 of this Information Statement for more detail. No approval of Illumina's stockholders is required in connection with the Spin-Off, and Illumina's stockholders will not have any appraisal rights in connection with the Spin-Off.

Completion of the Spin-Off is subject to the satisfaction, or the waiver by Illumina's board of directors (the "Illumina Board"), of a number of conditions. If the Illumina Board waives any condition prior to the effectiveness of the Registration Statement on Form 10, of which this Information Statement is a part, and the result of such waiver is material to Illumina stockholders, Illumina will file an amendment to the Registration Statement to revise the disclosure in this Information Statement accordingly. In the event that the Illumina Board waives a condition after the Registration Statement on Form 10, of which this Information Statement is a part, becomes effective and such waiver is material to Illumina stockholders, Illumina will communicate such change to Illumina stockholders by filing a Current Report on Form 8-K describing the change.

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In addition, Illumina has the right not to complete the Spin-Off if, at any time, the Illumina Board determines, in its sole and absolute discretion, that the Spin-Off is not in the best interests of Illumina or its stockholders or is otherwise not advisable. If the Spin-Off is not completed for any reason, Illumina and GRAIL will have incurred significant costs related to the Spin-Off, including fees for consultants, financial and legal advisors, accountants and auditors, that will not be recouped. Total one-time transaction costs associated with the Spin-Off are preliminarily estimated to range from $ to $ if the Spin-Off is completed. If the Spin-Off is not completed for any reason, the one-time transaction costs will generally be limited to the transaction costs incurred for services rendered as of the date the Spin-Off is abandoned, which will be less than the range noted above. Our management will also have devoted significant time to manage the Spin-Off process, which will decrease the time they will have to manage our business. See the section entitled "The Spin-Off—Conditions to the Spin-Off" beginning on page 108 of this Information Statement for more detail.

Reasons for the Spin-Off

In connection with the EC Divestment Decision and with the goal of enhancing stockholder value, the Illumina Board conducted a process through which it considered a range of potential divestment transactions. After evaluating various factors and other considerations, the Illumina Board concluded that the Spin-Off presented the most attractive alternative for enhancing long-term stockholder value while complying with the requirements of the EC Divestment Decision and that proceeding with the Spin-Off would be in the best interests of Illumina and its stockholders.

Among other things, the Illumina Board considered a number of potential benefits of the Spin-Off, including:

- ***Opportunity for continued ownership of GRAIL by Illumina stockholders.*** The Spin-Off will provide Illumina stockholders the opportunity to determine whether they wish to continue to own an interest in GRAIL despite GRAIL's required separation from Illumina.
- ***Distinct and clear financial profiles and compelling investment cases***. Investment in one or the other company may appeal to investors with different goals, interests and expectations. The Spin-Off will allow investors to make independent investment decisions with respect to Illumina and GRAIL and may result in greater alignment between the interests of each company's stockholder base and the characteristics of its respective business, capital structure, and financial results.
- ***Separate capital structures and allocation flexibility***. The Spin-Off will permit each of Illumina and GRAIL to allocate its financial resources to meet the unique needs of its own businesses, which will allow each company to focus on its distinct strategic priorities and individual business risk and return profiles.
- ***Creation of independent equity securities and increased strategic opportunities***. The Spin-Off will afford Illumina and GRAIL the ability to offer their independent equity securities to the capital markets and enable each standalone company to use its own industry-focused stock to pursue portfolio enhancing acquisitions or other strategic opportunities that are more closely aligned with each company's strategic goals and expected growth opportunities.

The Illumina Board also considered a number of potentially negative factors in evaluating the Spin-Off, including:

- ***Risk of failure to achieve the anticipated benefits of the Spin-Off***. Illumina and GRAIL may not achieve the anticipated benefits of the Spin-Off for a variety of reasons, including, among others: the Spin-Off will require significant amounts of management's time and effort, which may divert management's attention from operating and growing our businesses; there may be dis-synergy costs

related to the Spin-Off; and following the Spin-Off, each company may be more susceptible to certain economic and market fluctuations and other adverse events than if GRAIL were still a part of Illumina because each company will be less diversified than Illumina prior to the separation.

- ***Limitations on strategic transactions***. Under the terms of the Tax Matters Agreement that GRAIL will enter into with Illumina, GRAIL expects to be restricted from taking certain transactions that could cause the Distribution or certain related transactions to fail to qualify as tax-free transactions under applicable law. These restrictions may limit for a period of time GRAIL's ability to pursue certain strategic transactions and equity issuances or engage in other transactions that otherwise might increase the value of our business.

- ***Disruptions and costs related to the Spin-Off***. The actions required to separate GRAIL from Illumina could disrupt both Illumina's and GRAIL's operations. In addition, Illumina and GRAIL will incur substantial costs in connection with the Spin-Off and GRAIL's transition to being a standalone public company, which may include accounting, tax, legal and other professional services costs, and recruiting and relocation costs associated with hiring directors and management who are new to GRAIL.

- ***Uncertainty regarding share prices***. We cannot predict the effect of the Distribution on the trading prices of Illumina's and GRAIL's common stock or know with certainty whether the combined market value of the shares of GRAIL common stock to be distributed per share of Illumina common stock in the Distribution and Illumina's common stock following the Distribution will be less than, equal to, or greater than the market value of the shares of Illumina's common stock prior to the Distribution. Furthermore, there is the risk of volatility in each company's stock price following the Distribution due to sales by certain stockholders whose investment objectives may not be met by each company's common stock, and it may take time for each company to attract its optimal stockholder base.

Notwithstanding these costs and risks, the anticipated costs of which are not reasonably quantifiable, and considering the factors discussed above, the Illumina Board determined that the Spin-Off provided the best opportunity to achieve the above benefits and enhance stockholder value. Neither Illumina nor GRAIL can assure you that, following the Spin-Off, any of the benefits described above or otherwise will be realized to the extent anticipated or at all. For additional information, see the sections entitled "Risk Factors" and "The Spin-Off—Reasons for the Spin-Off" beginning on pages 30 and 100, respectively, of this Information Statement.

Emerging Growth Company Status

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 Securities Exchange Act of 1934 (the "Exchange Act"), for at least one year (and have 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.

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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 in the assessment of our internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act of 2002, 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 stockholder approval on golden parachute compensation not previously approved. We may choose to take advantage of some or all of these reduced burdens. For example, we have taken advantage of the reduced disclosure obligations regarding executive compensation in this Information Statement. For as long as we take advantage of the reduced reporting obligations, the information we provide stockholders 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 the price of our common stock.

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 included in this Information Statement, as well as 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.

Other Information

We are a Delaware limited liability company. Prior to the completion of the Spin-Off, we will be converted into a Delaware corporation and change our name to GRAIL, Inc. Our headquarters are located in Menlo Park and our principal executive offices are located at 1525 O'Brien Drive, Menlo Park, California 94025. Our telephone number is (833) 694-2553. Our website address is https://grail.com. Information contained on, or connected to, our website or Illumina's website does not and will not constitute part of this Information Statement or the Registration Statement on Form 10, of which this Information Statement is a part, or any other filings with, or any information furnished or submitted to, the Securities and Exchange Commission (the "SEC").

Reasons for Furnishing This Information Statement

We are furnishing this Information Statement solely to provide information to Illumina's stockholders who will receive shares of our common stock in the Distribution. Illumina's stockholders are not required to vote on the Distribution. Therefore, you are not being asked for a proxy and you are not required to send a proxy to Illumina. You do not need to pay any consideration, exchange or surrender your existing shares of Illumina common stock or take any other action to receive your shares of GRAIL common stock to which you are entitled in the Spin-Off. You should not construe this Information Statement as an inducement or encouragement to buy, hold or sell any of our securities or any securities of Illumina. We believe that the information contained in this Information Statement is accurate as of the date set forth on the cover. Changes to the information contained in this Information Statement may occur after that date, and neither we nor Illumina undertake any obligation to update the information except in the normal course of our and Illumina's respective public disclosure obligations and practices.

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QUESTIONS AND ANSWERS ABOUT THE SPIN-OFF

The following provides only a summary of certain information regarding the Spin-Off. You should read this Information Statement in its entirety for a more detailed description of the matters described below.

Q: Why am I receiving this Information Statement?

A: Illumina is making this Information Statement available to you because you are a holder of shares of Illumina common stock. If you are a holder of shares of Illumina common stock as of the Record Date (as defined below), for every share[s] of Illumina common stock that you hold as of the Record Date, you will be entitled to receive share[s] of GRAIL common stock. This Information Statement is intended to help you understand how the Spin-Off will affect your post-Distribution ownership in each of Illumina and GRAIL.

Q: What is the Spin-Off?

A: The Spin-Off is the method by which we will separate from Illumina. In the Spin-Off, Illumina will distribute to its stockholders at least 85.5% of the outstanding shares of our common stock owned by Illumina in a transaction (the "Distribution"). Following the Spin-Off, we will be an independent, publicly traded company, and Illumina may retain up to 14.5% ownership interest in us. Illumina will continue as an independent, publicly traded company.

Q: Will the number of Illumina shares I own change as a result of the Spin-Off?

A: No, the number of shares of Illumina common stock you own will not change as a result of the Spin-Off.

Q: What are the reasons for the Spin-Off?

A: In connection with the EC Divestment Decision and with the goal of enhancing stockholder value, the Illumina Board conducted a process through which it considered a range of potential divestment transactions. After evaluating various factors and other considerations, the Illumina Board concluded that the Spin-Off presented the most attractive alternative for enhancing long-term stockholder value while complying with the requirements of the EC Divestment Decision and that proceeding with the Spin-Off would be in the best interests of Illumina and its stockholders.

Among other things, the Illumina Board considered a number of potential benefits of the Spin-Off, including:

- ***Opportunity for continued ownership of GRAIL by Illumina stockholders.*** The Spin-Off will provide Illumina stockholders the opportunity to determine whether they wish to continue to own an interest in GRAIL despite GRAIL's required separation from Illumina.
- ***Distinct and clear financial profiles and compelling investment cases***. Investment in one or the other company may appeal to investors with different goals, interests and expectations. The Spin-Off will allow investors to make independent investment decisions with respect to Illumina and GRAIL and may result in greater alignment between the interests of each company's stockholder base and the characteristics of its respective business, capital structure, and financial results.
- ***Separate capital structures and allocation flexibility***. The Spin-Off will permit each of Illumina and GRAIL to allocate its financial resources to meet the unique needs of its own businesses, which will allow each company to focus on its distinct strategic priorities and individual business risk and return profiles.

- ***Creation of independent equity securities and increased strategic opportunities***. The Spin-Off will afford Illumina and GRAIL the ability to offer their independent equity securities to the capital markets and enable each standalone company to use its own industry-focused stock to pursue portfolio enhancing acquisitions or other strategic opportunities that are more closely aligned with each company's strategic goals and expected growth opportunities.

The Illumina Board also considered a number of potentially negative factors in evaluating the Spin-Off. Notwithstanding these costs and risks, the anticipated costs of which are not reasonably quantifiable, and considering the factors discussed above, the Illumina Board determined that the Spin-Off provided the best opportunity to achieve the above benefits and enhance stockholder value. Neither Illumina nor GRAIL can assure you that, following the Spin-Off, any of the benefits described above or otherwise will be realized to the extent anticipated or at all. For additional information, see the sections entitled "Risk Factors" and "The Spin-Off—Reasons for the Spin-Off" beginning on pages 30 and 100, respectively, of this Information Statement.

Q: Why is the separation of GRAIL structured as a spin-off?

A: Illumina believes that a tax-free distribution of our shares is the most efficient way to separate our business from Illumina in a manner that will achieve the above benefits.

Q: What will I receive in the Spin-Off in respect of my shares of Illumina common stock?

A: As a holder of Illumina common stock, for every share[s] of Illumina common stock you hold on the Record Date, you will receive a dividend of share[s] of GRAIL common stock. The distribution agent will distribute only whole shares of our common stock in the Spin-Off. See "—How will fractional shares be treated in the Distribution?" beginning on page 20 of this Information Statement for more information on the treatment of the fractional shares you may be entitled to receive in the Distribution. Your proportionate interest in Illumina will not change as a result of the Spin-Off.

Q: What is being distributed in the Spin-Off?

A: Illumina will distribute approximately shares of our common stock in the Spin-Off, based on the approximately shares of Illumina common stock outstanding as of , 2024. The actual number of shares of our common stock that Illumina will distribute will depend on the total number of shares of Illumina common stock outstanding on the Record Date. The shares of our common stock that Illumina distributes will constitute at least 85.5% of the issued and outstanding shares of our common stock immediately prior to the Distribution. For more information on the shares being distributed in the Spin-Off, see the section entitled "Description of Our Capital Stock —Common Stock" beginning on page 221 of this Information Statement.

Q: What is the record date for the Distribution?

A: Illumina will determine record ownership as of the close of business on , 2024 (the "Record Date").

Q: When will the Distribution occur?

A: The Distribution will be effective as of , New York City time, on , 2024 (the "Distribution Date"). On or shortly after the Distribution Date, the whole shares of our common stock will be credited in book-entry accounts for Illumina stockholders entitled to receive the shares in the

Distribution. See "—How will Illumina distribute shares of our common stock?" beginning on page 19 of this Information Statement for more information on how to access your book-entry account or your bank, brokerage or other account holding the GRAIL common stock you receive in the Distribution on and following the Distribution Date.

Q: What do I have to do to participate in the Distribution?

A: All holders of Illumina common stock as of the Record Date will participate in the Distribution. You are not required to take any action in order to participate, but we urge you to read this Information Statement carefully. Holders of Illumina common stock on the Record Date will not need to pay any cash or deliver any other consideration, including any shares of Illumina common stock, in order to receive shares of our common stock in the Distribution. In addition, no stockholder approval of the Distribution is required. We are not asking you for a vote and request that you do not send us a proxy card.

Q: If I sell my shares of Illumina common stock on or before the Distribution Date, will I still be entitled to receive shares of GRAIL common stock in the Distribution?

A: If you sell your shares of Illumina common stock before the Record Date, you will not be entitled to receive shares of GRAIL common stock in the Distribution. If you hold shares of Illumina common stock on the Record Date and decide to sell them on or before the Distribution Date, you may be able to choose to sell your Illumina common stock with or without your entitlement to the GRAIL common stock to be distributed in the Spin-Off. You are encouraged to consult with your bank, broker or other nominee, as applicable, and your financial advisor regarding your options and the specific implications of selling your shares of Illumina common stock prior to or on the Distribution Date. See the section entitled "The Spin-Off—Trading Prior to the Distribution Date" beginning on page 107 of this Information Statement for more information.

Q: Is the completion of the Spin-Off subject to the satisfaction or waiver of any conditions?

A: Yes, the completion of the Spin-Off is subject to the satisfaction, or the Illumina Board's waiver, of the following conditions:

- the Illumina Board shall have authorized and approved the Distribution and not withdrawn such authorization and approval, and shall have declared the dividend of our common stock to Illumina stockholders;
- the ancillary agreements contemplated by the Separation and Distribution Agreement shall have been executed by each party to those agreements;
- our common stock shall have been accepted for listing on the Nasdaq Global Select Market ("Nasdaq"), or another national securities exchange approved by Illumina, subject to official notice of issuance;
- the SEC shall have declared effective our Registration Statement on Form 10, of which this Information Statement is a part, under the Exchange Act, and no stop order suspending the effectiveness of the Registration Statement shall be in effect and no proceedings for that purpose shall be pending before or threatened by the SEC;
- Illumina shall have received a private letter ruling from the U.S. Internal Revenue Service ("IRS") and the written opinion of Cravath, Swaine & Moore LLP, each of which shall remain in full force and effect, 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;

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- the Illumina Board shall have received one or more opinions (which have not been withdrawn or adversely modified) in customary form from one or more nationally recognized valuation, appraisal or accounting firms, or investment banks, as to the solvency and financial viability of Illumina prior to the Spin-Off and each of Illumina and GRAIL after the consummation of the Spin-Off;
- no order, injunction or decree issued by any governmental authority of competent jurisdiction or other legal restraint or prohibition preventing consummation of the Distribution shall be in effect, and no other event outside the control of Illumina shall have occurred or failed to occur that prevents the consummation of the Distribution;
- no other events or developments shall have occurred prior to the Distribution Date that, in the judgment of the Illumina Board, would result in the Distribution having a material adverse effect on Illumina or its stockholders;
- prior to the Distribution Date, notice of Internet availability of this Information Statement or this Information Statement shall have been mailed to the holders of Illumina common stock as of the Record Date;
- Illumina shall have duly elected as members of our post-Distribution Board of Directors (the "Board"), the individuals listed in this Information Statement, and such individuals shall be the members of our Board immediately after the Distribution; and
- immediately prior to the Distribution Date, our Certificate of Incorporation and Bylaws, each in substantially the form filed as an exhibit to the Registration Statement on Form 10, of which this Information Statement is a part, shall be in effect.

Illumina and GRAIL cannot assure you that any or all of these conditions will be met, or that the Distribution will be consummated even if all of the conditions are met. Illumina may at any time prior to the Distribution Date decide to abandon the Distribution or modify or change the terms of the Distribution. If the Illumina Board waives any condition prior to the effectiveness of the Registration Statement on Form 10, of which this Information Statement is a part, and the result of such waiver is material to Illumina stockholders, Illumina will file an amendment to the Registration Statement to revise the disclosure in this Information Statement accordingly. In the event that the Illumina Board waives a condition after the Registration Statement on Form 10, of which this Information Statement is a part, becomes effective and such waiver is material to Illumina stockholders, Illumina will communicate such change to Illumina stockholders by filing a Current Report on Form 8-K describing the change. For a complete discussion of the conditions to the Distribution, see the section entitled "The Spin-Off—Conditions to the Spin-Off" beginning on page 108 of this Information Statement.

Q: Can Illumina decide to cancel the Distribution even if all the conditions have been satisfied?

A: Yes. The Illumina Board may, in its sole discretion and at any time prior to the Distribution Date, decide to terminate or abandon the Distribution even if all the conditions to the Distribution have been satisfied if the Illumina Board determines that the Distribution is not in the best interests of Illumina or its stockholders or is otherwise not advisable. For a more detailed description, see the section entitled "The Spin-Off—Conditions to the Spin-Off" beginning on page 108 of this Information Statement.

Q: How will Illumina distribute shares of our common stock?

A: *Registered stockholders.* If you are a registered stockholder (meaning you own your shares of Illumina common stock directly through Illumina's transfer agent, Computershare Trust Company, N.A. ("Computershare")), our distribution agent will credit the whole shares of our common stock you receive in the Distribution to a new book-entry account with our transfer agent, Computershare, on or shortly after the

Distribution Date. Our distribution agent will mail you a book-entry account statement that reflects the number of whole shares of our common stock you own. You will be able to access information regarding your book-entry account holding the GRAIL shares at www. .com or by calling .

"Street name" or beneficial stockholders. If you own your shares of Illumina common stock beneficially through a bank, broker or other nominee, your bank, broker or other nominee will credit your account with the whole shares of our common stock you receive in the Distribution on or shortly after the Distribution Date. Please contact your bank, broker or other nominee for further information about your account.

We will not issue any physical stock certificates to any stockholders, even if requested. See the section entitled "The Spin-Off—When and How You Will Receive GRAIL Shares" beginning on page 102 of this Information Statement for a more detailed explanation.

Q: How will fractional shares be treated in the Distribution?

A: The distribution agent will not distribute any fractional shares of our common stock in connection with the Spin-Off. Instead, the distribution agent will aggregate all fractional shares into whole shares and sell the whole shares in the open market at prevailing market prices on behalf of Illumina stockholders entitled to receive a fractional share. The distribution agent will then distribute the aggregate cash proceeds of the sales, net of brokerage fees and other costs, pro rata to these holders (net of any required withholding for taxes applicable to each holder). We anticipate that the distribution agent will make these sales in the "when-issued" market, and "when-issued" trades will generally settle within two trading days following the Distribution Date. See "—How will GRAIL common stock trade?" beginning on page 21 of this Information Statement for additional information regarding "when-issued" trading and the section entitled "The Spin-Off—Treatment of Fractional Shares" beginning on page 103 of this Information Statement for a more detailed explanation of the treatment of fractional shares. The distribution agent will, in its sole discretion, without any influence by Illumina or us, determine when, how, through which broker-dealer and at what price to sell the whole shares of GRAIL common stock. The distribution agent is not, and any broker-dealer used by the distribution agent will not be, an affiliate of either Illumina or us.

Q: What are the U.S. federal income tax consequences to me of the Distribution?

A: Completion of the Spin-Off is conditioned upon Illumina's receipt of a private letter ruling from the IRS and a written opinion of Cravath, Swaine & Moore LLP, each of which shall remain in full force in effect, 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. If the Spin-Off qualifies for such treatment, for U.S. federal income tax purposes, no gain or loss will be recognized by, or be includible in the income of, a U.S. Holder (as defined in the section entitled "The Spin-Off—Material U.S. Federal Income Tax Consequences of the Spin-Off" beginning on page 103 of this Information Statement) as a result of the Distribution, except with respect to any cash received by Illumina stockholders in lieu of fractional shares. After the Distribution, Illumina stockholders generally should allocate their aggregate tax basis in their Illumina common stock held immediately before the Distribution between their Illumina common stock and our common stock in proportion to their relative fair market values on the date of the Distribution (subject to certain adjustments). See the section entitled "The Spin-Off—Material U.S. Federal Income Tax Consequences of the Spin-Off" beginning on page 103 of this Information Statement for more information regarding the potential tax consequences to you of the Spin-Off.

We urge you to consult your tax advisor as to the specific tax consequences of the Distribution to you, including the effect of any U.S. federal, state, local or foreign tax laws and of changes in applicable tax laws.

Q: ***Does GRAIL intend to pay cash dividends?***

A: We do not anticipate paying any cash dividends in the foreseeable future. We currently anticipate that we will retain all available funds for use in the operation and expansion of our business. Any future determination to pay dividends on our common stock will be made at the discretion of the Board and will depend upon, among other factors, our financial condition, results from operations, current and anticipated cash needs, plans for expansion, and other factors that our Board may deem relevant. We cannot assure you that we will pay a dividend in the future or continue to pay any dividend if we do commence paying dividends. See the section entitled "Dividend Policy" beginning on page 110 of this Information Statement for more information.

Q: ***How will GRAIL common stock trade?***

A: Currently, there is no public market for our common stock. We intend to list our common stock on Nasdaq under the ticker symbol "GRAL."

We anticipate that trading in our common stock will begin on a "when-issued" basis on or shortly before the Record Date for the Distribution and will continue up to and including the Distribution Date. "When-issued" trading in the context of a spin-off refers to a sale or purchase made conditionally on or before the Distribution Date because the securities of the spun-off entity have not yet been distributed. "When-issued" trades generally settle within two trading days after the Distribution Date. On the first trading day following the Distribution Date, any "when-issued" trading of our common stock will end and "regular-way" trading will begin. "Regular-way" trading refers to trading after the security has been distributed and typically involves a trade that settles on the second full trading day following the date of the trade. See the section entitled "The Spin-Off—Trading Prior to the Distribution Date" beginning on page 107 of this Information Statement for more information. We cannot predict the trading prices for our common stock before, on or after the Distribution Date.

Q: ***What will happen to the listing of Illumina's common stock?***

A: Illumina's common stock will continue to trade on Nasdaq under the ticker symbol "ILMN" after the Distribution.

Q: ***Will the Spin-Off affect the trading price of my Illumina common stock?***

A: We expect the trading price of shares of Illumina common stock immediately following the Distribution to be lower than the trading price immediately prior to the Distribution because the trading price will no longer reflect the value of GRAIL. Furthermore, until the market has fully analyzed the value of Illumina without GRAIL, the trading price of shares of Illumina common stock may fluctuate and result in a higher volatility in the price of our common stock. There can be no assurance that, following the Distribution, the combined trading prices of the Illumina common stock and the GRAIL common stock will equal or exceed what the trading price of Illumina common stock would have been in the absence of the Spin-Off.

It is possible that, after the Spin-Off, the combined equity value of Illumina and GRAIL will be less than Illumina's equity value before the Spin-Off.

Q: ***What will happen to Illumina's equity incentive awards in connection with the Spin-Off?***

A: We expect that each Illumina equity incentive award outstanding as of the Distribution Date held by directors and employees that will continue at Illumina will remain outstanding and continue to be subject to the same terms and conditions following the Distribution Date, but with adjustments to the number of shares of Illumina common stock subject to such award in order to preserve its value.

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Q: What will happen to GRAIL's cash-based equity incentive awards in connection with the Spin-Off?

A: Each GRAIL cash-based equity incentive award (each, a "Cash-Based Equity Award") outstanding as of the Distribution Date may convert into an equity-based award that settles in shares of GRAIL common stock. If converted, we expect that the number of shares subject to such award will be based on the value of the award at the time of the Distribution compared to the value of the GRAIL shares in the Distribution, and will otherwise continue to be subject to the same terms and conditions following the Distribution Date (each such converted award, a "GRAIL RSU").

Q: What will GRAIL's relationship be with Illumina following the Spin-Off?

A: Following the Distribution, GRAIL and Illumina will be separate companies with separate management teams and separate boards of directors and Illumina may retain up to 14.5% of the outstanding shares of our common stock. GRAIL will enter into a separation and distribution agreement with Illumina to effect the separation and provide a framework for the relationship between GRAIL and Illumina after the Spin-Off (the "Separation and Distribution Agreement"), and will enter into certain other agreements, including a Tax Matters Agreement (as defined below), and a Stockholder and Registration Rights Agreement (as defined below) with respect to Illumina's continuing ownership of GRAIL common stock. These agreements will allocate between GRAIL and Illumina the obligations of Illumina and its subsidiaries attributable to periods prior to, at and after the Distribution and govern the relationship between GRAIL and Illumina following the Spin-Off. In addition to the aforementioned agreements, we are also currently party to, or intend to enter into, various other agreements with Illumina and its subsidiaries, including a supply and commercialization agreement and license agreements. For additional information regarding the Separation and Distribution Agreement, Tax Matters Agreement, and Stockholder and Registration Rights Agreement, see the sections entitled "Risk Factors—Risks Relating to the Spin-Off" and "Certain Relationships and Related Party Transactions" beginning on pages 87 and 217, respectively, of this Information Statement.

Q: How will Illumina vote any shares of GRAIL common stock it retains?

A: Illumina is expected to agree to vote any shares of GRAIL common stock that it retains in proportion to the votes cast by GRAIL's other stockholders and is expected to grant GRAIL a proxy to vote its shares of GRAIL common stock in such proportion. For additional information on these voting arrangements, see "Certain Relationships and Related Party Transactions—Agreements with Illumina—Stockholder and Registration Rights Agreement" beginning on page 218 of this Information Statement.

Q: What does Illumina intend to do with any shares of GRAIL common stock it retains?

A: Illumina's plan to potentially distribute less than all of GRAIL's common stock to its stockholders in the Spin-Off is motivated by its desire to establish an appropriate capital structure for each of GRAIL and Illumina, including by strengthening Illumina's balance sheet or reducing Illumina's indebtedness, in any case directly or indirectly, following the Spin-Off. Illumina expects that the IRS private letter ruling will require that all retained shares be sold or otherwise disposed of by Illumina as soon as warranted consistent with the business reasons for the retention of those shares, but in no event later than five years after the Distribution. Such dispositions could include a sale of its shares for cash, distributions of GRAIL common stock to Illumina stockholders or securityholders as dividends or in exchange for outstanding shares of Illumina common stock, indebtedness or other securities, or any combination thereof.

Q: Who will manage GRAIL following the Spin-Off?

A: GRAIL is led by Robert Ragusa, who is GRAIL's Chief Executive Officer, and Aaron Freidin, who is GRAIL's Chief Financial Officer. For more information regarding GRAIL's directors and management, see the section entitled "Management" beginning on page 200 of this Information Statement.

Q: Do I have appraisal rights in connection with the Spin-Off?

A: No. Holders of Illumina common stock are not entitled to appraisal rights in connection with the Spin-Off.

Q: Who is the transfer agent and registrar for GRAIL common stock?

A: Computershare is the transfer agent and registrar for GRAIL common stock.

Q: Are there risks associated with owning shares of GRAIL common stock?

A: Yes. Our business faces both general and specific risks and uncertainties. Our business also faces risks relating to the Spin-Off. Following the Spin-Off, we will also face risks associated with being an independent, publicly traded company. Accordingly, you should read carefully the information set forth in the section entitled "Risk Factors" beginning on page 30 of this Information Statement.

Q: Where can I get more information?

A: If you have any questions relating to the mechanics of the Distribution, you should contact the distribution agent at:

Computershare Trust Company, N.A.
150 Royall Street
Canton, MA 02021
Phone: (877) 373-6374
Email: web.queries@computershare.com

Before the Spin-Off, if you have any questions relating to the Spin-Off, you should contact Illumina at:

Illumina, Inc.
5200 Illumina Way
San Diego, CA 92122
Phone: (858) 202-4500
Email: ir@illumina.com

After the Spin-Off, if you have any questions relating to GRAIL, you should contact us at:

GRAIL, Inc.
1525 O'Brien Drive
Menlo Park, California 94025
Phone: (833) 694-2553
Email:

A link to our investor relations website and additional contact information will be made available at https://grail.com. Information contained on, or connected to, our website does not and will not constitute part of this Information Statement or the Registration Statement on Form 10, of which this Information Statement is a part, or any other filings with, or any information furnished or submitted to, the SEC.

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	SUMMARY OF THE SPIN-OFF
Distributing Company	Illumina, Inc., or "Illumina," a Delaware corporation that holds all of our common stock issued and outstanding prior to the Distribution. After the Distribution, Illumina will own up to 14.5% of the shares of our common stock.
Distributed Company	GRAIL, LLC, or "GRAIL," a Delaware limited liability company and a wholly owned subsidiary of Illumina. Prior to the completion of the Spin-Off, GRAIL will be converted into a Delaware corporation and will be renamed GRAIL, Inc. After the Spin-Off, we will be an independent, publicly traded company.
Distributed Securities	At least 85.5% of the shares of our common stock owned by Illumina, which will be at least 85.5% of our common stock issued and outstanding immediately prior to the Distribution. Illumina may retain up to 14.5% of the outstanding shares of GRAIL's common stock. Illumina expects that the IRS private letter ruling will require that all retained shares be sold or otherwise disposed of by Illumina as soon as warranted consistent with the business reasons for the retention of those shares, but in no event later than five years after the Distribution. Such dispositions could include a sale of its shares for cash, distributions of GRAIL common stock to Illumina stockholders or securityholders as dividends or in exchange for outstanding shares of Illumina common stock, indebtedness or other securities, or any combination thereof. Based on the approximately shares of Illumina common stock outstanding on , 2024, and applying the distribution ratio pursuant to which, for every share[s] of Illumina common stock outstanding, share[s] of GRAIL common stock will be distributed, approximately shares of GRAIL common stock will be distributed in the aggregate. In connection with the Spin-Off, each Cash-Based Equity Award outstanding as of the Distribution Date may convert into GRAIL RSUs.
Record Date	The Record Date is the close of business on , 2024.
Distribution Date	The Distribution Date is , 2024.
Distribution Ratio	For every share[s] of Illumina common stock each Illumina stockholder holds on the Record Date, such stockholder will receive share[s] of our common stock. The distribution agent will distribute only whole shares of our common stock in the Spin-Off. See the section entitled "The Spin-Off—Treatment of Fractional Shares" beginning on page 103 of this Information Statement for more detail. Please note that if you sell your shares of Illumina common stock on or before the Distribution Date, the buyer of those shares may in some circumstances be entitled to receive the shares of our common stock to be distributed in respect of the Illumina shares that you sold. For more information, see the section entitled "The

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	Spin-Off—Trading Prior to the Distribution Date" beginning on page 107 of this Information Statement.
The Distribution	On the Distribution Date, Illumina will release the shares of our common stock to the distribution agent to distribute to Illumina stockholders. Illumina will distribute our shares in book-entry form and thus we will not issue any physical stock certificates. You will not be required to make any payment, surrender or exchange your shares of Illumina common stock or take any other action to receive your shares of our common stock.
Fractional Shares	The distribution agent will not distribute any fractional shares of our common stock to Illumina stockholders. Instead, the distribution agent will first aggregate fractional shares into whole shares, then sell the whole shares in the open market at prevailing market prices on behalf of Illumina stockholders entitled to receive a fractional share, and finally distribute the aggregate cash proceeds of the sales, net of brokerage fees and other costs, pro rata to these holders (net of any required withholding for taxes applicable to each holder). If you receive cash in lieu of fractional shares, you will not be entitled to any interest on the payments. The cash you receive in lieu of fractional shares generally will, for U.S. federal income tax purposes, be taxable as described under the section entitled "The Spin-Off—Material U.S. Federal Income Tax Consequences of the Spin-Off" beginning on page 103 of this Information Statement.
Conditions to the Spin-Off	Completion of the Spin-Off is subject to the satisfaction, or the Illumina Board's waiver, of the following conditions: • the Illumina Board shall have authorized and approved the Distribution and not withdrawn such authorization and approval, and shall have declared the dividend of our common stock to Illumina stockholders; • the ancillary agreements contemplated by the Separation and Distribution Agreement shall have been executed by each party to those agreements; • our common stock shall have been accepted for listing on Nasdaq or another national securities exchange approved by Illumina, subject to official notice of issuance; • the SEC shall have declared effective our Registration Statement on Form 10, of which this Information Statement is a part, under the Exchange Act, and no stop order suspending the effectiveness of the Registration Statement shall be in effect and no proceedings for that purpose shall be pending before or threatened by the SEC; • Illumina shall have received a private letter ruling from the IRS and the written opinion of Cravath, Swaine & Moore LLP, each of which shall remain in full force and effect, 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;

- the Illumina Board shall have received one or more opinions (which have not been withdrawn or adversely modified) in customary form from one or more nationally recognized valuation, appraisal or accounting firms, or investment banks, as to the solvency and financial viability of Illumina prior to the Spin-Off and each of Illumina and GRAIL after the consummation of the Spin-Off;
- no order, injunction or decree issued by any governmental authority of competent jurisdiction or other legal restraint or prohibition preventing consummation of the Distribution shall be in effect, and no other event outside the control of Illumina shall have occurred or failed to occur that prevents the consummation of the Distribution;
- no other events or developments shall have occurred prior to the Distribution Date that, in the judgment of the Illumina Board, would result in the Distribution having a material adverse effect on Illumina or its stockholders;
- prior to the Distribution Date, notice of Internet availability of this Information Statement or this Information Statement shall have been mailed to the holders of Illumina common stock as of the Record Date;
- Illumina shall have duly elected the individuals to be listed as members of our post-Distribution Board in this Information Statement, and such individuals shall be the members of our Board immediately after the Distribution; and
- immediately prior to the Distribution Date, our Certificate of Incorporation and Bylaws, each in substantially the form filed as an exhibit to the Registration Statement on Form 10, of which this Information Statement is a part, shall be in effect.

The fulfillment of the foregoing conditions will not create any obligation on the part of Illumina to complete the Spin-Off. If the Illumina Board waives any condition prior to the effectiveness of the Registration Statement on Form 10, of which this Information Statement is a part, and the result of such waiver is material to Illumina stockholders, Illumina will file an amendment to the Registration Statement to revise the disclosure in this Information Statement accordingly. In the event that the Illumina Board waives a condition after the Registration Statement on Form 10, of which this Information Statement is a part, becomes effective and such waiver is material to Illumina stockholders, Illumina will communicate such change to Illumina stockholders by filing a Current Report on Form 8-K describing the change. For a complete discussion of the conditions to the Distribution, see the section entitled “The

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	Spin-Off—Conditions to the Spin-Off" beginning on page 108 of this Information Statement. In addition, Illumina has the right not to complete the Spin-Off if, at any time, the Illumina Board determines, in its sole and absolute discretion, that the Spin-Off is not in the best interests of Illumina or its stockholders, or is otherwise not advisable. If the Spin-Off is not completed for any reason, Illumina and GRAIL will have incurred significant costs related to the Spin-Off, including fees for consultants, financial and legal advisors, accountants and auditors, that will not be recouped. Total one-time transaction costs associated with the Spin-Off are preliminarily estimated to range from $ to $ if the Spin-Off is completed. If the Spin-Off is not completed for any reason, the one-time transaction costs will generally be limited to the transaction costs incurred for services rendered as of the date the Spin-Off is abandoned, which will be less than the range noted above. Our management will also have devoted significant time to manage the Spin-Off process, which will decrease the time they will have to manage the business of GRAIL.
Trading Market and Ticker Symbol	We intend to file an application to list our common stock on Nasdaq under the ticker symbol "GRAL." We anticipate that, on or shortly before the Record Date, trading of shares of our common stock will begin on a "when-issued" basis and will continue up to and including the Distribution Date, and we expect that "regular-way" trading of our common stock will begin the first trading day after the Distribution Date. We also anticipate that, on or shortly before the Record Date, there will be two markets in Illumina common stock: (i) a "regular-way" market on which shares of Illumina common stock will trade with an entitlement for the purchaser of Illumina common stock to receive shares of our common stock to be distributed in the Distribution, and (ii) an "ex-distribution" market on which shares of Illumina common stock will trade without an entitlement for the purchaser of Illumina common stock to receive shares of our common stock. For more information, see the section entitled "The Spin-Off—Trading Prior to the Distribution Date" beginning on page 107 of this Information Statement.
Tax Consequences to Illumina Stockholders	Completion of the Spin-Off is conditioned upon Illumina's receipt of a private letter ruling from the IRS and a written opinion of Cravath, Swaine & Moore LLP, each of which shall remain in full force and effect, 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. If the Spin-Off qualifies for such treatment, for U.S. federal income tax purposes, no gain or loss will be recognized by, or be includible in the income of, a

	U.S. Holder (as defined in the section entitled "The Spin-Off—Material U.S. Federal Income Tax Consequences of the Spin-Off" beginning on page 103 of this Information Statement) as a result of the Distribution, except with respect to any cash received by Illumina stockholders in lieu of fractional shares. After the Distribution, Illumina stockholders generally should allocate their aggregate tax basis in their Illumina common stock held immediately before the Distribution between their Illumina common stock and our common stock in proportion to their relative fair market values on the date of the Distribution (subject to certain adjustments). See the section entitled "The Spin-Off—Material U.S. Federal Income Tax Consequences of the Spin-Off" beginning on page 103 of this Information Statement for more information regarding the potential tax consequences to you of the Spin-Off. We urge you to consult your tax advisor as to the specific tax consequences of the Distribution to you, including the effect of any U.S. federal, state, local or foreign tax laws and of changes in applicable tax laws.
Relationship with Illumina After the Spin-Off	Following the Distribution, Illumina may retain up to 14.5% of the outstanding shares of our common stock. Illumina expects that the IRS private letter ruling will require that all retained shares be sold or otherwise disposed of by Illumina as soon as warranted consistent with the business reasons for the retention of those shares, but in no event later than five years after the Distribution. Such dispositions could include a sale of its shares for cash, distributions of GRAIL common stock to Illumina stockholders or securityholders as dividends or in exchange for outstanding shares of Illumina common stock, indebtedness or other securities, or any combination thereof. We intend to enter into several agreements with Illumina related to the Spin-Off, which will govern the relationship between Illumina and us after completion of the Spin-Off and allocate between Illumina and us various assets, liabilities, rights and obligations. These agreements include: • a Separation and Distribution Agreement that will set forth Illumina's and our agreements regarding the principal actions that both parties will take in connection with the Spin-Off and aspects of our relationship following the Spin-Off; • a Tax Matters Agreement that will govern the respective rights, responsibilities and obligations of Illumina and us after the Spin-Off with respect to all tax matters and will include restrictions to preserve the tax-free status of the Distribution; and • a Stockholder and Registration Rights Agreement that will govern the respective rights, responsibilities and obligations of Illumina and us after the Spin-Off with respect to Illumina's continuing ownership of GRAIL common stock.

	In addition to the above agreements, we are also currently party to, or intend to enter into, various other agreements with Illumina and its subsidiaries, including a supply and commercialization agreement and license agreements. We describe these arrangements in greater detail under the section entitled "Certain Relationships and Related Party Transactions" beginning on page 217 of this Information Statement and describe some of the risks of these arrangements under the section entitled "Risk Factors—Risks Relating to the Spin-Off" beginning on page 87 of this Information Statement.
Dividend Policy	We do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends on our common stock will be made at the discretion of our Board and will depend upon certain factors. For more information, see the section entitled "Dividend Policy."
Transfer Agent	Computershare Trust Company, N.A. ("Computershare").
Risk Factors	Our business faces both general and specific risks and uncertainties. Our business also faces risks relating to the Spin-Off. Following the Spin-Off, we will also face risks associated with being an independent, publicly traded company. Accordingly, you should read carefully the information set forth under the section entitled "Risk Factors" beginning on page 30 of this Information Statement.

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RISK FACTORS

You should carefully consider the following risks and other information in this Information Statement in evaluating GRAIL and GRAIL common stock. 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.

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, and rapid growth 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 $1.5 billion for fiscal year 2023, $5.4 billion for fiscal year 2022, $911.5 million for the 2021 successor period, and $336.2 million for the 2021 predecessor period. 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 $718.5 million and $4.7 billion for fiscal year 2023 and fiscal year 2022, respectively, related to the intangible assets and goodwill recorded by Illumina upon the acquisition of GRAIL. As of December 31, 2023, we had an accumulated deficit of $7.8 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 improve Galleri and current and future products, including our diagnostic aid for cancer ("DAC") test, 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;
- continue our research and development activities;
- conduct our ongoing clinical studies and initiate and conduct additional clinical studies to support the development and commercialization of our products and future products;
- continue to expand our laboratory capacity and enhance operating capabilities for greater commercial scale;
- seek regulatory approvals, clearances, or certifications, or coverage and reimbursement, that may be necessary or desired for our products and future products;
- maintain and expand 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;
- provide additional 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 international commercial expansion of our products;
- continue to engage the medical community and others to drive awareness and adoption of multicancer 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. This could materially and adversely affect our business, financial condition, results of operations, and growth prospects.

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 our future products in development, including DAC, 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. For example, certain results of an early

analysis from the first screening test (the prevalent screening round) in the NHS-Galleri Trial will impact the extent to which NHS commences a potential two-year commercial pilot in England. These results represent limited information from only one year of results out of the three-year trial period, and final results from the full three-year period, which will inform the extent to which NHS commences broad commercial implementation, may differ from these initial results for a variety of reasons. The NHS may commence the commercial pilot if it determines that these results are exceptionally compelling, and it is possible that the results of the early analysis or final results will be unsuitable to the NHS, 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. We plan to complete a PMA submission for Galleri, for which the FDA has granted breakthrough device designation. Additionally, following the future launch of DAC as an LDT, we may voluntarily decide to seek clearance or approval from the FDA. The 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 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 clinical research organization ("CRO") 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 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. 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 operation 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 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 PATHFINDER 2 and REACH, 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 and the NHS-Galleri Trial, both of 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 or NHS-Galleri Trial. 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.

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 clinical studies such as the European Union’s (“EU”) or United Kingdom’s General Data Protection Regulation (“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 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, our precision oncology portfolio, or DAC, 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, including Galleri and DAC, 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 to conduct additional 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 December 31, 2023 we have sold more than 150,000 Galleri tests through our existing market channels. We also launched our precision oncology portfolio in 2023, which currently comprises a research use only ("RUO") offering, and have partnered with several biopharmaceutical companies to deploy this offering. While we plan to commercially launch DAC in the United States as an LDT, we cannot assure you that we will successfully be able to do so 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 any 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, DAC, 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 and DAC;
- 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" beginning on pages 115, 195, and 217, respectively, of this Information Statement.

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" beginning on page 156.

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.

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Pursuant to 17 C.F.R. Section 200.83

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", beginning on page 171 of this 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.

We continue to expand our research and development efforts to use our proprietary methylation platform and our large clinical and genomic datasets to develop enhanced versions of our products and future products. 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, prepare for the potential launch and commercialization of DAC, continue to enhance our core technology platform, broaden the applications of our technology platform, and develop new products. 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 January 1, 2023, we had $241.6 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” beginning on page 98 of this 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 for the development and potential commercialization of DAC, and for the development 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, such as DAC, 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.

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.

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 DAC, 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.

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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. 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 DAC and other 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 DAC, 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 depend on various third parties, including information technology, sample collection, processing, transfer facilities, and other patient-facing service providers. Any disruption, failure, or interruption at any of these third parties could materially adversely affect our business, results of operations, financial condition, and growth prospects.

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 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 will need to continue to ramp up laboratory capacity, including increasing the processing of Galleri in our Durham, North Carolina facility. This includes the transition of operations from 16 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 will 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 may be more challenging for our 24/7 operations when 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, DAC, 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, 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 Labs, 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, 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.

As of December 31, 2023, we had approximately 1,340 employees, substantially all of whom were full-time. As our development plans and strategies develop, and as we transition into operating 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.

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.

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 implementation of a pilot under our agreement with the NHS, and further commercialization of Galleri with the NHS after that pilot, 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" beginning on page 56 of this Information Statement.

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. 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.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

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;
- 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.

Risks Relating to Regulation and Legal Compliance

We have launched Galleri as an LDT, and plan to launch DAC as an LDT in the United States. If the FDA modifies its current policy of enforcement discretion on LDTs, as it has recently proposed through rulemaking, or if Congress enacts legislation that changes the current requirements or oversight for LDTs, we may lose the ability to commercialize any LDTs unless we have obtained FDA marketing authorization, which could require us to incur substantial costs and delays.

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 and intend to initially launch DAC 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 its current 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 that, if finalized, would 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. If this proposed rule or a similar rule is finalized and goes into effect, it would subject our products currently marketed as LDTs and any future products that we may market as LDTs in the future to the FDA's standard regulatory requirements applicable to medical devices, including the potential requirement for FDA approval. In such case, we may be required to cease marketing any products that we market as LDTs if we do not obtain marketing authorization, or have a market authorization pending with the FDA, prior to any relevant effective or enforcement date. 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, even if the FDA does not finalize its proposed rule or otherwise modify its current policy of enforcement discretion, the FDA may disagree that we are marketing our LDTs within the scope of its policy of enforcement discretion and may take enforcement action against us and/or require premarket review and marketing authorizations. 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. In addition, the FDA may choose not to exercise enforcement discretion with respect to the products we market or intend to market as LDTs. 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.

If the FDA changes its policy of enforcement discretion for LDTs as recently proposed, or because it withdraws its enforcement discretion for our specific products or for classes of products within which our products fall, or if LDTs become subject to affirmative FDA oversight through legislation, 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, such as DAC. 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.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

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, 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.

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 recently announced a November 29, 2023 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.

As part of our ongoing discussions with the FDA regarding the data that will be needed to support a PMA for a multi-cancer detection test based on a proposed intended use, 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, confirming the use of certain of our proposed

studies in our PMA submission and requesting or suggesting changes to certain of our proposed studies, for which we have reached mutual agreement. For example, the FDA stated that an analytical accuracy study would not be relevant to be performed due to the unique nature of our methylation-based signature assay and lack of precedent approved diagnostic assays. In addition, the FDA stated that we can perform our LoD studies using samples from known cancer cell lines instead of clinical samples due to the nature of the methylation-based functions and mechanics of the assay. While we plan to continue discussions with the FDA and provide the FDA with additional information, 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, we cannot be certain whether we will receive FDA approval for Galleri and whether 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 premarket 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. The FDA may require us to perform new analyses of our clinical data or perform additional clinical trials in addition to those we are contemplating. We may be required to undertake significant efforts to address the FDA's requests, which could 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.

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 operation.

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, 2022, the FDA issued a proposed rule to amend the Quality System Regulation ("QSR"), which establishes current good manufacturing practice requirements for medical device manufacturers, to align more closely with the International Organization for Standardization standards. This proposal has not yet been finalized or implemented. Accordingly, it is unclear the extent to which this or any other proposals, if adopted, 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. 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.

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Pursuant to 17 C.F.R. Section 200.83

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 has issued a proposed rule to amend the QSR to align more closely with the International Organization for Standardization standards. Although this proposal has not yet been finalized or implemented and it is unclear the extent to which this or any other proposals, if adopted, could impose additional or different regulatory requirements on us or our third-party manufacturers, the amendment could increase the costs of compliance or otherwise create market pressure that may negatively affect our business. Failure to comply with applicable FDA requirements or later discovery of previously unknown problems with our products or manufacturing processes 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.

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Pursuant to 17 C.F.R. Section 200.83

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 from third-party payors, if at all, our ability to expand access to our products beyond our existing sales channels will be limited and our overall commercial success will be limited" beginning on page 39 of this Information Statement.

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 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.

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.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

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.

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.

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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

If the Distribution does not qualify as a transaction that is tax-free for U.S. federal income tax purposes, Illumina and its stockholders could be subject to significant tax liability.

Completion of the Spin-Off is conditioned on Illumina's receipt of a private letter ruling from the IRS and a written opinion of Cravath, Swaine & Moore LLP, each of which shall remain in full force and effect, 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 Section 355 and 368 of the Code.

The private letter ruling and the opinion of counsel will not address any U.S. state or local or foreign tax consequences of the Spin-Off. The private letter ruling and the opinion will assume that the Spin-Off will be completed according to the terms of the Separation and Distribution Agreement and will rely on the facts as stated in the Separation and Distribution Agreement, the Tax Matters Agreement, the other ancillary agreements, this Information Statement, and certain other documents. In addition, the private letter ruling and the opinion will be based on certain representations as to factual matters from, and certain covenants by, Illumina and us. The private letter ruling and the opinion cannot be relied on if any of the assumptions, representations, or covenants is incorrect, incomplete or inaccurate or is violated in any material respect.

The opinion of counsel is not binding on the IRS or the courts, and there can be no assurance that the IRS or a court will not take a contrary position. Although a private letter ruling from the IRS is generally binding on the IRS, the ruling will be based on certain facts and representations and undertakings from Illumina and us that certain necessary conditions to obtain tax-free treatment under the Code have been satisfied.

If the Spin-Off were determined not to qualify for non-recognition of gain and loss under Section 355 and 368 of the Code, Illumina and its shareholders could be subject to tax. In this case, each U.S. Holder (as defined in "The Spin-Off—Material U.S. Federal Income Tax Consequences of the Spin-Off") who receives our common stock in the Distribution would generally, for U.S. federal income tax purposes, be treated as receiving a distribution in an amount equal to the fair market value of our common stock received, which would generally result in (i) a taxable dividend to the U.S. Holder to the extent of that U.S. Holder's pro rata share of Illumina's current and accumulated earnings and profits; (ii) a reduction in the U.S. Holder's basis (but not below zero) in Illumina common stock to the extent the amount received exceeds the shareholder's share of Illumina's earnings and profits; and (iii) a taxable gain from the exchange of Illumina common stock to the extent the amount received exceeds the sum of the U.S. Holder's share of Illumina's earnings and profits and the U.S. Holder's basis in its Illumina common stock. For more information, see below and the section entitled "The Spin-Off—Material U.S. Federal Income Tax Consequences of the Spin-Off" beginning on page 103 of this Information Statement.

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, which could materially adversely affect our business, financial condition, and results of operations.

If it were determined that the Spin-Off did not qualify for non-recognition of gain and loss under Section 355 and 368 of the Code, we expect that we could, under certain circumstances, be required to indemnify Illumina for the resulting taxes and related expenses. Any such expected indemnification obligation could materially adversely affect our business, financial condition, and results of operations. For a description of such indemnification obligation, see "Certain Relationships and Related Party Transactions—Agreements with Illumina—Tax Matters Agreement" beginning on page 218 of this Information Statement.

We intend to agree to numerous restrictions to preserve the non-recognition treatment of the Distribution, which may reduce our strategic and operating flexibility.

We expect to agree in the Tax Matters Agreement to certain covenants and indemnification obligations that address compliance with Section 355(e) of the Code. 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. For more information, see the section entitled "Certain Relationships and Related Party Transactions—Agreements with Illumina—Tax Matters Agreement" beginning on page 218 of this Information Statement.

We may be unable to achieve some or all of the benefits that we expect to achieve from the Spin-Off, which could materially adversely affect our business, financial condition, and results of operations.

We believe that, as a separate, publicly traded company, we will be able to, among other things:

- design and implement corporate strategies and policies that are targeted to our business;
- better focus our financial resources on our specific business;
- create effective incentives for our management and employees that are more closely tied to our business performance;
- more effectively articulate a clear investment proposition to attract a long-term investor base suited to our business, growth profile, and capital allocation priorities; and
- maintain a capital structure designed to meet our specific needs.

However, we may not achieve these and other anticipated benefits for a variety of reasons, including, among other things:

- the Spin-Off will require significant amounts of management's time and effort, which may divert management's attention from operating and growing our business and may disrupt our operations;
- due to the application of pushdown accounting, our balance sheet includes goodwill and intangible assets recognized by Illumina in connection with their acquisition of us that may be subject to additional impairment over time;
- following the Spin-Off, our obligation to pay to Illumina a royalty will resume, which was suspended while we were owned by Illumina and will continue to be suspended until the earlier of two-and-a-half years or any earlier change of control of GRAIL, at which time royalty payments will resume;
- following the Spin-Off, we may be more susceptible to market fluctuations, the risk of takeover by third parties and other adverse events because our business will be less diversified than Illumina's businesses prior to the Spin-Off;
- the Spin-Off may require us to incur significant costs, including accounting, tax, legal, and other professional services costs and recruiting and relocation costs associated with hiring key senior management personnel who are new to our company, and costs to retain key management personnel;
- certain costs and liabilities that were otherwise less significant to Illumina as a whole will be more significant for us and Illumina as separate companies after the separation; and
- under the terms of the Tax Matters Agreement that we will enter into with Illumina, we expect to be restricted from taking certain actions that could cause the Spin-Off or other related transactions to fail to qualify as a tax-free transaction and these restrictions may limit us for a period of time from pursuing certain strategic transactions and equity issuances or engaging in other transactions that might increase the value of our business.

If we fail to achieve some or all of the benefits expected to result from the Spin-Off, or if such benefits are delayed, our business, financial condition, and results of operations could be materially adversely affected.

We have no history of operating as a separate, publicly traded company, and 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 January 2016 until our acquisition by Illumina on August 18, 2021, we operated as an independent privately held company. Although we are a wholly owned subsidiary of Illumina, in connection with the legal and regulatory matters described under the section entitled "The Spin Off," our business is held and operated separately and independently from Illumina and Illumina must fund our operations and development. We derived the historical financial data included in this Information Statement 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 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 will be 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 "Selected Historical Financial Data," "Unaudited Pro Forma Condensed Consolidated Financial Information," and "Management's Discussion and Analysis of Financial Condition and Results of Operations" beginning on pages 112, 114, and 176, respectively, of this Information Statement and our Consolidated Financial Statements and the notes thereto included in "Index to Consolidated Financial Statements" beginning on page F-1 of this Information Statement.

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.

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The unaudited pro forma condensed consolidated financial information included in this Information Statement is presented for informational purposes only and may not be an indication of our financial condition or results of operations in the future.

The unaudited pro forma condensed consolidated financial information included in this Information Statement is presented for informational purposes only and are not necessarily indicative of what our actual financial condition or results of operations would have been had the Spin-Off been completed on the date indicated. The assumptions used in preparing the pro forma financial information may not prove to be accurate and other factors may affect our financial condition or results of operations. Accordingly, our financial condition and results of operations in the future may not be evident from or consistent with such pro forma financial information.

Until the distribution occurs, the Illumina Board may change the terms of the Spin-Off in ways that may be unfavorable to us.

Until the Distribution occurs, we will continue to be a wholly owned subsidiary of Illumina. Accordingly, Illumina has the discretion to determine and change the terms of the Spin-Off, including the establishment of the Record Date (as defined below) and the Distribution Date, and these changes could be unfavorable to us. In addition, the Illumina Board may decide not to proceed with the Spin-Off at any time prior to the Distribution.

No vote of Illumina shareholders is required in connection with the Spin-Off. As a result, if the Spin-Off occurs and you do not want to receive our common stock in the Distribution, your sole recourse will be to divest yourself of your Illumina common stock prior to the Record Date or in the "regular-way" trading market during the period prior to the Distribution.

No vote of Illumina shareholders is required in connection with the Spin-Off. Accordingly, if the Distribution occurs and you do not want to receive our common stock in the Distribution, your only recourse will be to divest yourself of your Illumina common stock prior to the Record Date or in the "regular-way" trading market during the period prior to the Distribution.

After the distribution, certain of our executive officers may have actual or potential conflicts of interest because of their equity interests in Illumina.

Because of their former positions with Illumina, certain of our executive officers own equity interests in Illumina. Continuing ownership of shares of Illumina common stock and equity awards (assuming such awards do not convert to GRAIL awards) could create, or appear to create, potential conflicts of interest if we and Illumina face decisions that could have implications for both Illumina and us after the separation.

Risks Relating to Our Common Stock

No market for our common stock currently exists and an active trading market may not develop or be sustained after the Spin-Off. Following the Spin-Off our stock price may fluctuate significantly.

There is currently no public market for our common stock. We intend to apply to list our common stock on Nasdaq. We anticipate that before the Distribution Date, trading of shares of our common stock will begin on a "when-issued" basis and this trading will continue up to and including the Distribution Date. However, an active trading market for our common stock may not develop as a result of the Spin-Off or 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.

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We cannot predict the prices at which our common stock may trade after the Spin-Off. 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 our other products, including DAC, 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” beginning on page 93 of this Information Statement. 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" beginning on page 96 of this Information Statement.

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 will rely in part on the research and reports that industry or securities analysts publish about us or our business. We do not currently have, and may never obtain, research coverage by industry or securities analysts. If no or few analysts commence coverage of us, the trading price of our stock could decrease. Even if we do obtain analyst coverage, 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. Prior to completion of the Spin-Off, we expect to approve an equity incentive plan that will provide for the grant of equity-based awards to our directors, officers, and other employees, including equity grants that are expected to be made upon completion of the Spin-Off. In addition, each Cash-Based Equity Award outstanding as of the Distribution Date may convert into GRAIL RSUs. For more information, see "Executive Compensation—Equity-Linked Compensation" beginning on page 205 of this Information Statement.

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 may choose to take advantage of some or all of these reduced burdens. For example, we have taken advantage of the reduced disclosure obligations regarding executive compensation in this Information Statement. 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 included in this Information Statement, as well as 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 receiving shares of our common stock in the Distribution generally may sell those shares immediately in the public market. It is likely that some Illumina shareholders, including some of its larger shareholders, will sell their shares of our common stock received in the Distribution 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.

Following the Distribution, Illumina will retain up to a 14.5% ownership interest of our common stock. We expect to enter into a Stockholder and Registration Rights Agreement with Illumina, pursuant to which we will

provide Illumina registration rights with respect to the shares of our common stock it will retain following the Distribution. In addition, Illumina will agree 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 Distribution. See "Certain Relationships and Related Party Transactions—Agreements with Illumina" beginning on page 217 of this Information Statement. Illumina is not required to hold any retained shares for any minimum period following the Distribution. We are unable to predict with certainty when Illumina will dispose of a substantial number of shares of common stock following the Distribution. 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.

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 % 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. For more information, see "Description of Our Capital Stock—Certain Provisions of Delaware Law, Our Certificate of Incorporation and Bylaws" beginning on page 222 of this Information Statement.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

Our Certificate of Incorporation will designate 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 will provide 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.

The rights associated with our common stock will differ from the rights associated with Illumina common stock.

Upon completion of the Distribution, the rights of Illumina shareholders who become our shareholders will be governed by our Certificate of Incorporation and Bylaws and by Delaware law. The rights associated with Illumina shares are different from the rights associated with our shares. Material differences between the rights of Illumina shareholders and the rights of our shareholders include differences with respect to, among other things:

- whether the board of directors is classified;
- the right of shareholders to call special meetings;
- the voting standard in director elections; and
- certain anti-takeover measures.

For more information, see "Description of Our Capital Stock—Certain Provisions of Delaware Law, Our Certificate of Incorporation and Bylaws" beginning on page 222 of this Information Statement.

We could be subject to 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.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This Information Statement 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, and anticipated trends in our business and the Spin-Off, including the expected timing of completion of the Spin-Off and estimated costs associated with the Spin-Off.

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 Information Statement to conform our prior statements to actual results or revised expectations or to reflect new information or the occurrence of unanticipated events.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

THE SPIN-OFF

Background

Illumina completed its acquisition of us on August 18, 2021 (the "Acquisition"). At the same time, Illumina executed binding commitments pursuant to which Illumina would hold GRAIL separately during the European Commission's review of the Acquisition (the "Hold Separate Commitments"). In April 2021, the European Commission asserted jurisdiction to review the Acquisition pursuant to Article 22 of Council Regulation (EC) No 139/2004 (the "EU Merger Regulation"). On July 13, 2022, the General Court of the European Union dismissed Illumina's action for annulment of the European Commission's jurisdictional claim and ruled in favor of the Commission, holding that the European Commission has jurisdiction to review the Acquisition under the EU Merger Regulation. Illumina maintains that the European Commission does not have jurisdiction over the Acquisition, and on September 22 and 30, 2022, Illumina and GRAIL, respectively, each filed a separate appeal in the Court of Justice of the European Union, both of which remain pending. On September 6, 2022, the European Commission adopted a decision finding that, in its view, Illumina's acquisition of GRAIL was incompatible with the internal market in Europe. On November 17, 2022, Illumina asked for annulment of this decision before the General Court of the European Union (GRAIL intervened in this procedure in support of Illumina). On July 12, 2023, the European Commission adopted a final decision finding that Illumina breached the EU Merger Regulation by, in its view, acquiring the possibility to exert decisive influence over GRAIL and exerting such influence during the pendency of the European Commission's review. On September 26, 2023, Illumina sought the annulment of this decision. On October 29, 2021, the European Commission adopted an order imposing interim measures, (the "Initial Interim Measures Orders") which was renewed on October 28, 2022 (the "Second Interim Measures Orders"). Illumina and GRAIL both sought the annulment of the initial interim measures, and Illumina—with GRAIL intervening in its support—also sought the annulment of the renewed interim measures. The European Commission imposed transitional measures on October 12, 2023 (the "Transitional Measures") pursuant to the EC Divestment Decision (as defined below), which replaced the Initial Interim Measures Orders and Second Interim Measures Orders. Such measures provide, among other things, that (i) Illumina ensure that Illumina and GRAIL continue to operate as independent legal entities that transact at arm's length, no integration activity takes place, the day-to-day operation of GRAIL remains the sole responsibility of GRAIL's management and Illumina's management has no involvement in or influence over GRAIL and (ii) Illumina take certain supportive measures to preserve GRAIL's viability, marketability, and competitiveness, including with respect to the provision of resources to GRAIL and the retention and/or replacement of key personnel of GRAIL. Currently, GRAIL is held and operated separately and independently from Illumina and Illumina must fund GRAIL's operations and development.

On December 5, 2022, the European Commission issued a Statement of Objections informing Illumina of the order it intended to adopt which would require Illumina to divest GRAIL (the "EC Divestment Decision"). On October 12, 2023, the European Commission announced that it had adopted the EC Divestment Decision, which orders Illumina to, among other things, divest GRAIL, and imposes the Transitional Measures. The EC Divestment Decision requires Illumina to dispose of GRAIL within 12 months of the date of the EC Divestment Decision (which date can be extended by three months in certain circumstances upon request by Illumina). The EC Divestment Decision permits Illumina to consider a range of methods of disposal including, but not limited to, a third-party sale or a capital markets transaction. On December 22, 2023, Illumina sought the annulment of the EC Divestment Decision. On , the European Commission approved a divestment plan (the "Divestment Plan") submitted by Illumina pursuant to which Illumina agreed to divest GRAIL on specified terms. The EC Divestment Decision permits Illumina to retain up to a 14.5% ownership interest in GRAIL and to re-establish the royalty arrangement it previously had in place with GRAIL. See the section entitled "Certain Relationships and Related Party Transactions—Agreements with Illumina" beginning on page 217 of this Information Statement for more detail. Assuming the Spin-Off is consummated, Illumina is required to, among other things, ensure that GRAIL has sufficient funding to cover a specified period of operations.

The risks and costs related to the foregoing proceedings, including the costs associated with our intervention in the proceedings and all other legal costs, are fundamentally borne by Illumina and not GRAIL. We expect that

future costs associated with these regulatory proceedings will be limited because the Separation and Distribution is anticipated to expedite resolution of such regulatory proceedings and we do not anticipate being a separate party to ongoing regulatory proceedings after the Spin-Off.

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 Acquisition and dismissed the FTC's complaint. The FTC's complaint counsel appealed to the full FTC. On March 31, 2023, the FTC issued a decision overturning the administrative law judge's prior ruling ("FTC Order"). GRAIL and Illumina appealed the FTC's decision to the U.S. Court of Appeals for the Fifth Circuit (the "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's decision, and in all other respects upheld the FTC's decision. We expect the Spin-Off to facilitate a prompt resolution of the FTC proceedings and, based on the fact that Illumina had a 14.5% ownership interest in GRAIL at the time of the Acquisition, do not expect that Illumina's potential retention of up to a 14.5% ownership interest in GRAIL will affect the resolution of these proceedings.

On December 17, 2023, Illumina announced it would divest GRAIL. On , 2024, Illumina announced plans for the separation of GRAIL from Illumina via the Spin-Off.

To effect the Spin-Off, Illumina will distribute at least 85.5% of the shares of GRAIL's common stock owned by Illumina as of the close of business on , 2024, which is the record date for the Distribution, to Illumina's stockholders, and GRAIL will become an independent, publicly traded company. Immediately after the Distribution becomes effective, Illumina may retain up to 14.5% of GRAIL's common stock.

Prior to completion of the Spin-Off, we intend to enter into a Separation and Distribution Agreement and several other agreements with Illumina related to the Spin-Off. These agreements will govern the relationship between Illumina and us after completion of the Spin-Off and allocate between Illumina and us various assets, liabilities and obligations, including tax-related assets and liabilities. See the section entitled "Certain Relationships and Related Party Transactions" beginning on page 217 of this Information Statement for more detail. No approval of Illumina's stockholders is required in connection with the Spin-Off, and Illumina's stockholders will not have any appraisal rights in connection with the Spin-Off.

Completion of the Spin-Off is subject to the satisfaction, or the waiver by Illumina's board of directors (the "Illumina Board"), of a number of conditions. If the Illumina Board waives any condition prior to the effectiveness of the Registration Statement on Form 10, of which this Information Statement is a part, and the result of such waiver is material to Illumina stockholders, Illumina will file an amendment to the Registration Statement to revise the disclosure in this Information Statement accordingly. In the event that the Illumina Board waives a condition after the Registration Statement on Form 10, of which this Information Statement is a part, becomes effective and such waiver is material to Illumina stockholders, Illumina will communicate such change to Illumina stockholders by filing a Current Report on Form 8-K describing the change. For a complete discussion of the conditions to the Distribution, see the section entitled "The Spin-Off—Conditions to the Spin-Off" beginning on page 107 of this Information Statement.

In addition, Illumina has the right not to complete the Spin-Off if, at any time, the Illumina Board determines, in its sole and absolute discretion, that the Spin-Off is not in the best interests of Illumina or its stockholders or is otherwise not advisable. If the Spin-Off is not completed for any reason, Illumina and GRAIL will have incurred significant costs related to the Spin-Off, including fees for consultants, financial and legal advisors, accountants and auditors, that will not be recouped. Total one-time transaction costs associated with the Spin-Off are preliminarily estimated to range from $ to $ if the Spin-Off is completed. If the Spin-Off is not completed for any reason, the one-time transaction costs will generally be limited to the transaction costs

incurred for services rendered as of the date the Spin-Off is abandoned, which will be less than the range noted above. Our and Illumina's management will also have devoted significant time to manage the Spin-Off process, which will decrease the time they will have to manage their respective businesses. See the section entitled "The Spin-Off—Conditions to the Spin-Off" beginning on page 107 of this Information Statement for more detail.

Reasons for the Spin-Off

In connection with the EC Divestment Decision and with the goal of enhancing stockholder value, the Illumina Board conducted a process through which it considered a range of potential divestment transactions.

As part of this evaluation, the Illumina Board considered a number of factors, including the long-term prospects and strategic viability of GRAIL, the strategic clarity and flexibility for Illumina and GRAIL after the Spin-Off, the ability of GRAIL to compete and operate efficiently and effectively (including GRAIL's ability to retain and attract management talent) after the Spin-Off, the financial profile of GRAIL, the expected timing of completion of each structural alternative, the expected tax impact of each structural alternative, the probability of successful execution of each structural alternative, and the potential reaction of investors. After evaluating these and other considerations, the Illumina Board concluded that the Spin-Off presented the most attractive alternative for enhancing long-term stockholder value while complying with the requirements of the EC Divestment Decision and that proceeding with the Spin-Off would be in the best interests of Illumina and its stockholders.

In particular, the Illumina Board considered a number of potential benefits of this approach, including:

- ***Opportunity for continued ownership of GRAIL by Illumina stockholders.*** The Spin-Off will provide Illumina stockholders the opportunity to determine whether they wish to continue to own an interest in GRAIL despite GRAIL's required separation from Illumina.
- ***Distinct and clear financial profiles and compelling investment cases***. Investment in one or the other company may appeal to investors with different goals, interests, and expectations. The Spin-Off will allow investors to make independent investment decisions with respect to Illumina and GRAIL and may result in greater alignment between the interests of each company's stockholder base and the characteristics of its respective business, capital structure, and financial results.
- ***Separate capital structures and allocation flexibility***. The Spin-Off will permit each of Illumina and GRAIL to allocate its financial resources to meet the unique needs of its own businesses, which will allow each company to focus on its distinct strategic priorities and individual business risk and return profiles.
- ***Creation of independent equity securities and increased strategic opportunities***. The Spin-Off will afford Illumina and GRAIL the ability to offer their independent equity securities to the capital markets and enable each standalone company to use its own industry-focused stock to pursue portfolio-enhancing acquisitions or other strategic opportunities that are more closely aligned with each company's strategic goals and expected growth opportunities.

The Illumina Board also considered a number of potentially negative factors in evaluating the Spin-Off, including:

- ***Risk of failure to achieve the anticipated benefits of the Spin-Off***. Illumina and GRAIL may not achieve the anticipated benefits of the Spin-Off for a variety of reasons, including, among others: the Spin-Off will require significant amounts of management's time and effort, which may divert management's attention from operating and growing our businesses; there may be dis-synergy costs related to the Spin-Off; and following the Spin-Off, each company may be more susceptible to certain economic and market fluctuations and other adverse events than if GRAIL were still a part of Illumina because each company will be less diversified than Illumina prior to the separation. For more information on the specific risks to GRAIL of the failure to achieve the anticipated benefits of the

Spin-Off, see the section entitled "Risk Factors—Risks Relating to the Spin-Off—We may be unable to achieve some or all of the benefits that we expect to achieve from the Spin-Off, which could materially adversely affect our business, financial condition, and results of operations" beginning on page 88 of this Information Statement.

- ***Limitations on strategic transactions***. Under the terms of the Tax Matters Agreement that GRAIL will enter into with Illumina, GRAIL expects to be restricted from taking certain actions that could cause the Distribution or certain related transactions to fail to qualify as tax-free transactions under applicable law. These restrictions may limit for a period of time GRAIL's ability to pursue certain strategic transactions and equity issuances or engage in other transactions that otherwise might increase the value of our business. For more information, see the section entitled "Certain Relationships and Related Party Transactions—Agreements with Illumina—Tax Matters Agreement" beginning on page 218 of this Information Statement.
- ***Disruptions and costs related to the Spin-Off***. The actions required to separate GRAIL from Illumina could disrupt both Illumina's and GRAIL's operations. In addition, Illumina and GRAIL will incur substantial costs in connection with the Spin-Off and GRAIL's transition to being a standalone public company, which may include accounting, tax, legal and other professional services costs, and recruiting and relocation costs associated with hiring directors and management who are new to GRAIL.
- ***Uncertainty regarding share prices***. We cannot predict the effect of the Distribution on the trading prices of Illumina's and GRAIL's common stock or know with certainty whether the combined market value of the shares of GRAIL common stock to be distributed per share of Illumina common stock in the Distribution and Illumina's common stock following the Distribution will be less than, equal to, or greater than the market value of the shares of Illumina's common stock prior to the Distribution. Furthermore, there is the risk of volatility in each company's stock price following the Distribution due to sales by certain stockholders whose investment objectives may not be met by each company's common stock, and it may take time for each company to attract its optimal stockholder base.

Notwithstanding these factors, the anticipated costs of which are not reasonably quantifiable, and considering the potential benefits discussed above, the Illumina Board determined that the Spin-Off provided the best opportunity to achieve the above benefits and enhance stockholder value. For additional information, see the section entitled "Risk Factors" beginning on page 30 of this Information Statement.

Reasons for Illumina's Retention of up to 14.5% of GRAIL Common Stock

Immediately after the Distribution becomes effective, Illumina may retain up to 14.5% of GRAIL's common stock. Illumina's plan to potentially distribute less than all of GRAIL's common stock to its stockholders in the Spin-Off is motivated by its desire to establish an appropriate capital structure for each of GRAIL and Illumina, including by strengthening Illumina's balance sheet or reducing Illumina's indebtedness, in any case directly or indirectly, following the Spin-Off. Illumina expects that the IRS private letter ruling will require that all retained shares be sold or otherwise disposed of by Illumina as soon as warranted consistent with the business reasons for the retention of those shares, but in no event later than five years after the Distribution. Such dispositions could include a sale of its shares for cash, distributions of GRAIL common stock to Illumina stockholders or securityholders as dividends or in exchange for outstanding shares of Illumina common stock, indebtedness or other securities, or any combination thereof.

We expect to enter into a Stockholder and Registration Rights Agreement with Illumina, pursuant to which we will provide Illumina registration rights with respect to the shares of our common stock it will retain following the Distribution. Illumina is not required to hold any retained shares for any minimum period following the Distribution. We are unable to predict with certainty when Illumina will dispose of a substantial number of shares of common stock following the Distribution. The sales of significant amounts of our common stock by Illumina, or the perception in the market that this will occur, may decrease the market price of our

common stock. See "Risk Factors—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" beginning on page 93 of this Information Statement.

When and How You Will Receive GRAIL Shares

Illumina will distribute to its stockholders, as a pro rata dividend, for every share[s] of Illumina common stock outstanding as of the close of business on the Record Date, , 2024, share[s] of our common stock.

Prior to the Distribution, Illumina will deliver at least 85.5% of the issued and outstanding shares of our common stock to the distribution agent. Computershare Trust Company, N.A. ("Computershare") will serve as distribution agent in connection with the Distribution and as transfer agent and registrar for our common stock.

If you own Illumina common stock as of the close of business on , 2024, the shares of our common stock that you are entitled to receive in the Distribution will be issued to your account as follows:

- *Registered stockholders*. If you own your shares of Illumina common stock directly through Illumina's transfer agent, Computershare, you are a registered stockholder. In this case, the distribution agent will credit the whole shares of our common stock you receive in the Distribution by way of direct registration in book-entry form to a new account with our transfer agent. Registration in book-entry form refers to a method of recording share ownership where no physical stock certificates are issued to stockholders, as is the case in the Distribution. You will be able to access information regarding your book-entry account holding the GRAIL shares at or by calling .

  Commencing on or shortly after the Distribution Date, the distribution agent will mail to you an account statement that indicates the number of whole shares of our common stock that have been registered in book-entry form in your name. We expect it will take the distribution agent up to two weeks after the Distribution Date to complete the distribution of the shares of our common stock and mail statements of holding to all registered stockholders.

- "*Street name*" *or beneficial stockholders*. If you own your shares of Illumina common stock beneficially through a bank, broker, or other nominee, such bank, broker, or other nominee holds the shares in "street name" and records your ownership on its books. If you own your shares of Illumina common stock through a bank, broker, or other nominee, your bank, broker, or other nominee will credit your account with the whole shares of our common stock that you receive in the Distribution on or shortly after the Distribution Date. We encourage you to contact your bank, broker, or other nominee if you have any questions concerning the mechanics of having shares held in "street name."

If you sell any of your shares of Illumina common stock on or before the Distribution Date, the buyer of those shares may, in some circumstances, be entitled to receive the shares of our common stock to be distributed in respect of the Illumina shares you sold. For more information, see the section entitled "—Trading Prior to the Distribution Date" beginning on page 107 of this Information Statement.

We are not asking Illumina stockholders to take any action in connection with the Spin-Off. No stockholder approval of the Spin-Off is required. We are not asking you for a proxy and request that you not send us a proxy. We are also not asking you to make any payment or surrender or exchange any of your shares of Illumina common stock for shares of our common stock. The number of outstanding shares of Illumina common stock will not change as a result of the Spin-Off.

Number of Shares You Will Receive

On the Distribution Date, for every share[s] of Illumina common stock you owned as of the Record Date, you will receive share[s] of our common stock.

Treatment of Fractional Shares

The distribution agent will not distribute any fractional shares of our common stock in connection with the Spin-Off. Instead, the distribution agent will aggregate all fractional shares into whole shares and sell the whole shares in the open market at prevailing market prices on behalf of Illumina stockholders entitled to receive a fractional share. The distribution agent will then distribute the aggregate cash proceeds of the sales, net of brokerage fees, transfer taxes and other costs, pro rata to these holders (net of any required withholding for taxes applicable to each holder). We anticipate that the distribution agent will make these sales in the "when-issued" market, and "when-issued" trades will generally settle within two trading days following the Distribution Date. For more information regarding "when-issued" trading, see the section entitled "—Trading Prior to the Distribution Date" beginning on page 107 of this Information Statement. The distribution agent will, in its sole discretion, without any influence by Illumina or us, determine when, how, through which broker-dealer, and at what price to sell the whole shares. The distribution agent is not, and any broker-dealer used by the distribution agent will not be, an affiliate of either Illumina or us.

The distribution agent will send to each registered holder of Illumina common stock entitled to a fractional share a check in the cash amount deliverable in lieu of that holder's fractional share as soon as practicable following the Distribution Date. We expect the distribution agent to take about two weeks after the Distribution Date to complete the distribution of cash in lieu of fractional shares to Illumina stockholders. If you hold your shares of GRAIL common stock through a bank, broker, or other nominee, your bank, broker, or nominee will receive, on your behalf, your pro rata share of the aggregate net cash proceeds of the sales. No interest will be paid on any cash you receive in lieu of a fractional share. The cash you receive in lieu of a fractional share will generally be taxable to you for U.S. federal income tax purposes. For more information, see the section below entitled "—Material U.S. Federal Income Tax Consequences of the Spin-Off" beginning on this page 103 of this Information Statement.

Treatment of Outstanding Equity Incentive Awards

We expect that each Illumina equity incentive award outstanding as of the Distribution Date held by directors and employees who will continue at Illumina will remain outstanding and continue to be subject to the same terms and conditions following the Distribution Date, but with adjustments to the number of shares of Illumina common stock subject to such award in order to preserve its value.

Each Cash-Based Equity Award outstanding as of the Distribution Date may convert into GRAIL RSUs.

Material U.S. Federal Income Tax Consequences of the Spin-Off

Consequences to U.S. Holders of Illumina Common Stock

The following is a summary of the material U.S. federal income tax consequences to holders of Illumina common stock in connection with the Distribution. This summary is based on the Internal Revenue Code of 1986, as amended (the "Code"), the Treasury Regulations promulgated under the Code and judicial and administrative interpretations of those laws, in each case as in effect and available as of the date of this Information Statement and all of which are subject to change at any time, possibly with retroactive effect. Any such change could affect the tax consequences described below.

This summary is limited to holders of Illumina common stock who hold their Illumina common stock as a capital asset. For purposes of this summary, a "U.S. Holder" is a beneficial owner of Illumina common stock that is, for U.S. federal income tax purposes:

- an individual who is a citizen or a resident of the U.S.;
- a corporation, or other entity taxable as a corporation for U.S. federal income tax purposes, created or organized under the laws of the U.S. or any state thereof or the District of Columbia;

- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if (i) a court within the U.S. is able to exercise primary jurisdiction over its administration and one or more U.S. persons have the authority to control all of its substantial decisions or (ii) in the case of a trust that was treated as a domestic trust under law in effect before August 20, 1996, a valid election is in place under applicable Treasury Regulations.

This summary does not discuss all tax considerations that may be relevant to shareholders in light of their particular circumstances, nor does it address the consequences to shareholders subject to special treatment under the U.S. federal income tax laws, such as:

- dealers or traders in securities or currencies;
- tax-exempt entities;
- banks, financial institutions, or insurance companies;
- real estate investment trusts, regulated investment companies, or grantor trusts;
- persons who acquired Illumina common stock pursuant to the exercise of employee stock options or otherwise as compensation;
- shareholders who own, or are deemed to own, 10% or more, by voting power or value, of Illumina equity;
- shareholders owning Illumina common stock as part of a position in a straddle or as part of a hedging, conversion, or other risk-reduction transaction for U.S. federal income tax purposes;
- certain former citizens or long-term residents of the U.S.;
- shareholders who are subject to the alternative minimum tax;
- persons who own Illumina common stock through partnerships or other pass-through entities; or
- persons who hold Illumina common stock through a tax-qualified retirement plan.

This summary does not address any U.S. state or local or foreign tax consequences or any estate, gift, or other non-income tax consequences.

If a partnership, or any other entity treated as a partnership for U.S. federal income tax purposes, holds Illumina common stock, the tax treatment of a partner in that partnership will generally depend on the status of the partner and the activities of the partnership. Such a partner or partnership is urged to consult its own tax advisor as to its tax consequences.

YOU ARE URGED TO CONSULT YOUR OWN TAX ADVISOR WITH RESPECT TO THE U.S. FEDERAL, STATE, AND LOCAL, AND FOREIGN TAX CONSEQUENCES OF THE DISTRIBUTION.

General

Completion of the Spin-Off is conditioned upon Illumina's receipt of a private letter ruling from the IRS and of a written opinion of Cravath, Swaine & Moore LLP, counsel to Illumina, each of which shall remain in full force and effect, that the Spin-Off will qualify for non-recognition of gain and loss under Sections 355 and 368 of the Code. The private letter ruling and the opinion will be based on the assumption that, among other things, the representations made, and information submitted, in connection with them are accurate, and that we and Illumina will comply with certain warranties and covenants specified therein. If the Spin-Off qualifies for this treatment and subject to the qualifications and limitations set forth herein (including the discussion below relating to the receipt of cash in lieu of fractional shares), for U.S. federal income tax purposes:

- no gain or loss will be recognized by, or be includible in the income of, a U.S. Holder as a result of the Distribution, except with respect to any cash received in lieu of fractional shares;

- the aggregate tax basis of the Illumina common stock and our common stock held by each U.S. Holder immediately after the Distribution will be the same as the aggregate tax basis of the Illumina common stock held by the U.S. Holder immediately before the Distribution, allocated between the Illumina common stock and our common stock in proportion to their relative fair market values on the date of the Distribution (subject to reduction upon the deemed sale of any fractional shares, as described below); and
- the holding period of our common stock received by each U.S. Holder should include the holding period of its Illumina common stock.

U.S. Holders who have acquired different blocks of Illumina common stock at different times or at different prices are urged to consult their tax advisors regarding the allocation of their aggregate adjusted tax basis among, and the holding period of, shares of our common stock distributed with respect to such blocks of Illumina common stock.

If a U.S. Holder receives cash in lieu of a fractional share of common stock as part of the Distribution, the U.S. Holder will be treated as though it first received a distribution of the fractional share in the Distribution and then sold it for the amount of cash actually received. The U.S. Holder will generally recognize capital gain or loss measured by the difference between the cash received for such fractional share and the U.S. Holder's tax basis in that fractional share, as determined above. Such capital gain or loss will be long-term capital gain or loss if the U.S. Holder's holding period for the Illumina common stock is more than one year on the date of the Distribution.

The private letter ruling and the opinion of counsel will not address any U.S. state or local or foreign tax consequences of the Spin-Off. The private letter ruling and the opinion will assume that the Spin-Off will be completed according to the terms of the Separation and Distribution Agreement and will rely on the facts as stated in the Separation and Distribution Agreement, the Tax Matters Agreement, the Stockholder and Registration Rights Agreement, the other ancillary agreements, this Information Statement, and a number of other documents. In addition, the private letter ruling and the opinion will be based on certain representations as to factual matters from, and certain covenants by, Illumina and us. The private letter ruling and the opinion cannot be relied on if any of the assumptions, representations or covenants are incorrect, incomplete, or inaccurate, or are violated in any material respect.

The opinion of counsel will not be binding on the IRS or the courts, and there can be no assurance that the IRS or a court will not take a contrary position. Although a private letter ruling from the IRS is generally binding on the IRS, the ruling will be based on certain facts and representations and undertakings from Illumina and us that certain necessary conditions to obtain tax-free treatment under the Code have been satisfied, and the private letter ruling will not address every requirement for the Spin-Off to qualify for tax-free treatment.

If the Spin-Off were determined not to qualify for non-recognition of gain and loss under Sections 355 and 368 of the Code, the above consequences would not apply, and U.S. Holders could be subject to tax. In this case, each U.S. Holder who receives our common stock in the Distribution would generally be treated as receiving a distribution in an amount equal to the fair market value of our common stock received, which would generally result in:

- a taxable dividend to the U.S. Holder to the extent of that U.S. Holder's pro rata share of Illumina's current and accumulated earnings and profits;
- a reduction in the U.S. Holder's basis (but not below zero) in Illumina common stock to the extent the amount received exceeds the shareholder's share of Illumina's earnings and profits; and
- a taxable gain from the exchange of Illumina common stock to the extent the amount received exceeds the sum of the U.S. Holder's share of Illumina's earnings and profits and the U.S. Holder's basis in its Illumina common stock.

Backup Withholding and Information Statement

Payments of cash in lieu of a fractional share of our common stock may, under certain circumstances, be subject to "backup withholding," unless a U.S. Holder provides proof of an applicable exemption or a correct taxpayer identification number, and otherwise complies with the requirements of the backup withholding rules. Corporations will generally be exempt from backup withholding, but may be required to provide a certification to establish their entitlement to the exemption. Backup withholding is not an additional tax, and it may be refunded or credited against a U.S. Holder's U.S. federal income tax liability if the required information is timely supplied to the IRS.

Treasury Regulations require each Illumina shareholder that, immediately before the Distribution, owned 5% or more (by vote or value) of the total outstanding stock of Illumina to attach to such shareholder's U.S. federal income tax return for the year in which the Distribution occurs a statement setting forth certain information related to the Distribution.

Consequences to Illumina

The following is a summary of the material U.S. federal income tax consequences to Illumina in connection with the Spin-Off that may be relevant to holders of Illumina common stock.

As discussed above, completion of the Spin-Off is conditioned upon Illumina's receipt of a private letter ruling from the IRS and of a written opinion of Cravath, Swaine & Moore LLP, counsel to Illumina, each of which shall remain in full force and effect, that the Spin-Off will qualify for non-recognition of gain and loss under Sections 355 and 368 of the Code. If the Spin-Off so qualifies, no gain or loss will be recognized by Illumina as a result of the Distribution. The opinion of counsel is subject to the qualifications and limitations as are set forth above under the section above entitled "—Consequences to U.S. Holders of Illumina Common Stock" beginning on page 103 of this Information Statement.

If the Spin-Off were determined not to qualify for non-recognition of gain and loss under Sections 355 and 368 of the Code, then Illumina would generally recognize gain equal to the excess of the fair market value of our common stock distributed to Illumina shareholders over Illumina's tax basis in our common stock.

Indemnification Obligation

If it were determined that the Spin-Off did not qualify for non-recognition of gain and loss under Sections 355 and 368 of the Code, we expect that we could, under certain circumstances, be required under the Tax Matters Agreement to indemnify Illumina for certain taxes resulting from the recognition of gain described above and related expenses. In addition, current tax law generally creates a presumption that the Distribution 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, Illumina would recognize gain equal to the excess of the fair market value of our common stock distributed to Illumina shareholders over Illumina's tax basis in our common stock and we expect that 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.

Results of the Spin-Off

After the Spin-Off, we will be an independent, publicly traded company. Immediately following the Spin-Off, we expect to have approximately beneficial holders of shares of our common stock and

approximately shares of our common stock outstanding, based in part on the number of Illumina stockholders and shares of Illumina common stock outstanding on , 2024. Up to 14.5% of our common stock will be held by Illumina. The actual number of shares of our common stock Illumina will distribute in the Spin-Off will depend on the actual number of shares of Illumina common stock outstanding on the Record Date, which will reflect any issuance of new shares in respect of settlements or exercises of outstanding equity-based awards pursuant to Illumina's equity plans, on or prior to the Record Date. The Spin-Off will not affect the number of outstanding shares of Illumina common stock or any rights of Illumina stockholders, although we expect the trading price of shares of Illumina common stock immediately following the Distribution to be lower than immediately prior to the Distribution because the trading price of Illumina common stock will no longer reflect the value of GRAIL. Furthermore, until the market has fully analyzed the value of Illumina without GRAIL, the trading price of shares of Illumina common stock may fluctuate and result in a higher volatility in the price of our common stock.

Before our separation from Illumina, we intend to enter into a Separation and Distribution Agreement and several other agreements with Illumina related to the Spin-Off. These agreements will govern the relationship between Illumina and GRAIL after completion of the Spin-Off and allocate between Illumina and GRAIL various assets, liabilities, rights, and obligations, including tax-related assets and liabilities. We describe these arrangements in greater detail under the section entitled "Certain Relationships and Related Party Transactions—Agreements with Illumina" beginning on page 217 of this Information Statement.

Listing and Trading of Our Common Stock

As of the date of this Information Statement, we are a wholly owned subsidiary of Illumina. Accordingly, no public market for our common stock currently exists, although a "when-issued" market in our common stock may develop prior to the Distribution. For an explanation of a "when-issued market," see the section below entitled "—Trading Prior to the Distribution Date" beginning on page 107 of this Information Statement. We intend to list our shares of common stock on Nasdaq under the ticker symbol "GRAL." Following the Spin-Off, Illumina common stock will continue to trade on Nasdaq under the ticker symbol "ILMN."

Neither we nor Illumina can assure you as to the trading price of Illumina common stock or our common stock after the Spin-Off, or as to whether the combined trading prices of our common stock and the Illumina common stock after the Spin-Off will be less than, equal to or greater than the trading prices of Illumina common stock prior to the Spin-Off. The trading price of our common stock may fluctuate significantly following the Spin-Off and result in a higher volatility in the price of our common stock. For more detail, see the section entitled "Risk Factors—Risks Relating to Our Common Stock" beginning on page 90 of this Information Statement.

The shares of our common stock distributed to Illumina stockholders will be freely transferable, except for shares received by individuals who are our affiliates. Individuals who may be considered our affiliates after the Spin-Off include individuals who control, are controlled by, or are under common control with us, as those terms generally are interpreted for U.S. federal securities law purposes. These individuals may include some or all of our directors and executives. Individuals who are our affiliates will be permitted to sell their shares of our common stock only pursuant to an effective registration statement under the Securities Act of 1933 (the "Securities Act") or an exemption from the registration requirements of the Securities Act, such as those afforded by Section 4(a)(1) of the Securities Act or Rule 144 thereunder.

Trading Prior to the Distribution Date

We expect a "when-issued" market in our common stock to develop on or shortly before the Record Date for the Distribution and continue up to and including the Distribution Date. "When-issued" trading refers to a sale or purchase made conditionally on or before the Distribution Date because the securities of the spun-off entity have not yet been distributed. If you own shares of Illumina common stock at the close of business on the

Record Date, you will be entitled to receive shares of our common stock in the Distribution. You may trade this entitlement to receive shares of our common stock, without the shares of Illumina common stock you own, on the "when-issued" market. We expect "when-issued" trades of our common stock to settle within two trading days after the Distribution Date. On the first trading day following the Distribution Date, we expect that "when-issued" trading of our common stock will end and "regular-way" trading will begin.

We also anticipate that, on or shortly before the Record Date and continuing up to and including the Distribution Date, there will be two markets in Illumina common stock: a "regular-way" market and an "ex-distribution" market. Shares of Illumina common stock that trade on the "regular-way" market will trade with an entitlement to receive shares of our common stock in the Distribution. Shares that trade on the "ex-distribution" market will trade without an entitlement to receive shares of our common stock in the Distribution. Therefore, if you sell shares of Illumina common stock in the "regular-way" market up to and including the Distribution Date, you will be selling your right to receive shares of our common stock in the Distribution. However, if you own shares of Illumina common stock at the close of business on the Record Date and sell those shares on the "ex-distribution" market up to and including the Distribution Date, you will still receive the shares of our common stock that you would otherwise be entitled to receive in the Distribution.

Following the Distribution Date, we expect shares of our common stock to be listed on Nasdaq under the ticker symbol "GRAL." If "when-issued" trading occurs, the listing for our common stock is expected to be under a ticker symbol different from our "regular-way" ticker symbol. We will announce our "when-issued" ticker symbol when and if it becomes available. If the Spin-Off does not occur, all "when-issued" trading will be null and void.

Conditions to the Spin-Off

We expect that the separation will be effective on the Distribution Date, provided that the following conditions shall have been satisfied or waived by Illumina:

- the Illumina Board shall have authorized and approved the Distribution and not withdrawn such authorization and approval, and shall have declared the dividend of our common stock to Illumina stockholders;
- the ancillary agreements contemplated by the Separation and Distribution Agreement shall have been executed by each party to those agreements;
- our common stock shall have been accepted for listing on Nasdaq or another national securities exchange approved by Illumina, subject to official notice of issuance;
- the SEC shall have declared effective our Registration Statement on Form 10, of which this Information Statement is a part, under the Securities Exchange Act of 1934, and no stop order suspending the effectiveness of the Registration Statement shall be in effect and no proceedings for that purpose shall be pending before or threatened by the SEC;
- Illumina shall have received a private letter ruling from the IRS and the written opinion of Cravath, Swaine & Moore LLP, each of which shall remain in full force and effect, 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;
- the Illumina Board shall have received one or more opinions (which have not been withdrawn or adversely modified) in customary form from one or more nationally recognized valuation, appraisal, or accounting firms or investment banks as to the solvency and financial viability of Illumina prior to the Spin-Off and each of Illumina and GRAIL after the consummation of the Spin-Off;
- no order, injunction, or decree issued by any governmental authority of competent jurisdiction or other legal restraint or prohibition preventing consummation of the Distribution shall be in effect, and no

other event outside the control of Illumina shall have occurred or failed to occur that prevents the consummation of the Distribution;

- no other events or developments shall have occurred prior to the Distribution Date that, in the judgment of the Illumina Board, would result in the Distribution having a material adverse effect on Illumina or its stockholders;
- prior to the Distribution Date, notice of Internet availability of this Information Statement or this Information Statement shall have been mailed to the holders of Illumina common stock as of the Record Date;
- Illumina shall have duly elected the individuals to be listed as members of our post-Distribution Board in this Information Statement, and such individuals shall be the members of our Board of Directors (the "Board"), immediately after the Distribution; and
- immediately prior to the Distribution Date, our Certificate of Incorporation and Bylaws, each in substantially the form filed as an exhibit to the Registration Statement on Form 10, of which this Information Statement is a part, shall be in effect.

The fulfillment of the above conditions will not create any obligation on Illumina's part to complete the Spin-Off. If the Illumina Board waives any condition prior to the effectiveness of the Registration Statement on Form 10, of which this Information Statement is a part, and the result of such waiver is material to Illumina stockholders, Illumina will file an amendment to the Registration Statement to revise the disclosure in this Information Statement accordingly. In the event that the Illumina Board waives a condition after the Registration Statement on Form 10, of which this Information Statement is a part, becomes effective and such waiver is material to Illumina stockholders, Illumina will communicate such change to Illumina stockholders by filing a Current Report on Form 8-K describing the change.

In addition, Illumina has the right not to complete the Spin-Off if, at any time, the Illumina Board determines, in its sole and absolute discretion, that the Spin-Off is not in the best interests of Illumina or its stockholders, or is otherwise not advisable. If the Spin-Off is not completed for any reason, Illumina and GRAIL will have incurred significant costs related to the Spin-Off, including fees for consultants, financial and legal advisors, accountants and auditors, that will not be recouped. Total one-time transaction costs associated with the Spin-Off are preliminarily estimated to range from $ to $ if the Spin-Off is completed. If the Spin-Off is not completed for any reason, the one-time transaction costs will generally be limited to the transaction costs incurred for services rendered as of the date the Spin-Off is abandoned, which will be less than the range noted above. Our and Illumina's management will also have devoted significant time to manage the Spin-Off process, which will decrease the time they will have to manage their respective businesses.

Reasons for Furnishing This Information Statement

We are furnishing this Information Statement solely to provide information to Illumina's stockholders who will receive shares of our common stock in the Distribution. Illumina's stockholders are not required to vote on the Distribution. Therefore, you are not being asked for a proxy and you are not required to send a proxy to Illumina. You do not need to pay any consideration, exchange or surrender your existing shares of Illumina common stock, or take any other action to receive the shares of our common stock to which you are entitled in the Spin-Off. You should not construe this Information Statement as an inducement or encouragement to buy, hold, or sell any of our securities or any securities of Illumina. We believe that the information contained in this Information Statement is accurate as of the date set forth on the cover. Changes to the information contained in this Information Statement may occur after that date, and neither we nor Illumina undertake any obligation to update the information except in the normal course of our and Illumina's public disclosure obligations and practices.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

DIVIDEND POLICY

We do not anticipate paying any cash dividends in the foreseeable future. We currently anticipate that we will retain all available funds for use in the operation and expansion of our business. Any future determination to pay dividends on our common stock will be made at the discretion of our Board and will depend upon, among other factors, our financial condition, results from operations, current and anticipated cash needs, plans for expansion, and other factors that our Board may deem relevant. We cannot assure you that we will pay a dividend in the future or continue to pay any dividend if we do commence paying dividends. See also "Risk Factors—Risks Relating to Our Common Stock—We do not expect to pay any dividends for the foreseeable future" beginning on page 94 of this Information Statement.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

CAPITALIZATION

The following table sets forth the cash, cash equivalents and marketable securities, and capitalization of GRAIL as of December 31, 2023:

- on an actual basis;
- on a pro forma basis to give effect to our conversion from a limited liability company to a corporation; and
- on a pro forma as adjusted basis to give effect to the Distribution and other related transactions, as if they occurred on December 31, 2023.

The information below is not necessarily indicative of what our capitalization would have been had the conversion to a corporation, the Distribution, and other related transactions been completed as of December 31, 2023. In addition, it is not indicative of our future capitalization and may not reflect the capitalization or financial condition that would have resulted had we operated as an independent, publicly traded company as of the applicable dates presented. You should review the following table in conjunction with the sections entitled "Unaudited Pro Forma Condensed Consolidated Financial Information" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" beginning on pages 114 and 176 of this Information Statement, respectively, and our Consolidated Financial Statements and accompanying notes set forth in the section entitled "Index to Consolidated Financial Statements" beginning on page F-1 of this Information Statement.

	As of December 31, 2023		
	Actual	Pro Forma	Pro Forma as Adjusted
	(in thousands, except share and per share data)		
Cash and cash equivalents	$ 97,287	$	$
Member's equity	$ 11,421,446	$ —	$
Accumulated other comprehensive income	$ 1,066	$	$
Accumulated deficit	$ (7,776,325)	$	$
Total member's equity	$ 3,646,187	$	$
Stockholders' (deficit) equity:			
Common stock, $0.001 par value per share, no shares authorized, issued and outstanding, actual; shares authorized, pro forma and pro forma as adjusted; shares issued and outstanding, pro forma; shares issued and outstanding pro forma as adjusted	—		
Additional paid-in capital	—		
Accumulated other comprehensive income	—		
Accumulated deficit	—		
Total stockholders' (deficit) equity	$ —	$	$
Total capitalization	$	$	$

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

SELECTED HISTORICAL FINANCIAL DATA

The following tables present selected historical financial data as of and for each of the fiscal years ended December 31, 2023 and January 1, 2023 and for the periods from August 19, 2021 to January 2, 2022 and January 1, 2021 to August 18, 2021. We have derived our summary historical statements of operations data for the years ended December 31, 2023 and January 1, 2023 and for the periods from August 19, 2021 to January 2, 2022 and January 1, 2021 to August 18, 2021, and summary historical balance sheet data as of December 31, 2023 and January 1, 2023, as set forth below, from our audited historical consolidated financial statements and related notes included elsewhere in this Information Statement. We refer to our audited financial statements as the "Consolidated Financial Statements," which are included in this Information Statement.

The selected historical financial data presented below should be read in conjunction with our Consolidated Financial Statements and the accompanying notes thereto, the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" beginning on page 176 of this Information Statement, and the section entitled "Unaudited Pro Forma Condensed Consolidated Financial Information" beginning on page 114 of this Information Statement. On August 18, 2021, we became a wholly owned subsidiary of Illumina. Although we were held and operated separately and independently from Illumina, the selected historical financial data does not necessarily reflect what our results of operations and financial position would have been if we had operated as an independent, publicly traded company during the periods presented. In addition, our historical financial data does not reflect changes that we expect to experience in the future as a result of our separation from Illumina, including changes, if any, in the financing of our business. Accordingly, the historical results should not be relied upon as an indicator of our future performance.

	(Successor)			(Predecessor)
	Year Ended December 31, 2023	Year Ended January 1, 2023	August 19, 2021 to January 2, 2022	January 1 to August 18, 2021
		(in thousands)		
Consolidated Statements of Operations Data:				
Screening revenue	$ 74,347	$ 39,123	$ 7,074	$ 1,953
Screening revenue—related parties	652	694	381	46
Development services revenue	18,106	15,733	4,978	180
Total revenue	93,105	55,550	12,433	2,179
Costs and operating expenses:				
Cost of screening revenue (exclusive of amortization of intangible assets)	39,284	27,998	4,664	4,965
Cost of screening revenue—related parties	8,682	4,142	662	227
Cost of development services revenue	6,623	5,741	624	261
Cost of development services revenue—related parties	238	227	133	—
Cost of revenue—amortization of intangible assets	133,889	133,889	44,630	—
Research and development	318,088	310,431	309,781	138,366
Research and development—related parties	20,657	19,145	1,475	10,590
Sales and marketing	162,292	122,328	100,512	24,814
General and administrative	200,062	173,494	478,071	160,140
General and administrative—related parties	206	614	35	4
Goodwill and intangible impairment	718,466	4,700,431	—	—
Total costs and operating expenses	1,608,487	5,498,440	940,587	339,367
Loss from operations	(1,515,382)	(5,442,890)	(928,154)	(337,188)
Other income (expense):				
Interest income	7,954	1,740	19	313
Other income (expense), net	(208)	(238)	(884)	642
Total other income (expense), net	7,746	1,502	(865)	955
Loss before income taxes	(1,507,636)	(5,441,388)	(929,019)	(336,233)
Benefit from income taxes	41,951	42,290	17,477	—
Net loss	**$ (1,465,685)**	**$ (5,399,098)**	**$ (911,542)**	**$ (336,233)**

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

	(Successor)	
	December 31, 2023	January 1, 2023
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$ 97,287	$ 241,596
Total assets	3,913,814	4,937,986
Total liabilities	267,627	291,825
Member's equity	11,421,446	10,955,907
Accumulated deficit	(7,776,325)	(6,310,640)
Total liabilities and member's equity	**$ 3,913,814**	**$ 4,937,986**

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

UNAUDITED PRO FORMA CONDENSED CONSOLIDATED FINANCIAL INFORMATION

On , 2024, Illumina announced plans for the separation of GRAIL from Illumina. To effect the Spin-Off, Illumina will distribute at least 85.5% of the shares of GRAIL's common stock owned by Illumina to Illumina's stockholders, and GRAIL will become an independent, publicly traded company. Immediately after the Distribution becomes effective, Illumina may retain up to 14.5% of GRAIL's common stock.

The unaudited pro forma condensed consolidated financial information of GRAIL has been derived from the historical consolidated financial statements, which we refer to as the "Consolidated Financial Statements," included in the section entitled "Index to Consolidated Financial Statements" beginning on page F-1 of this Information Statement. The unaudited pro forma condensed consolidated statement of operations data for the year ended December 31, 2023 has been prepared as though the Distribution occurred on January 2, 2023. The unaudited pro forma condensed consolidated balance sheet data as of December 31, 2023 has been prepared as though the Distribution occurred on December 31, 2023. The unaudited pro forma condensed consolidated financial information was prepared in accordance with Article 11 of Regulation S-X, updated for Release No. 33-10786, which became effective January 1, 2021. The unaudited pro forma condensed consolidated financial information has been adjusted to give effect to pro forma adjustments referred to as "Transaction Accounting Adjustments" including:

- the conversion of GRAIL from a limited liability company to a corporation.

The unaudited pro forma condensed consolidated financial information is presented for illustrative purposes only and is not necessarily indicative of the operating results or financial position that would have been achieved had the Spin-Off occurred on January 2, 2023 or December 31, 2023, respectively, nor is it indicative of GRAIL's future operating results or financial position. The pro forma adjustments are based upon information and assumptions available at the time of the filing of this Information Statement as set forth in the notes to the unaudited pro forma condensed consolidated financial information. Because this unaudited pro forma condensed consolidated financial information has been prepared based upon preliminary estimates, the impact of the Spin-Off and the timing thereof could cause material differences from the information presented herein.

The unaudited pro forma condensed consolidated financial information should be read in conjunction with our Consolidated Financial Statements and accompanying notes included under the section entitled "Index to Consolidated Financial Statements" beginning on page F-1 of this Information Statement and the sections entitled "Capitalization" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" beginning on pages 111 and 176 respectively, of this Information Statement. The unaudited pro forma condensed consolidated financial information constitutes forward-looking information and is subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated. For more information, see the sections entitled "Cautionary Statement Concerning Forward-Looking Statements" and "Risk Factors" beginning on pages 97 and 30, respectively, of this Information Statement.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

BUSINESS

Our Company

Our mission is to detect cancer early, when it can be cured.

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 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, which can help guide next steps for diagnosis, and yield high positive predictive values and low false positive rates, all from a simple blood draw. We launched Galleri in the United States in mid-2021. As of December 31, 2023, we have sold more than 150,000 commercial tests and established over 100 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.

Cancer is a major public health crisis. It is the second leading cause of death both in the United States and worldwide. Most cancers that result in death are diagnosed too late, in advanced stages when they are most challenging to treat. We estimate that more than 60% of cancer deaths result from cancers that have no recommended screening guidelines. In the United States, we consider standard of care screening for cancer to consist of the grade A and B recommendations published by the United States Preventive Services Task Force ("USPSTF"), which currently recommend broad population screening for only four types of cancer using single-cancer screening tests (breast, cervical, colorectal, and lung cancer), and prostate cancer screening, which is USPSTF grade C and is widely implemented in the United States. Grade A and B recommendations are services that USPSTF most highly recommends for preventative care and that have a high or moderate net benefit for patients. Grade C recommendations are services that USPSTF recommends selectively offering or providing to patients based on individual circumstances and that have a moderate certainty of a small net benefit for patients. According to data in the American Cancer Society's *Cancer Facts & Figures 2024*, cancers for which there are grade A and B recommendations published by the USPSTF (breast, cervical, colorectal, and lung cancer) are expected to result in approximately 225,000 deaths out of approximately 612,000 cancer-related deaths in the United States in 2024, and prostate cancer is expected to resulted in approximately 35,000 additional deaths. We believe that expanding upon these current guidelines to screen individuals for many types of cancer with a single test represents a significant opportunity to reduce cancer mortality and the cost of cancer care. In 2021, we published modeling data in *Cancer Epidemiology, Biomarkers & Prevention* (Cancer Epidemiol Biomarkers Prev. 2021; 30:460–8) that estimated the potential impact of MCED testing on mortality reduction based on test performance in our CCGA-2 study and using 2006 to 2015 data from the Surveillance, Epidemiology, and End Results Program of the U.S. National Cancer Institute ("SEER") for ages 50-79. Based on this model, we estimate that by adding Galleri to the five standard of care single-cancer screening tests (breast, cervical, colorectal, lung cancer, and prostate), there is potential to detect many more cancers at an earlier stage, which could translate into the potential to avert approximately 100,000 deaths per year in the United States as measured by five-year survival. In addition, an analysis published in *Data* (Data. 2017; 2(30):2–16) estimated that diagnosing cancer early could result in $26 billion in annual cost-savings in the United States.

We designed Galleri to detect cancer early. If cancer is detected early, it is more amenable to curative treatment. Galleri works by detecting DNA fragments shed into the bloodstream by tumor cells. In cancerous cells, methylation, a natural biological process that determines which sections of DNA to turn on or off and that drives tissue differentiation, becomes abnormal. As a result, DNA from cancer has specific methylation patterns

that can be used to both identify a general cancer signal and localize that signal to a specific organ or tissue type. In our CCGA study, Galleri identified a shared cancer signal across more than 50 types of cancer, often at an early stage. If a cancer signal is detected, Galleri can accurately predict the tissue type or organ associated with the cancer signal (the cancer signal origin). In our PATHFINDER study, Galleri correctly predicted the first or second cancer signal origins in 22 of 25 participants with a cancer diagnosis following a cancer signal detected (positive) test result (*i.e.*, participants with true positive test results), demonstrating a high cancer signal origin prediction accuracy of 88%. Test results are then used by healthcare providers to guide follow-up diagnostic testing.

As an early proponent of MCED testing, we have established strong relationships within the cancer and primary care community, including through partnerships with academic and community medical centers, key opinion leaders, and governmental policy and advocacy partners. We have shared evidence supporting our MCED testing at renowned medical conferences, such as the American Association of Cancer Research ("AACR"), American Society of Clinical Oncology ("ASCO"), European Society of Medical Oncology ("ESMO"), and American Academy of Family Physicians ("AAFP"). We have also published results from our studies in leading scientific and medical journals, including *The Lancet*, *Nature*, *Nature Medicine*, *Cancer Cell*, and *The Lancet Oncology*. Our industry leadership has been recognized with multiple national high-profile accolades, including being acknowledged by *Time Magazine* as one of the Best Inventions of 2022, and *The Atlantic* as one of the top breakthroughs of 2022 and being named in *Fast Company* World Changing Ideas of 2022 and in the *Fortune* Change the World List in 2023.

To support broad access for Galleri in the United States, we plan to complete a premarket approval application ("PMA") submission with the FDA in . We seek to use data from the NHS-Galleri Trial, together with data from our PATHFINDER 2 study, as well as supplemental data from other clinical studies, to support our planned PMA submission for Galleri in the United States. We believe that FDA approval could unlock broad coverage by large commercial payors in the United States. 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. We are working with stakeholders to advance and shape the public reimbursement landscape in the United States to enable coverage of FDA-approved MCED tests by Medicare. Galleri has not been approved or cleared by the FDA and 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. Following FDA approval, we also expect to pursue inclusion of Galleri in the USPSTF's guideline recommendation, although such inclusion is not certain even with FDA approval. In the United Kingdom, we are working with NHS England to complete our NHS-Galleri Trial. Subject to results of an early analysis from the first screening test (the prevalent screening round) representing one year of results out of the three-year trial period, the NHS may commence phased commercial implementation in England, beginning with a two-year pilot, and with the potential for further expansion subject to final results from the trial. We believe our work with the NHS and the 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.

Since our founding, we have undertaken a rigorous approach to identify in a blood sample the most informative markers of cancer through what we believe is the largest clinical program in genomic medicine to date. We are collecting population-scale clinical data from more than 385,000 participants across nine clinical studies, with more than 21,000 of these participants included in the studies that supported the development and launch of Galleri, and over 165,000 individuals enrolled and an additional approximately 60,000 anticipated to be enrolled in interventional studies (NHS-Galleri and PATHFINDER 2, which support our PMA submission, and the first-of-its kind Galleri-Medicare real-world study). These studies include our foundational case-control CCGA study to develop and validate our MCED technology, multiple large-scale observational studies in asymptomatic individuals, and multiple large-scale interventional studies in intended use populations. Our

interventional studies include our NHS-Galleri Trial, which is the first and largest randomized controlled trial of an MCED test, and which enrolled more than 140,000 individuals in just over 10 months. These studies also include our initiation of the Real-world Evidence to Advance multi-Cancer early detection Health equity ("REACH") interventional study. This first-of-its kind real-world "Galleri-Medicare" study will further evaluate the clinical impact of the Galleri multi-cancer early detection test among Medicare beneficiaries, including racial and ethnic minorities, and seniors from historically underserved communities. Through these studies and our ongoing collection of real-world data, we have built what we believe is an unprecedented longitudinal dataset of high quality, linked clinical and genomic data. We believe our clinical studies, including our early discovery work, have demonstrated robust and reproducible test performance. Notably, data from our interventional PATHFINDER study, including PPV, cancer signal original prediction accuracy, and specificity, were generally consistent with data from our case-control CCGA study, which is evidence supporting the generalizability and robustness of Galleri in an interventional study involving analysis of returned Galleri results on clinical diagnostic and care pathways, outside of the foundational case-control context. Specifically the 43% positive predictive value ("PPV") achieved in the study is similar to our previously published modeled PPV of 44% based on test performance in our CCGA study extrapolated to a potential representative population aged 50-79 based on 2016 to 2017 SEER data. We extrapolated the CCGA-based modeled PPV to a representative population due to the limitations of measuring PPV in a case controlled study with enrichment of cancer cases in the sample set, whereas the PATHFINDER study was performed in an intended use population and PPV was measured directly. We expect to continue to report ongoing and long-term follow-up clinical data from these studies over many years.

Based on our extensive discovery work, we believe that targeted methylation is the best approach for detecting a cancer signal and identifying a cancer signal origin. In our head-to-head analyses we compared multiple different classifiers that were trained to detect a cancer signal and predict the cancer signal origin, and which were independently validated. We found that interrogating methylation patterns yielded significantly better results for cancer detection (based on sensitivity, cancer signal origin prediction accuracy, and clinical limit of detection (a measure of the how much signal must exist in order to be detected)) than was observed by interrogating mutations (changes in a DNA sequence), chromosomal alterations (changes to the structure or number of chromosomes, which are strands of genetic material), fragment lengths (differences in length of DNA fragments), and other genomic features, either alone or in combination. In contrast to well-established cancer mutations that only affect a handful of genomic locations, there are nearly 30 million methylation sites across the human genome, making them a ubiquitous and rich signal for cancer detection. After comprehensive analysis of whole-genome methylation patterns in connection with our CCGA study, we discovered highly informative and low-noise methylation sites for cancer signal and cancer signal origin detection. Highly informative sites are likely to have abnormal methylation patterns resulting from cancer, and low-noise sites are less likely to be subject to confounding signals from biological noise resulting from confounding conditions (such as aging, inflammatory conditions) and circulating DNA from non-cancerous cells. This discovery led to our development of a targeted methylation approach, which entails interrogating specific methylation sites within a genome to assess methylation patterns and which serves as the technological basis for our Galleri test. Our targeted methylation approach can detect lower levels of cancer signal in blood compared to other approaches we examined, enabling early cancer detection in asymptomatic individuals more efficiently compared to whole-genome methylation. For additional information, see "— Methylation Technology Platform."

Our proprietary targeted methylation platform, as well as our growing body of clinical and real-world data, have provided us with unique insights into cancer biology that enable development of products beyond asymptomatic screening. We are leveraging our proprietary platform for additional applications, including:

- *Precision oncology portfolio*: We are developing our precision oncology portfolio and launched our research use only ("RUO") targeted methylation platform with customizable classifiers in 2023. We have partnered with a number of leading oncology therapeutics companies to test applications of biomarkers with the goal of optimizing the use of therapeutic interventions. Some of our partnerships also include development of customized applications to support clinical studies and companion

diagnostic development and commercialization. Potential applications for our technology in a precision oncology setting include pre-treatment prognosis, post-treatment prognosis or minimal residual disease ("MRD"), biomarker discovery, recurrence, and clinical monitoring. We believe the research and clinical development settings represent significant opportunities with biopharmaceutical companies given the large number of ongoing oncology studies and the significant need to identify residual disease or recurrence early and help inform treatment decisions. In addition to companion diagnostic opportunities, we believe that our methylation platform could enable standalone clinical products to support patient care across the cancer care continuum.

- *Diagnostic aid for cancer test*: We are developing our diagnostic aid for cancer ("DAC") test to accelerate diagnostic resolution for patients with non-specific signs and symptoms, but with a clinical suspicion of cancer. Through a simple blood test, DAC is designed to provide physicians with a powerful decision-making tool to aid diagnosis, achieve resolution more quickly, and avoid unnecessary workups. Symptomatic detection of cancer is a significant unmet need; we estimate that approximately 16 million patients in the United States present with non-specific signs and symptoms each year. Data from our SYMPLIFY study published in *The Lancet Oncology* showed that, in a symptomatic patient population, our methylation technology was able to detect many cancer types and accurately identify where they were located in the body. In our SYMPLIFY study, our technology correctly predicted the first or second cancer signal origins in 214 of 237 participants with a cancer diagnosis following a cancer signal detected (positive) test result (*i.e.*, participants with true positive test results), demonstrating a high cancer signal origin prediction accuracy of 90%. Product development efforts are ongoing, and we currently consider the launch of our DAC test as a medium- to longer-term objective, subject to a number of factors, including determining the requirements for reimbursement in the United States.

We believe these products and other future products in development have the potential to reach additional customers and may result in additional patient care solutions across the cancer care continuum.

Our Strengths

We believe our continued growth will be driven by the following strengths:

- **Our clinically-validated, commercially available, MCED test, Galleri.** Galleri is a commercially available, MCED test that is setting the standard for multi-cancer early detection. We believe Galleri is clinically validated based on the results of our clinical studies completed to date. From a simple blood draw, Galleri can detect a cancer signal shared by over 50 types of cancer, over 45 of which do not have recommended screening guidelines. We believe Galleri enables the early detection of cancer in asymptomatic individuals by screening for multiple types of cancer, and in clinical trials Galleri has demonstrated a high PPV and a low false positive rate, and an ability to predict the location of the suspected cancer with high accuracy (88%), which can help guide an efficient diagnostic evaluation. Further, as Galleri relies on a blood draw, the test can be integrated into existing care pathways, such as annual health checks, which can enable wide-scale implementation and increase access to cancer screening, thus helping to address well-known disparities in cancer care. Our industry leadership in MCED testing has been recognized with multiple national high profile accolades, including being acknowledged by *Time Magazine* as one of the Best Inventions of 2022, and *The Atlantic* as one of the top breakthroughs of 2022 and being named in *Fast Company* World Changing Ideas of 2022 and in the *Fortune* Change the World List in 2023.
- **Our established commercial leadership is driving the development of a significant market.** The commercial opportunity for Galleri is significant, with more than 300 million individuals globally over the age of 50 (our intended use population), including more than 100 million individuals in the United States. We launched Galleri in the United States in mid-2021. As of December 31, 2023, we have sold more than 150,000 commercial tests and established over 100 commercial partnerships, including leading

healthcare systems, employers, payors, and life insurance providers. In this real-world setting, Galleri is detecting deadly cancers in early stages. As an early proponent of MCED testing, we have established strong relationships within the cancer and primary care community, including through partnerships with academic and community medical centers, key opinion leaders, and governmental policy and advocacy partners. Our partnership with the NHS presents an opportunity to drive further adoption of Galleri, including by payors and health systems around the world. Subject to the results of an early analysis from the first screening test (the prevalent screening round) in the NHS-Galleri Trial, the NHS may commence phased commercial implementation in England, beginning with a two-year pilot, and with the potential for further expansion subject to final results from the trial. Our commercial leadership is further supported by our high-capacity laboratories to enable population screening volumes.

- **Clinical validation through unprecedented clinical studies and real-world experience.** We designed and executed what we believe is the largest clinical program in genomic medicine to date. We are collecting population-scale clinical data from more than 385,000 participants across nine clinical studies, with more than 21,000 of these participants included in the studies that supported the development and launch of Galleri, and over 165,000 individuals enrolled and an additional approximately 60,000 anticipated to be enrolled in interventional studies (NHS-Galleri and PATHFINDER 2, which support our PMA submission, and the first-of-its kind Galleri-Medicare real-world study). These studies include our foundational case-control CCGA study to develop and validate our MCED technology, multiple large-scale observational studies in asymptomatic individuals, and multiple large-scale interventional studies. Our interventional studies include our NHS-Galleri Trial, which is the first and largest randomized controlled trial of an MCED test, and which enrolled more than 140,000 individuals in just over 10 months. Through these studies and our ongoing collection of real-world data, we have built what we believe is an unprecedented longitudinal dataset of high quality, linked clinical and genomic data. We believe our clinical studies, including our early discovery work, have demonstrated robust and reproducible test performance. Notably, data from our interventional PATHFINDER study, including PPV, cancer signal original prediction accuracy, and specificity, were generally consistent with data from our case-control CCGA study, which is evidence supporting the generalizability and robustness of Galleri in an interventional study involving analysis of returned Galleri results on clinical diagnostic and care pathways, outside of the foundational case-control context. Together with our partners at leading community and academic medical centers in the United States and United Kingdom, we expect to continue to report ongoing and long-term follow-up clinical data from these studies over many years.
- **Our highly-differentiated methylation platform, which enables product opportunities across the cancer care continuum.** We have taken a scientifically rigorous approach to develop a deep and comprehensive understanding of cancer biology. We built an atlas to characterize the landscape of cell-free nucleic acids (“cfDNA”) across a broad and diverse population and in individuals with and without cancer. We then used this atlas and other data to train our machine learning algorithms to recognize methylation patterns indicative of cancer and accurately predict the cancer signal origin. These efforts supported the development of our proprietary methylation platform on which Galleri is based, and which we will continue to leverage to advance a number of clinical applications across the cancer care continuum. For example, we developed and launched our post-diagnosis RUO offering and are working closely with biopharmaceutical companies to develop products and services to optimize treatment once a cancer has been diagnosed. Potential applications for our technology in a post-diagnosis setting include pre-treatment prognosis, post-treatment prognosis or MRD, biomarker discovery, detection of recurrence, and clinical monitoring. We are also developing our DAC test to enable faster diagnosis and care for patients presenting with non-specific symptoms that are suspicious for cancer.
- **Our intellectual property portfolio.** We own or license exclusive worldwide commercial rights to intellectual property covering Galleri and our products in development. Specifically, as of December 31, 2023, we have exclusive licenses to more than 470 granted patents globally, and own or

co-own more than 120 issued patents, with more than 800 pending patent applications (licensed, owned, or co-owned) covering methylation and other technologies. In addition, our patents, trade secrets, and know-how provide broad intellectual property coverage for our products, including chemistry, bioinformatics, and machine learning algorithms used in Galleri and our product development pipeline. Our exclusively licensed patents will begin to expire in 2027. Our owned or co-owned patents will begin to expire in 2037.

- **Our highly experienced and multidisciplinary team.** Since our founding, we have built an entrepreneurial culture driven to improve outcomes for cancer patients. We are led by a multidisciplinary team with extensive experience across biotechnology, life sciences, public health, genomics, computer science, data science, biostatistics, clinical development, medical affairs, government and regulatory affairs, quality assurance, and laboratory and commercial operations. We believe this confluence of talent from multiple disciplines has enabled us to make significant progress in improving cancer care and will enable us to remain at the forefront of our industry.

Our Strategy

Key elements of our strategy include:

- **Establishing Galleri as the population multi-cancer screening standard and extending commercial leadership in large global markets.** We believe we have an unprecedented opportunity to establish a new standard of care by adding Galleri to existing single-cancer screenings, and establish and maintain the market-leading position in cancer detection. The commercial opportunity for Galleri is significant, with more than 300 million individuals globally over the age of 50, including over 100 million individuals in the United States. Our goal is to address cancer screening globally, beginning in large markets with established health systems, such as the United States and United Kingdom, and thereafter extending to other markets. We will continue to engage with key opinion leaders, healthcare providers, advocacy organizations, regulators, and payors to help drive broader scientific and commercial endorsement worldwide. In addition, we believe Galleri's performance will drive clinical outcomes and high patient and provider satisfaction that will lead to further awareness and adoption.
- **Expanding access to our products by pursuing reimbursement and coverage from payors.** Our ability to impact cancer outcomes will be accelerated in markets where we secure reimbursement for our products. 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. In the United States, we have established private reimbursement from over 80 self-insured employers and multiple payors and health systems as of December 31, 2023, but do not currently have broader coverage and reimbursement by government healthcare programs, such as Medicare. To support broad access for Galleri in the United States, we plan to complete a PMA submission with the FDA in . We seek to use data from the NHS-Galleri Trial, together with data from our PATHFINDER 2 study, as well as supplemental data from other clinical studies, to support our planned PMA submission for Galleri in the United States. We believe that FDA approval could unlock large commercial payors in the United States and we are working with stakeholders to advance and shape the public reimbursement landscape in the United States to enable coverage of FDA-approved MCED tests for Medicare. Galleri has not been approved or cleared by the FDA and 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. Following FDA approval, we also expect to pursue inclusion of Galleri in the USPSTF's guideline recommendation, although such inclusion is not certain even with FDA approval. In the United Kingdom, we are working with NHS

England to complete our NHS-Galleri Trial. Subject to results of an early analysis from the first screening test (the prevalent screening round) representing one year of results out of the three-year trial period, the NHS may commence phased commercial implementation in England, beginning with a two-year pilot, and with the potential for further expansion subject to final results from the trial. We believe our work with the NHS and the 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. We will continue to invest in clinical evidence generation and work with regulatory bodies and payors in our target markets to expand coverage for early cancer screening and to increase access.

- **Defining, leading, and expanding adoption of MCED.** We coined the term "multi-cancer early detection" and will continue to drive MCED as a solution to one of healthcare's most important challenges. Since our inception in 2016, we have established and maintained a leading voice regarding the early detection of multiple cancer types in peer-reviewed literature. As of December 31, 2023, we have published more than 60 manuscripts, including in high profile journals like *The Lancet*, *Nature*, *Nature Medicine*, *Cancer Cell*, and *The Lancet Oncology*. We have also presented our data in more than 20 podium and 170 poster presentations at renowned medical conferences, including AACR, ASCO, ESMO, and AAFP. We fund medical education programs for MCED and intend to continue to educate healthcare providers, as well as key opinion leaders, regulators, professional societies, and policymakers on the clinical benefits and public health impact of MCED. In addition, we believe this market development strategy will drive adoption of our products and further awareness of the benefits of MCED testing generally.
- **Driving cutting edge science and technology to continuously improve existing products and develop new products.** Our methylation platform and extensive technological infrastructure, together with expansive ongoing data collection, will continue to drive improvements to Galleri and enable the development of additional products. Our technology has broad applicability in cancer detection and management, and findings from our SYMPLIFY study demonstrated the potential of our platform to extend beyond asymptomatic screening, into symptomatic detection. We launched our RUO offering, a part of our precision oncology portfolio, in 2023, which has formed the basis of additional biopharmaceutical partnerships to enable further discovery and execution of new development programs. In addition, these partnerships have generated findings that support expansion into precision oncology applications, including pre-and post-treatment prognosis, recurrence detection, and clinical monitoring. We continually seek to enhance the performance of our products through a comprehensive, rigorous approach to ongoing classifier training, improvement of features, and reduced processing time and cost. New products, including enhanced versions of current products, will require the completion of certain clinical development and regulatory activities, such as bridging studies agreed upon with regulatory authorities. We will continue to improve our technologies and launch innovative products across the cancer care continuum.
- **Leveraging our existing infrastructure to enable and scale our growing business.** Over the last several years, we have made significant investments to build a scalable infrastructure capable of meeting significant demand while satisfying stringent certification parameters. Our high-capacity laboratories are accredited by the College of American Pathologists ("CAP") and certified by the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") and the New York Department of Health, which represents one of the most rigorous levels of validation required for laboratory-developed tests. Our facilities are able to process a substantial number of tests per year and we expect to be able to meet our anticipated near-term needs. In addition, we engineered custom technology infrastructure and cloud-based tools to enable scalable data collection and analysis capabilities. Our ability to collect, manage, and integrate high-quality genomic and clinical data is central to our business, and our automated laboratory workflows and processes enable high volumes of tests and samples to be processed automatically with high efficiency and speed and low failure rates. As demand for our products increases, we expect to leverage the scale efficiencies of our infrastructure and platform technology, which we believe will positively impact margins over time.

- **Sustaining a patient-first corporate culture that champions diversity.** We have built a multi-disciplinary organization of leading scientists, engineers, and clinicians driven to improve outcomes for cancer patients. In our pursuit to improve cancer care and solve one of healthcare's most important challenges, we intend to grow our diversity among employees and will continue to foster an agile and inclusive environment that is a destination for world-class talent. We believe our mission, values, and leadership attributes all contribute to this vibrant and inclusive culture and serve as a powerful magnet for talent.

Improving Cancer Care

The Burden of Cancer and the Benefits of Earlier Detection

Cancer is the second leading cause of death in both the United States and worldwide, with more than 19 million new cases and 10 million deaths globally in 2020. This burden is expected to grow as the global population ages. According to the data in the American Cancer Society's *Cancer Facts & Figures 2024*, there will be approximately 2.0 million new cancer cases and 611,000 cancer deaths in the United States in 2024. An analysis published in the AACR's Cancer Epidemiology, Biomarkers and Prevention Journal (Cancer Epidemiol Biomarkers Prev. 2020; 29(7):1304–1312) estimated that $201 billion was spent on cancer care in the United States in 2020, with some of the costliest treatments targeting late-stage cancers that are highly challenging to treat. The same analysis projected that by 2030, the cost of cancer in the United States would rise to more than $246 billion annually, driven by an aging population and rising costs of care. According to an article published in *JAMA Oncology* in February 2023 (JAMA Oncol. 2023; 9(4):465–472), it is estimated that the global economic cost of cancer from 2020 to 2050 will be approximately $25 trillion.

A fundamental driver of cancer mortality today is that most cancers that result in death are diagnosed too late, in advanced stages when they are most challenging to treat. If cancer is detected early, when it is localized, it is more amenable to curative treatment. According to 2006 to 2015 data from the Surveillance, Epidemiology, and End Results Program of the U.S. National Cancer Institute ("SEER"), across all cancers, the five-year cancer-specific survival rate is approximately 89% when localized, compared to 21% when the cancer is metastasized. Historically, a key challenge to early detection is that there has been no mechanism to detect most cancers while individuals are asymptomatic. Detecting cancers at earlier stages could potentially reduce cancer-related five-year mortality by at least 15-24%, according to a model published in the AACR's *Cancer Epidemiology, Biomarkers & Prevention Journal* in May 2020 (Cancer Epidemiol Biomarkers Prev. 2020; 29 (5): 895–902.

Treatment costs increase by stage across all cancers, and, according to an article published in the *Journal of the National Comprehensive Cancer Network* in April 2018, (J Natl Compr. Canc. Netw. 2018 Apr; 16(4):402–410), treating cancers that are in more advanced stages can be up to two to four times more costly than treating cancers at earlier stages. In addition, an analysis published in Data (Data. 2017; 2(30):2–16) estimated that diagnosing cancer early could result in $26 billion (approximately 17% of total treatment costs) in annual cancer treatment cost-savings in the United States.

Cancer Screening Today and Limitations of the Current Cancer Screening Paradigm

In the United States, we consider standard of care screening for cancer to consist of the grade A and B recommendations published by the USPSTF, which currently recommend broad population screening for only four types of cancer using single-cancer screening tests (breast, cervical, colorectal, and lung cancer), and prostate cancer screening, which is USPSTF grade C and is widely implemented in the United States. These screening tests have helped to reduce mortality for these specific types of cancer; however, there are a number of limitations to the current paradigm.

First, existing standard of care screening is limited to a minority of cancers. For the majority of cancer types, there are no recommended screening guidelines or no screening tests exist. Only 14% of cancers in the

United States are diagnosed through screening, according to NORC at the University of Chicago. We estimate that more than 60% of cancer deaths result from cancers that have no recommended screening guidelines. For example, according to data in the American Cancer Society's *Cancer Facts & Figures 2024*, cancers for which there are grade A and B recommendations published by the USPSTF (breast, cervical, colorectal, and lung cancer) are expected to result in approximately 225,000 deaths out of approximately 612,000 cancer-related deaths in the United States in 2024, and prostate cancer is expected to resulted in approximately 35,000 additional deaths. Many patients are diagnosed when presenting with symptoms, by which time these cancers may be advanced and harder to treat. Additionally, we estimate that asymptomatic individuals undertaking a standard of care screening test are many times more likely to have a different type of cancer than the cancer type for which they are being screened. For example, we supported the publication of a letter, Multi-cancer early detection: A new paradigm for reducing cancer-specific and all-cause mortality, *Cancer Cell*, in April 2021, which included an analysis of cancer incidence and mortality rates available from SEER. This analysis examined the USPSTF's recommended screening for the general population—biennial mammography for women aged 50-74, cervical cancer screening for women aged 21-64, and colorectal cancer screening for persons aged 50-79—and quantified for each of these target populations the rates of incidence and death due to cancers other than the one being screened. This analysis found that asymptomatic individuals undertaking a standard of care screening test are between 2-24x more likely to have a different type of cancer than the cancer type for which they are being screened.

Second, the existing standard of care screening tests are each for a single cancer type and prioritize high sensitivity, resulting in higher false positive rates. Even if single-cancer screening tests were available for every cancer type, the administration of many single-cancer screening tests, either as independently administered tests or as a string of individual screens combined into a single test, would be clinically and economically untenable at population-scale. Screening individuals with multiple single-cancer screening tests adds incrementally to the total number of independent tests conducted and therefore to the cumulative false positive rate. For example, in the Prostate, Lung, Colorectal and Ovarian ("PLCO") Cancer Screening Trial, which was a large randomized controlled trial designed and sponsored by the U.S. National Cancer Institute, the cumulative risk of a false positive after 14 sequential single-cancer screening tests over a three-year period covering only four cancer types was 50% or greater. In addition, we developed a model using SEER data to analyze, among others, the false positive rate of a hypothetical screening system in which a patient is screened using single-cancer screening tests for the 11 most deadly types of cancer in the United States (excluding prostate) over a one-year period, with each of the 11 single-cancer screening tests having an assumed false positive rate of 11%. Based on this model, we estimate that the cumulative risk of a false positive after these 11 single-cancer screening tests would be approximately 80%.

Third, we believe single-cancer screening tests are also unlikely to be developed for detecting less common cancers, which we estimate account for a majority of all cancer deaths in the United States, based on data in the American Cancer Society's *Cancer Facts & Figures 2024* regarding estimated new cancer cases and cancer deaths. In many instances, we believe the incidence of such cancers is too low to undertake the required clinical studies. For example, the American Cancer Society's *Cancer Facts & Figures 2024* categorizes cancer cases by 46 sites in the human body, with cancers at more than half of these sites expected to result in less than 10,000 deaths in 2024. Additionally, achieving cost effectiveness for a test for a less common cancer type would be challenging. Developing single-cancer screening tests for individual cancer types with lower incidence presents significant logistical burdens and expense.

Opportunity for Multi-Cancer Early Detection

We believe a population-scale, MCED screening test will help address these limitations of the current cancer screening paradigm and can be a powerful tool to reduce the burden of cancer.

How to Measure Performance of a Population Screening Test

There are a number of measures of performance for cancer screening tests. These include:

- **Sensitivity**: The proportion of patients with cancer who receive a positive test result = A / (A+C) *100
- **Specificity**: The proportion of patients without cancer who receive a negative test result also equal to 1- **False Positive Rate** or D / (B+D) * 100
- **PPV**: The proportion of patients with a positive test result who actually have cancer = A / (A+B) * 100
- **NPV**: The proportion of patients with a negative test result who do not have cancer = D / (C+D) * 100
- **Yield**: The proportion of cancers detected by screening = A / (A+B+C+D)

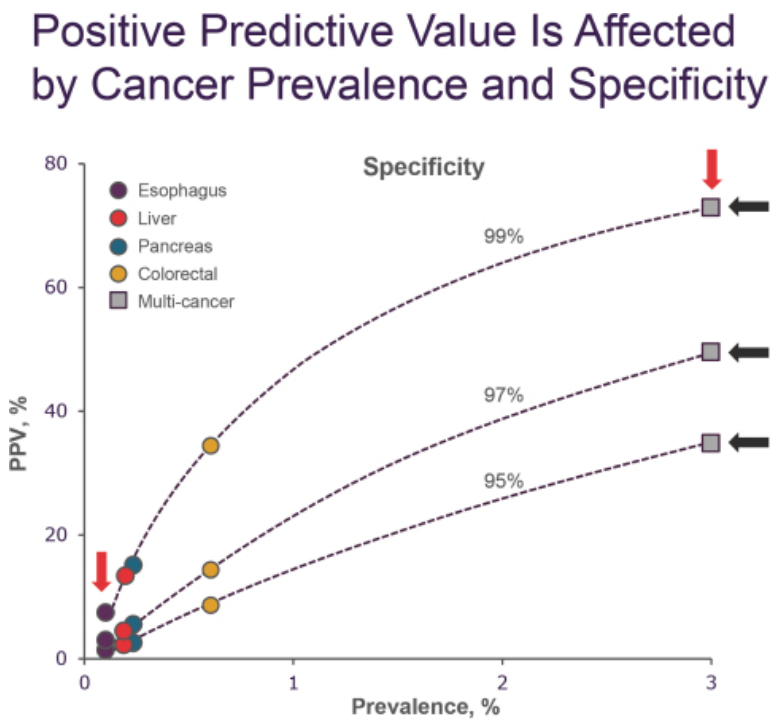
		Test Result: Positive	Test Result: Negative
True Condition	Cancer	True Positive (A)	False Negative (C)
True Condition	Non-cancer	False Positive (B)	True Negative (D)

While sensitivity has become an established measure in evaluating the performance of single-cancer screening tests, we do not believe that sensitivity is the best measure to evaluate MCED tests for two primary reasons. First, sensitivity in blood-based cancer screening tests is largely dependent on the amount of cfDNA in the blood. The levels of cfDNA are driven by the cancer types (certain cancers shed more circulating tumor DNA (ctDNA) than others) and stage (earlier stage cancers shed less ctDNA than later stage) in the population being tested. This variability can make it challenging to measure and interpret the overall performance of a test that identifies a shared cancer signal, and is not searching for any particular cancer, and is deployed across broad populations. Second, tests that are optimized for sensitivity often sacrifice specificity, which results in a higher rate of false positive results. While this tradeoff is generally accepted for single-cancer screening tests, it is critical to retain high specificity for a multi-cancer screening test due to the substantial resulting impact that false positive results could have across the population if a significant number of individuals are screened. This is particularly relevant when screening the general population for a low-incidence disease, like cancer.

Rather than sensitivity, we believe that the two most appropriate metrics for evaluating the effectiveness of an MCED test screening at population-scale are PPV, which incorporates both sensitivity and specificity, and yield. An MCED that has high PPV and high yield would result in identifying more cancers earlier. PPV represents the probability that a positive test result is a true positive and directly answers the patient-centric clinical question, “if my patient has a positive test result, what is the likelihood they truly have cancer?” We believe a high PPV can give clinicians confidence in a positive test result and a sense of urgency to initiate confirmatory diagnostic workups. The ability to detect as many cancer types as possible drives a high yield, enabling detection of as many cancer cases in a population as possible. We believe that a high yield maximizes the population-scale impact of an MCED test in detecting cancer early. We believe dramatically increasing the yield of a cancer screening program will be necessary to address the global burden of cancer and provide the potential to significantly improve cancer care.

For a condition like cancer that has a low prevalence in the population, PPV is significantly impacted by prevalence and specificity, such that PPV increases with the prevalence of cancer in the population and with the specificity. This is because in diseases, like cancer, with low prevalence, the population without cancer will be much larger and therefore small changes in specificity will result in relatively large changes in the number of

false positives. The relationship between specificity, prevalence, and PPV is illustrated by the figure below. For example, to illustrate how prevalence impacts PPV, note the "esophagus" single-cancer screening test data, depicted by purple circles in the figure, which has a significantly lower PPV than the "multi-cancer" screening data, depicted by the gray squares in the figure. For convenience, these data points are highlighted with two red vertical arrows. The higher PPV of the multi-cancer screening test is due to the aggregate prevalence of multiple cancers using a single test. To illustrate how specificity impacts PPV, note the three gray squares indicating "multi-cancer" screening data, which are indicated by three black horizontal arrows. The increase in specificity from 95% to 99% results in a significant increase in PPV due to the reduction in false positives.



We believe another critical metric for measuring the performance of a multi-cancer early detection test is the yield. Single-cancer screening tests are, by definition, limited in their maximum yield, as they are focused on only one cancer type. By contrast, multi-cancer screening tests increase the yield by detecting multiple cancer types simultaneously in a population. There is an inverse relationship between aggregate sensitivity and yield; for example, low signal cancer types will drive down aggregate sensitivity but will increase the yield.

Requirements of a Population-Scale MCED Screening Test

We believe the following features are essential for an MCED test to be accepted as a broad-based screening test in asymptomatic populations:

- *Ability to identify a broad range of cancer types*: An MCED test should identify many cancer types to maximize the absolute number of clinically significant cancer cases detected in a population and yield.

- *High PPV and low false positive rate*: An MCED test should have a high PPV and low false positive rate to help maximize physician confidence in a positive test result, drive a sense of urgency to perform confirmatory diagnostic workups, and minimize the number of unnecessary workups in a population.
- *Ability to predict with high accuracy the cancer signal origin and direct diagnostic workup*: An MCED test should predict the cancer signal origin with high accuracy to facilitate efficient diagnostic workups.
- *Backed by robust analytical and clinical performance*: An MCED test should be rigorously validated to account for non-cancer biological signals and the underlying heterogeneity of populations without cancer. We believe clinical validation should be performed using a locked assay and classifier and should be analyzed in case-control and intended-use populations.
- *Ability to limit overdiagnosis of indolent cancers*: An MCED test should preferentially detect the cancers most likely to result in death, which are aggressive and clinically significant cancers warranting treatment, and should not result in overdiagnosis of more indolent cancers.
- *Application to a diverse population*: An MCED test should be built on a comprehensive evidence program that supports implementation in the broad elevated risk population (such as those over the age of 50). To support this, clinical studies should evaluate effectiveness in diverse and high-risk populations, including populations that are diverse in behaviors (such as smoking), non-cancer diseases, environmental exposures, age, gender, race, ethnicity, socio-economic status, and other confounding indications and differences.
- *Complementary to standard of care screenings*: An MCED test should serve as a complement to, not a replacement for, current standard of care screening tests so as not to discourage adherence to existing USPSTF guidelines.
- *Simple to implement and access*: An MCED test should be easy to implement in clinical practice and reduce or avoid common barriers to screening such as requirements for access to specialized equipment.

Our Products: Galleri and Beyond

Our Multi-Cancer Early Detection Test: Galleri

Our commercially available multi-cancer early detection test, Galleri, is transforming cancer care and has the potential to unlock substantial improvements in cancer detection and mortality.

A fundamental driver of cancer mortality today is that most cancers that result in death are diagnosed too late, in advanced stages when they are most challenging to treat. If cancer is detected early, when it is localized, it is more amenable to curative treatment. Galleri is designed to complement the USPSTF's recommended screenings, be easy to implement in practice, and improve overall population cancer detection. From a simple blood draw, Galleri can detect a cancer signal shared by over 50 types of cancer, over 45 of which do not have recommended screening guidelines. We believe Galleri enables the early detection of cancer in asymptomatic individuals by screening for multiple types of cancer, and in clinical studies Galleri has demonstrated an ability to predict the location of the suspected cancer with high accuracy (88%), which can help guide next steps for diagnosis, and high PPVs and low false positive rates. We launched Galleri in the United States in mid-2021. As of December 31, 2023, we have sold more than 150,000 commercial tests and established over 100 commercial partnerships. In this real-world setting, Galleri has detected deadly cancers in early stages. Our test has been deployed across healthcare systems, employers, payors, and life insurance providers, and for additional at-risk groups such as first responders, including firefighters, and continues to unlock the promise of early cancer detection.

We developed Galleri with the following critical features necessary to address the requirements of a population-scale MCED screening test:

Ability to identify a broad range of cancer types

Galleri is able to detect a cancer signal shared in over 50 types of cancer, including the most deadly types of cancer that do not have recommended screens. We believe that Galleri can significantly increase the number of cancer types screened for in the population and has the potential to increase yield of cancers in the United States that are diagnosed through screening from 14% to 49%.

High PPV and low false positive rate

In clinical studies, Galleri has demonstrated a high PPV of approximately 43% and a low false positive rate of less than 1%. A high PPV, which is enabled in part by a low false positive rate, is important in clinical practice because it represents the probability that a positive test result is a true positive and can give clinicians high confidence and a sense of urgency to initiate confirmatory diagnostic workups. A low false positive rate can help to limit unnecessary workups on patients who do not have cancer. The image below sets forth certain key performance information from our PATHFINDER study.

Galleri Performance

Test performance metric	Galleri results[1] (Results not returned to participants or providers)
Positive predictive value (PPV)	43.1%
False positive rate[2]	0.5%
Yield	0.5%
Cancer signal origin accuracy[3]	88.0%

[1] Results based on MCED test that became Galleri. Results were returned to participants by an earlier version of Galleri.
[2] Based on cancer status assessment at the end of the study ("EOS"). Cancer status assessments were conducted on all patients that received a cancer signal detected (positive) test result. Assessments were conducted through electronic health record review and patient follow-up.
[3] Proportion of first or second origins correctly predicted among true positive participants.

While Galleri is designed to complement the current standard of care screening tests, Galleri's high PPV of approximately 43% is significantly higher than the PPV of all of the standard of care single-cancer screening tests. Galleri's low false positive rate of less than 1% is also significantly lower than the false positive rate of all of the standard of care single-cancer screening tests. The table below presents the PPVs and number of false positives associated with the current standard of care screening tests:

Galleri and standard of care performance

Cancer	Testing Method	Positive Predictive Value	False Positive Rate
Multi	**Galleri*** (Blood Test)	**43.1%**	**0.5%**
Breast[1]	Mammography	4.4%	11.1%
Cervical[2]	Cytology / HPV test	19.0%	7.4%
Colorectal[3]	Colonoscopy**	**	**
	Stool-based screening (FIT)	1.2%	13.0%
	Cologuard (sDNA-FIT)***	3.7%	13.4%
Lung[4]	A low-dose CT scan	3.8%	12.8%
Prostate^[5]	Blood Test	30%	10.4%

* Results based on MCED test that became Galleri.
** Colonoscopy is considered both a screening and diagnostic test, in part because it detects both precancerous and cancerous lesions. As a result, it is not comparable across PPV and false positive rates.
*** United States Food and Drug Administration Premarket Approval P130017. FDA Summary of Safety and Effectiveness Data.
^ Prostate screening is an USPSTF grade C
1. Source for PPV and False Positive Rate: Radiology. 2017; 283(1): 49-58.
2. Source for (i) PPV: Int. J. Cancer. 2019; 144, 2587-2595 and (ii) False Positive Rate: JAMA. 2018; 320(7):687-705.
3. Source for PPV and False Positive Rate: Abdom Radiol (NY). 2016; 41(8): 1441–1444.
4. Source for (i) PPV: N Engl J Med. 2013; 368(21): 1980-1991 and (ii) False Positive Rate: Ann Intern Med. 2015; 162(7): 485-491
5. Source for (i) PPV: CA Cancer J Clin. 2010; 60(2): 70-98 and (ii) False Positive Rate: Ann Fam Med. 2009; 7(3): 212-222

Ability to predict with high accuracy the cancer signal origin and direct diagnostic workup

In our PATHFINDER study, Galleri demonstrated a high (88%) cancer signal origin prediction accuracy for identifying the location of cancer, which supports physician approaches to diagnostic resolution through well-established workup pathways. Cancer signal origin prediction accuracy represents the extent to which first and second origins identified were correct among true positive tests. In our PATHFINDER study, the first workup based on cancer signal origin facilitated a diagnostic resolution in 25 of the 32 participants who had diagnostic resolution (approximately 80%). Importantly, this group of 32 participants consisted of only those who received a cancer signal detected result from both Galleri and an earlier version of our MCED test also being studied in our PATHFINDER study. We also found that Galleri's cancer signal origin prediction generally facilitated diagnosis in less than three months (median of 79 days) among participants who had a cancer signal detected. Further, Galleri's cancer signal origin prediction capability enables physicians to limit the use of full body imaging following cancer signal detected results, which can be expensive, not readily accessible to broad patient populations, exposes patients to radiation, and can lead to false alarms and unnecessary ancillary workups.

Backed by robust analytical and clinical performance

Galleri test performance is validated by extensive clinical studies. We have established a broad population-scale clinical evidence program, including the more than 21,000 participants included in the studies that supported the development and launch of Galleri. We established clinical validation using a locked assay and classifier in case-control and intended-use populations. A locked assay means that the assay and classifier are fully specified, with no further adjustments. A locked assay and classifier produce the same result, within process control limits, when the same input is applied. A case-control study is a type of observational study that interrogates factors associated with diseases or outcomes. These studies include a group of "cases" (*e.g.*, participants with cancer) and a group of "controls" (*e.g.*, participants without cancer). A case-control study can, for example, be used to establish performance characteristics and for clinical validation. Our CCGA study is an example of a case-control study, in that it enrolled participants with a cancer diagnosis (cases) and participants without a cancer diagnosis (controls). Importantly, we were able to translate performance from our foundational case control CCGA study to our interventional PATHFINDER study. We have shared evidence supporting Galleri's performance at renowned medical conferences and published results from our studies in leading scientific and medical journals.

Ability to limit overdiagnosis of indolent cancers

Data across our clinical studies suggests that although Galleri detects cancer signals for some of the most aggressive cancers, detection of cancer signals for indolent cancer types, which people are less likely to die from, is low. Based on the Kaplan-Meier curves in the figure below, which show survival over time, detected cancers have a similar prognosis to that expected based on our analysis of SEER data, whereas cancers not detected by Galleri had a more favorable prognosis than would be expected. At any given stage, survival was worse for cancers detected by Galleri, as shown in the figure below. More specifically, the blue curves, which represent detected cancers, are steeper than the purple curves, which represent undetected cancers, meaning that cancers detected by Galleri have a worse prognosis than those cancers that were not detected. These findings were consistent across stages of cancer. Because this effect could be influenced by the types of cancer being evaluated, we adjusted for the age and cancer type distribution reported in the SEER data, and showed that this result is consistent if our detection rate were applied to the cancer and age distribution present in the SEER data (represented by the dashed lines in the figure below). This suggests that indolent cancers are unlikely to be detected by Galleri, and Galleri would be unlikely to contribute to the problem of overdiagnosis, and the associated harms related to treatment of over-diagnosed cancers.

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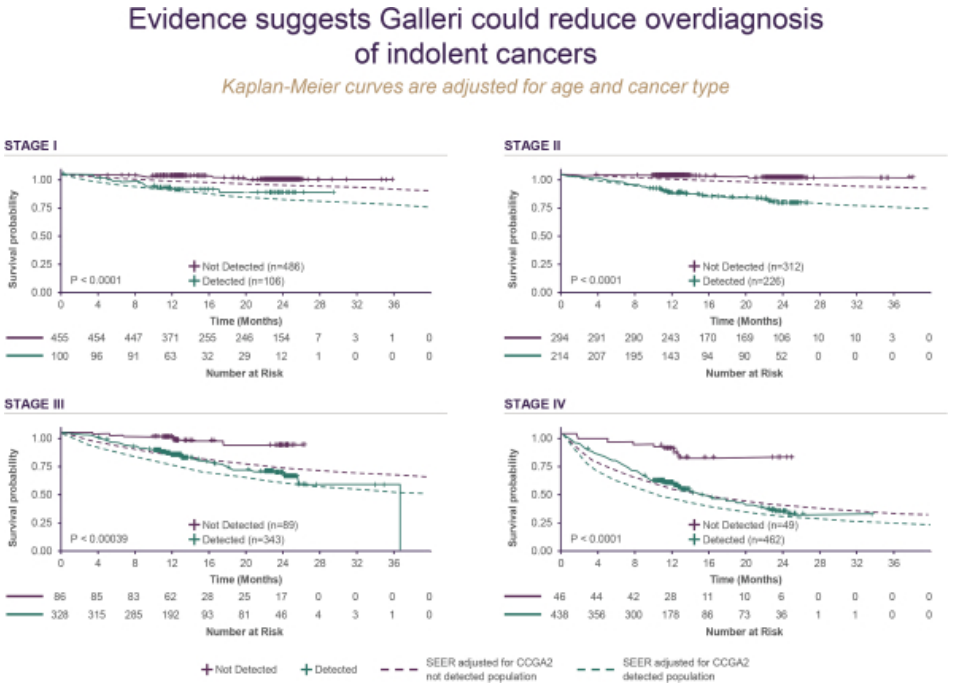


The p-values shown in the figure above indicate the likelihood that this result might be due to chance. The smaller the p-value, the less likely these results are due to chance (for example, a p-value = 0.001 means that there is a 0.1% probability that the result is purely due to chance). The small p-value reflects both the magnitude of the difference as well as the large sample size. We believe these findings are biologically consistent with evidence suggesting that indolent, less aggressive cancers are less likely to shed DNA into the blood.

Application to a diverse population

Galleri has been validated in population-scale clinical studies to help detect cancer across broad populations that are diverse in behaviors (such as smoking), non-cancer diseases, environmental exposures, age, gender, race, ethnicity, socio-economic status, and other confounding indications and differences. For example, in published data from our CCGA study, we found no differences in performance across racial subgroups. Understanding the signals associated with population diversity is important to our ability to account for biological noise and develop high-specificity tests for a broad testing population. The inclusion of confounding conditions in our studies, such as aging and inflammatory conditions, enables us to discriminate true cancer signals from biological noise.

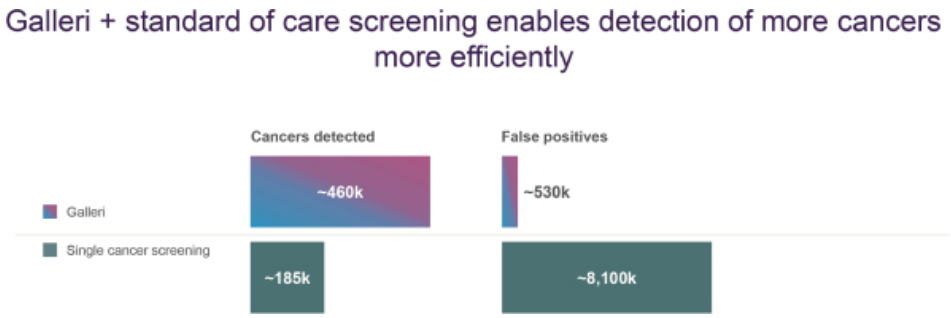
We continue to study Galleri in population-scale studies that evaluate the effectiveness of the test in diverse and high-risk populations. For example, we have worked with clinics, fire departments, municipalities, and unions to test thousands of firefighters, who generally have exposure-related increased risk of cancer. We established a research collaboration with the U.S. Department of Veterans Affairs ("VA"), the largest healthcare system in the United States, and the Veterans Health Foundation to provide Galleri to 10,000 veterans, many of whom are at high risk for cancer, across multiple participating VA sites over a three-year clinical study period. In addition, in our SUMMIT study, we are evaluating Galleri in a population of individuals at high risk for lung and other smoking-related cancers.

Complementary to standard of care screenings

In the United States, the five standard of care single-cancer screening tests (breast, cervical, colorectal, lung cancer, and prostate) have helped to reduce mortality for these specific types of cancer. Galleri expands upon the current standard of care guidelines to screen individuals with a single test for many types of cancer, most of which have no recommended screenings. We envision a world where Galleri is broadly accessible and used routinely alongside current standard of care screenings, potentially annually, to drive significant improvements in patient care and reduce cancer mortality and the cost of cancer care.

To estimate the potential impact of early cancer detection and mortality reduction, we developed and published a cancer epidemiology forecast model. In 2021, we published modeling data in *Cancer Epidemiology, Biomarkers & Prevention* (Cancer Epidemiol Biomarkers Prev. 2021; 30:460–8) that estimated the potential impact of MCED testing on mortality reduction based on test performance in our CCGA-2 study and using 2006 to 2015 SEER data for ages 50-79. Based on this model, we estimate that by adding Galleri to the five standard of care single-cancer screening tests (breast, cervical, colorectal, lung cancer, and prostate), there is potential to detect many more cancers at an earlier stage, which could translate into the potential to avert approximately 100,000 deaths per year in the United States as measured by five-year survival, or 39% of the five-year deaths expected if not for early detection by Galleri.

In addition, we estimate that in a population of approximately 107 million individuals between the ages of 50-79 in the United States, adding Galleri to the five standard of care single-cancer screening tests could result in the detection of an additional 460,000 cancer cases. Our model shows that the use of Galleri together with standard of care screenings could lead to the detection of three times as many cancer cases overall as compared to standard of care screenings alone, with only 6.5% more incremental false positives. We estimate that identification of many more cancer cases with a limited number of additional false positives would reduce the cost to diagnose one cancer by approximately 68%.



Simple to implement and access

Galleri is administered via a simple blood draw that enhances patient access and is easy for healthcare providers to implement. We believe ease of a blood draw can increase compliance by reducing some of the barriers that have limited the adoption of certain individual cancer screening tests, including the time to obtain the screening test as well as access to specialists and specialized equipment. The test is available through a wide range of in-person and telemedicine care settings in the United States. Galleri is conveniently accessible to patients who can complete the blood draw at physician offices, reference labs, and mobile phlebotomy labs, among other locations. In addition, Galleri can be easily integrated into routine practice, where healthcare providers can order Galleri as part of an annual examination.

Support Services for Physicians that Drive a Positive Patient Experience

We have developed a suite of support services to optimize the test experience for healthcare providers and patients. We believe it is important that cancer signal detected patients and their healthcare providers are supported as they navigate follow-ups such as scheduling a confirmatory diagnostic procedure. For all cancer signal detected results, our medical science liaisons connect with the ordering provider via email or phone to offer support in clinical decision making. Clinical care documents are shared with the healthcare provider that describe published clinical guidelines to help guide next steps in the diagnostic work-up. Healthcare providers can additionally elect to access a Galleri experience council—a cohort of physicians (including experts from National Cancer Institute designated cancer centers) with experience with Galleri who can provide peer-to-peer consultations. We also operate an early cancer detection board, analogous to a tumor board, that includes third-party experts across specialties to discuss any challenging cases for which advice is sought. We offer patients a post-cancer signal detected result support center that provides materials they can bring to a referral to ensure the receiving physician understands the cancer signal detected test result to facilitate urgent care for such patients.

In addition, our software systems support a positive experience for physicians and their patients. Our physician portal is designed to allow physicians to order our test and obtain patient consent electronically, which is efficient and helps minimize errors and incomplete user information. We designed our software systems to integrate with third-party electronic medical record systems to streamline test ordering and results delivery. Importantly, for every test we process, we provide a clinically actionable test report, as depicted in the graphic below, that is delivered through our secure web portal to the ordering healthcare providers to show whether or not a cancer signal is detected, and if so, to predict where in the body the cancer signal is located.

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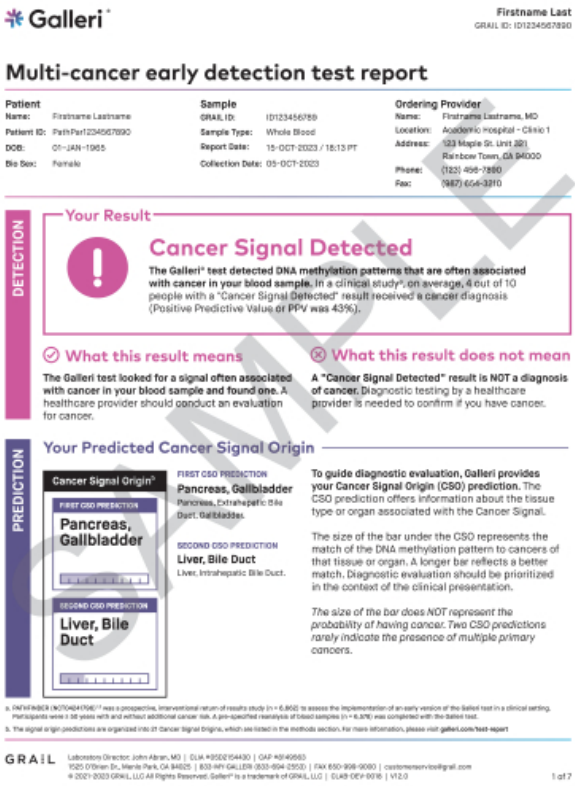
The image below depicts an illustrative cancer signal detected test report.



Investment to Enhance Versions of Tests

We seek to continually enhance the performance and features of Galleri. Commercial use and ongoing research programs provide valuable data that we believe can enhance test performance. Real-world evidence is already informing product improvements today. We will leverage even larger datasets to further develop our advanced machine learning algorithms. By further refining and selecting subsets of highly informative regions for cancer signal origin detection to reduce panel size, we could achieve deeper sequencing coverage and lower sequencing costs. We also aim to further improve the sensitivity of our tests by obtaining deeper sequencing coverage and a better understanding of noise and leveraging even larger datasets to further develop our advanced machine learning algorithms. We also continue to research and develop technologies that have the potential to complement methylation through orthogonal biological information, including additional analytes and biofluids such as proteins and urine. New products, including enhanced versions of current products, will require the completion of certain clinical development and regulatory activities, such as bridging studies to measure and evaluate concordance, performance and safety of a subsequent, enhanced version of our product versus the relevant existing product. Any bridging study may use previously collected clinical study data and other samples, and will need to be agreed upon with regulatory authorities.

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Precision Oncology Portfolio

The precision oncology market is expected to grow significantly in the coming years, and multiple research studies have indicated that liquid biopsies and ctDNA detection will play a major part in this growth. Our precision oncology portfolio currently consists of an RUO-targeted methylation-based platform with customizable classifiers that enables applications for disease prognostication, risk stratification, minimal residual disease ("MRD") detection and recurrence and relapse monitoring across many cancer types. To date, we have run more than 6,000 samples in our development services programs across multiple partners.

We initiated early collaborations with select, leading biopharmaceutical companies beginning in 2020, and the launch of our RUO offering in early 2023 has unlocked additional 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 first companion diagnostic partnership was announced in 2022 with AstraZeneca. We have published or presented early performance data on MCED testing at multiple academic conferences, including ASCO, AACR and ESMO, across different use cases and indications. These data demonstrate the versatility of the platform across multiple applications and areas of clinical unmet need.

Our RUO offering uses our proprietary targeted methylation platform to analyze cfDNA isolated from peripheral blood for cancer signal interrogation. Our RUO technology estimates tumor burden based on tumor methylation fraction, enabling longitudinal monitoring and surveillance solutions. Data from our studies have demonstrated analytically validated performance, and robust analytical sensitivity, specificity, and precision. For example, in a recent analytical validation study, cfDNA was analyzed from donors with and without cancer. Analytical sensitivity was assessed in 12 different solid tumor types. Results demonstrated strong median limit of detection ("LoD") of 0.023% based on measures of the abnormally methylated ctDNA fraction. Analytical specificity was 98.5% and overall precision across all replicates was 94.6%. The low input requirements support retrospective research studies. Retrospective studies are generally performed using banked samples stored in a freezer. Banked samples may be subject to reduced cfDNA levels (due to reduced plasma volume, sample degradation, or collection in tubes not optimized for cfDNA stability). As a result, a low limit of detection is important to facilitate performance of retrospective research studies.

In addition to our biopharmaceutical business, we believe that our targeted methylation platform could enable clinical products to support patient care across the cancer care continuum. For example, many tests available today for solid tumors require tissue samples and development of patient-specific assays, which contributes to longer turnaround times and potential delays in treatment decisions. Our multi-cancer, non-invasive targeted methylation platform enables cancer detection, classification and monitoring with limited plasma input and no tumor tissue. Test results can be returned rapidly with a 7-10 day clinical turnaround time. The blood-only liquid biopsy approach eliminates challenges with obtaining tissue samples and avoids bias due to tumor heterogeneity and disease evolution. The targeted methylation approach is also able to enhance accuracy as compared to mutation-based approaches which are known to be confounded by normal biological processes, such as those associated with aging. In the clinical monitoring application, the difficulty of obtaining serial tissue samples, particularly in cancer types such as lung and liver, means a blood-based approach is likely to be much more attractive to clinicians and biopharmaceutical partners.

Further, we have validated performance of our technology in an MRD setting, with sensitivity on par with tumor-informed methods. For example, as presented at the American Association of Cancer Research meeting in 2023, GRAIL's analytical sensitivity is reported as the tumor methylation fraction at which the assay detects 95% of samples ("median LoD95"). Our median LoD95 across participants in 12 different cancer types (breast, colorectal, esophagus, head and neck, kidney, liver/bile duct, lung, ovary, pancreas/gallbladder, sarcoma, stomach, uterus) was 0.023%, which means that above 0.023% tumor methylation fraction the assay detected 95% of samples. As a reference, Natera's tumor-informed Signatera RUO assay for use in several solid tumor cancers, an MRD test, reported similar analytical validation with greater than 65% sensitivity above 0.03% tumor

fraction, meaning that above 0.03% tumor fraction (as measured using single nucleotide variants in an analogous approach to calculating the amount of tumor content in circulation) the assay detected 65% of samples. Above 0.1% the assay reported a 100% sensitivity. Accordingly, we believe our median LoD95 of 0.023% is on par with these results. MRD testing is used in pharmaceutical studies and clinical practice to detect the presence or absence of residual disease and inform treatment decisions, including identifying patients who may be eligible for adjuvant therapy.

Our Diagnostic Aid for Cancer Test

To accelerate diagnostic resolution for patients with non-specific signs and symptoms, but with a clinical suspicion of cancer, we are developing our DAC test using the same proprietary platform used to develop Galleri. Through a simple blood draw, DAC is designed to provide physicians with a powerful decision-making tool to aid diagnosis, achieve resolution more quickly, and avoid unnecessary workups. Data from our SYMPLIFY study published in *The Lancet Oncology* showed that, in a symptomatic patient population, our methylation platform was able to detect many cancer types and identify where the cancer signal origin was located in the body.

Symptomatic detection of cancer is a significant unmet need; we estimate that approximately 16 million patients in the United States present with non-specific signs and symptoms each year. These patients are subject to potentially invasive and time-consuming diagnostic workups. Further, over 70% of patients with non-specific, but concerning symptoms, undergo imaging, scoping, biopsies and other procedures, and over 25% of patients take more than four months to reach a diagnosis once they have already been referred for investigation. There is currently no option for multi-cancer detection for these patients, meaning they will need to potentially undergo multiple single cancer workups. Only around 4% of these patients are ultimately diagnosed with cancer. As demonstrated through SYMPLIFY and other published studies, primary care physicians frequently have difficulty determining which investigations and specialists a patient should be referred to having presented with a non-specific symptom such as unexplained weight loss. This can sometimes result in a prolonged diagnostic odyssey for the patient, with multiple investigations over many months.

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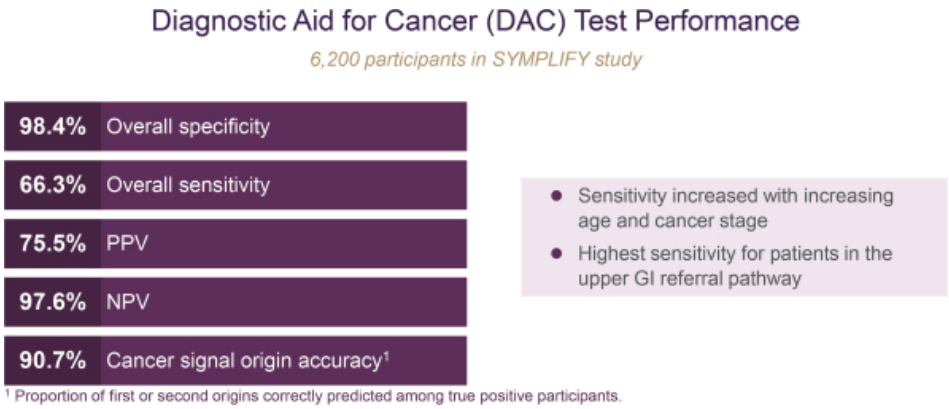
Based on our findings in the SYMPLIFY study that included more than 6,200 participants and was published in *The Lancet Oncology*, DAC demonstrated an overall PPV of approximately 76% with an overall NPV of approximately 98%. NPV is an important measurement in a symptomatic population because we believe it provides a physician with more certainty that a negative test indicates a patient does not have cancer that will go untreated. In addition, the overall cancer signal origin prediction accuracy was approximately 90% (first origin indicated had a cancer signal origin prediction accuracy of approximately 85%). Test performance was the strongest in patients referred for investigation of a possible upper gastrointestinal cancer, which has historically been more difficult to diagnose, with a PPV of approximately 66% and an NPV of approximately 99%. The high overall PPV, NPV, and cancer signal origin prediction accuracy results demonstrated in the SYMPLIFY study provide further evidence that our methylation-based platform can help clinicians in difficult non-specific symptomatic situations determine the likelihood that an individual might have cancer, and if a cancer signal is reported, where to direct patients based on the predicted cancer signal origin. The image below summarizes information from our SYMPLIFY study.



Our DAC test has the potential to be reimbursed as a medical benefit, which is an existing, established coverage pathway in the United States. Product development efforts are ongoing, and we currently consider the launch of our DAC test as a medium- to longer-term objective, subject to a number of factors, including determining the requirements for reimbursement in the United States. Efforts we have made to develop DAC include measuring DAC performance in our SYMPLIFY study, taking efforts to secure reimbursement, and evaluating commercial launch, including whether to launch prior to reimbursement. In deploying DAC in clinical practice, we expect to leverage our existing commercial salesforce and infrastructure.

Additional Products in Development

Our rigorous discovery efforts have already enabled us to build unique technologies and develop a powerful platform for early detection. Moving forward, we will continue to research and develop technologies that have the potential to complement and enhance our capabilities. We have conducted early research and development in areas such as immunology and biofluids such as urine. We also plan to leverage relationships, including with academic and industry partners, to help expedite bringing potential new applications of our technology to market.

Methylation Technology Platform

Origin Story

Although the presence of tumor DNA in the blood was discovered in 1948, it has largely been used as a non-invasive method to select targeted therapies for patients with late-stage cancer. More recently, evidence supported the idea that DNA in the blood could also detect cancer in earlier stages, which raised the possibility of

utilizing cfDNA for early cancer detection (i.e., when patients are asymptomatic). This idea originated in part at Illumina from incidental findings from a study involving a commercial cfDNA-based non-invasive prenatal test. This study leveraged whole-genome sequencing to interrogate copy-number variations to identify fetal chromosomal abnormalities from fetal cfDNA in maternal circulation. From an overall cohort of 125,426 pregnant women, 10 cases of maternal cancer were identified. In cancer cases that presented with advanced symptoms, the treating clinician noted that earlier detection of the malignancy would have had a positive effect on their care. This incidental detection of multiple cancer types via cancer-specific chromosomal changes suggested that a cfDNA-based MCED was possible and GRAIL was founded shortly thereafter.

Detecting Cancer Signals in the Blood

Blood contains circulating genomic material, including fragments of tumor DNA in an individual with cancer, which makes it well suited for detecting cancer signals. The genome is a set of DNA instructions found in a cell that contains information for how an organism and its cells function. Changes to one or more genes, often referred to as mutations, can disrupt a cell's normal functioning and cause disease. Genetic mutations can be indicative of cancer, and the reason why cancer is often called a disease of the genome. Although understanding an individual's genetic mutations can help diagnose and treat cancer (for example, by selecting a therapy known to target a specific mutation or set of mutations), mutations only provide part of the picture that drives the complex biology of cancer.

It is well recognized that a hallmark of cancer is abnormally methylated DNA. Methylation is a fundamental biological process active in all living cells that regulates gene expression (i.e., which sections of the DNA "turn on" or "turn off") and thus drives cellular function. A methylation site is a location on the genome where a methyl group, made up of one carbon atom and three hydrogen atoms, is attached to a cytosine base along the DNA strand. An abnormal methylation site is either hyper (normally not methylated but is then methylated) or hypo (normally methylated but is not then methylated). Hypermethylation can lead to silencing of tumor suppressor genes, transcription factors, and DNA repair mechanisms and therefore increase the likelihood of tumor formation. Hypomethylation can lead to genomic instability and chromosomal rearrangements. Modifications in methylation patterns can result in changes in protein levels, which can trigger changes in cellular function and lead to disease, including cancer. For example, hypermethylation of the genome's regulatory region that activates a tumor suppressor gene can turn off expression and lead to tumor growth. Additionally, because each cell type in the body has a unique methylation pattern, or "fingerprint," evaluation of methylation patterns can enable the determination of a cancer signal origin.

Nucleic acids, including tumor DNA and its methylation patterns, can shed from cells into the bloodstream. Short DNA fragments in the blood are known as cfDNA and come from nearly all cell types in the body, including normal cells, diseased cells, cancerous cells, microbes such as parasites, bacteria, and viruses, and, in pregnant women, the placenta. The cfDNA fragments shed into the blood can be sequenced, and their exact sequences and methylation patterns can be used to identify disease and to determine the location from which they originated. When a person has cancer, the DNA from cancerous cells circulate as part of the blood plasma. Cancerous tumor DNA in the blood is specifically referred to as circulating tumor DNA ("ctDNA").

The ability to sequence cfDNA from blood allows for a direct interrogation of methylation patterns that are shared by many types of cancer. To successfully develop cfDNA sequencing technology into an effective, highly-specific MCED test, we had to overcome a number of technical, biological, and clinical challenges. Due to the very small amount of ctDNA present in a blood sample, the sequencing assay must achieve a sufficiently LoD to capture signals that are derived from a tumor versus those from healthy cells in the body, and be able to distinguish this signal from noise in a population of asymptomatic individuals with other confounding conditions and circulating DNA from normal cells.

Our Proprietary Methylation Platform

We have developed a targeted methylation platform, comprising wet lab workflows and machine learning algorithms, to recognize a shared cancer signal by efficiently interrogating over one million methylation sites on DNA fragments found in blood. We leveraged our methylation platform to produce our first MCED test, Galleri.

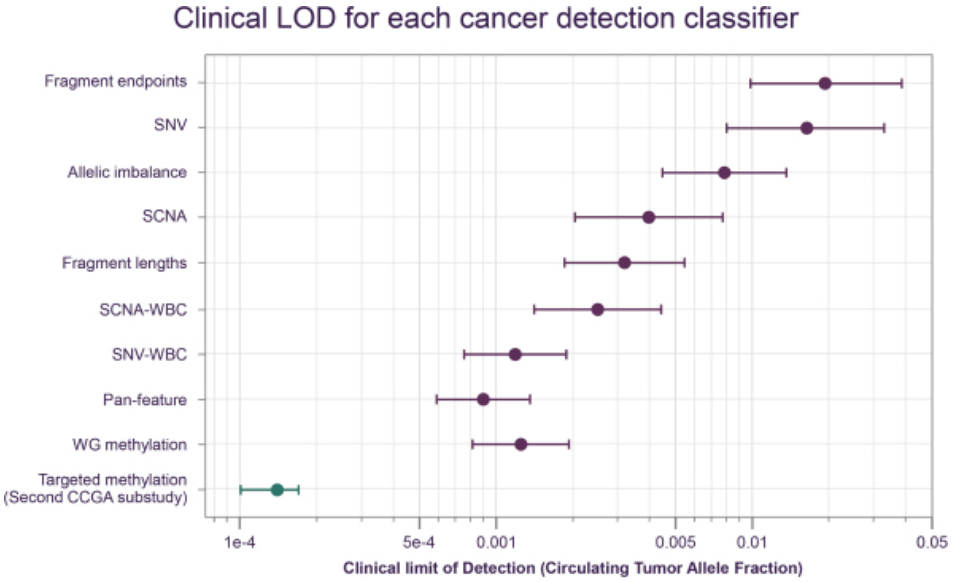
We invested heavily to develop our methylation platform and have built what we believe is an unprecedented longitudinal dataset of high-quality, linked clinical and genomic data. Our proprietary wet lab procedures enable a rich retention of DNA signal in our bisulfite sequencing process, and are designed to optimize the processing of data and improve the quality of our assays. Investments in scalable data management infrastructure enable collection, management, and integration of data from our population-scale clinical program. Sophisticated machine learning algorithms efficiently analyze these extremely large data sets and differentiate cancer signal from technical and biological noise. Our algorithms learn from the growing aggregate data set over time and derive biological insights that we believe will enable both product improvements and new product development over time.

Our Unbiased Discovery Approach

To identify the most effective way of detecting cancer signals in the blood, we took a comprehensive and unbiased discovery approach to evaluate multiple next-generation sequencing ("NGS") prototype assays. We designed our CCGA study to characterize the range of genomic signals in the blood of people with and without cancer. Our goal was to develop and evaluate computational models to distinguish cancer cfDNA from non-cancer cfDNA and to develop machine learning algorithms to identify and localize the cancer signal within the body. Notably, the non-cancer participants included individuals with varied age, sex, ethnicity, cancer risk factors such as smoking status, and body mass index and comorbid conditions, increasing the generalizability of this study. This study led to the development, refinement, and clinical validation of our targeted methylation platform.

We developed multiple prototype assays to identify and measure a wide variety of cancer genome signals that are found in cfDNA. Our prototype assays used targeted sequencing to measure single nucleotide variants ("SNV") and small variants to evaluate cancer-derived mutations (with and without white blood cell ("WBC") noise removal); whole-genome ("WG") sequencing to analyze somatic copy number alterations ("SCNA") and fragment features such as length and endpoint; and whole-genome bisulfite sequencing ("WGBS") to identify methylation patterns.

We demonstrated that a WGBS approach to characterizing methylation patterns performed as well or better than the other approaches we tested, either as standalone or in combination, and showed the most potential for further optimization. We found that the methylation signatures were shared across more than 50 cancer types. Additionally, the methylation assay performed better to determine the cancer signal origin. After comprehensive analysis of whole-genome methylation patterns in connection with our CCGA study, we discovered highly informative and low noise methylation sites for cancer signal detection and cancer signal origin detection. Highly informative sites are likely to have abnormal methylation patterns resulting from cancer, and low-noise sites are less likely to be subject to confounding signals from biological noise resulting from confounding conditions (such as aging, inflammatory conditions) and circulating DNA from non-cancerous cells. This discovery led to our development of a targeted methylation approach, which entails interrogating specific methylation sites within a genome to assess methylation patterns and serves as the basis for our Galleri test. Our targeted methylation approach can detect lower levels of cancer signal in blood compared to the other approaches examined, enabling early cancer detection in asymptomatic individuals more efficiently compared to whole-genome methylation. The graphic below shows that our targeted methylation assay had a LoD of approximately 150 parts per million ("PPM") which is significantly lower than other NGS approaches we assessed. LoD is the tumor fraction (or the estimated fraction of tumor genomes in a cfDNA sample) at which the probability of detecting the cancer is at least 50%.



Note: SNV: Single nucleotide variants; SCNA: Somatic copy number alterations, SCNA-WBC: Somatic copy number alterations with white blood cell noise removal; SNV-WBC Single nucleotide variants with white blood cell noise removal; WG methylation: Whole genome methylation

We believe the performance advantage of ctDNA methylation is largely due to its biological characteristics, which make it more robust at the low signal-to-noise ratios inherent in cfDNA. In contrast to typical cancer mutations that only affect a handful of genomic locations, there are nearly 30 million methylation sites across the human genome, making them a ubiquitous and rich signal for detecting cancer. When localizing cancer signal origin, methylation signals inherently reflect tissue differentiation and malignant cancer states which makes them significantly more informative than other approaches we tested. Data describing our CCGA discovery approach was published in 2022 in Cancer Cell (Cancer Cell 40, 1537–1549 December 12, 2022).

Methylation-based Platform is Highly-Differentiated – Technology Advantages and Validated Performance

We believe our targeted methylation approach is differentiated from other blood-based detection technologies. Whole-genome methylation from cfDNA used in our prototype MCED test performed strongly with respect to cancer signal detection and cancer signal origin prediction, without requiring additional sequencing to correct for the high background noise due to DNA from WBCs. Importantly, subsequent technology improvements led to our development of the targeted methylation approach that has superior performance and lower costs compared to whole-genome methylation. These performance improvements (specificity, sensitivity, and cancer signal origin prediction accuracy) were recently reported in large-scale clinical validations studies, CCGA and PATHFINDER, which supported the commercial launch of Galleri. We continue to learn from our clinical studies and apply these learnings to our methylation platform.

In our studies, methylation outperformed WGS and targeted sequencing in cancer detection and cancer signal origin for a number of reasons. First, methylation is more pervasive compared with the mutation sites typically interrogated in traditional liquid biopsy approaches. Our targeted methylation approach interrogates approximately one million informative sites of cytosine and guanine separated by a phosphate group ("CpG sites") out of the roughly 30 million CpG sites across the genome. We identified these 1 million CpG sites as the most informative regions for cancer signal detection and cancer signal origin prediction. This allows deeper sequencing of those informative regions compared with WGBS and may overcome expected cost and efficiency limitations of WGS or WGBS approaches. Second, although WGS detected cancer at high tumor fractions, it had a worse limit of detection than a methylation-based approach. Targeted sequencing for mutation detection was also subject to highly prevalent mutations present in individuals due to other biological processes and aging. As such, unlike methylation, targeted sequencing required concurrent WBC sequencing to achieve strong performance. Finally, epigenetic signals inherently reflect tissue differentiation and malignant cancer states; this likely contributes to the strong cancer detection and cancer signal origin classification. Importantly, we found there was little to no value in combining approaches to improve clinical LoD or sensitivity above WGBS.

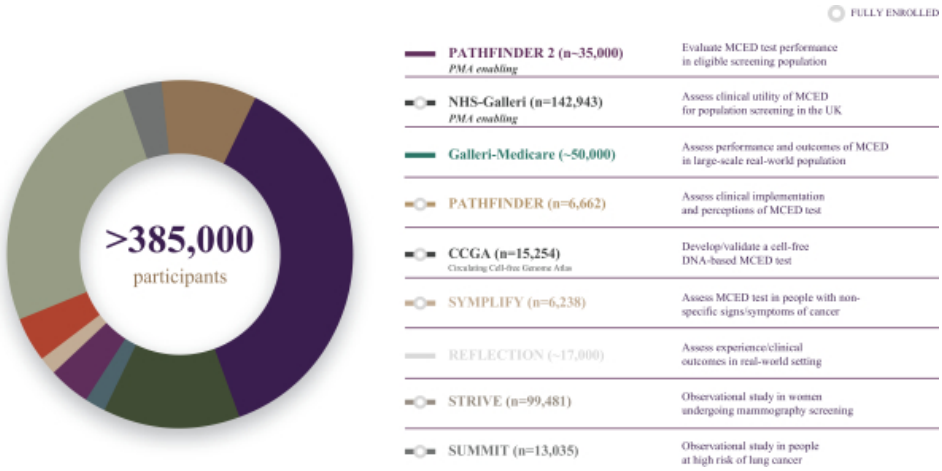
Our Clinical Studies

We have built what we believe is one of the largest clinical programs in genomic medicine, which has generated what we believe is an unprecedented longitudinal dataset of high-quality, linked clinical and genomic data. We are collecting population-scale clinical data from more than 385,000 participants in numerous clinical studies, with more than 21,000 of these participants included in the studies that supported the development and launch of Galleri, and over 165,000 individuals enrolled and an additional approximately 60,000 anticipated to be enrolled in interventional studies (NHS-Galleri and PATHFINDER 2, which support our PMA submission, and the first-of-its kind Galleri-Medicare real-world study). The PATHFINDER 2 study and NHS-Galleri Trial are designed to support a PMA submission, with select inclusion criteria (matching the intended use population for Galleri), use of an appropriate assay (developed and commercially available), and enrollment of a sufficient number of participants to facilitate the generation appropriate data and evidence. This design differs from our other studies, such as our CCGA study, which included participants outside of the intended use population for Galleri, and PATHFINDER study, which enrolled fewer participants and utilized an earlier version of Galleri for initial results. Additionally, we announced plans for a 100,000 individual real world study in the Medicare population, with a focus on racial and ethnic minorities and seniors aged 65 and above from under-served communities. The study seeks to compare up to 50,000 prospectively enrolled Medicare beneficiaries who have received usual care plus an annual Galleri test with a matched comparator arm of beneficiaries who receive usual care alone, for up to three annual testing cycles. The study will also include a 50,000-person synthetic control arm. GRAIL is responsible for designing and executing this study and is planning to work with leading health care systems across the country and other key partners over the next few years. Our studies have supported the development of our methylation platform, Galleri, and are facilitating the development of DAC. These foundational population-scale studies involve partnerships with numerous leading

academic and cancer institutions and large community networks, including, among others, the Cleveland Clinic, Dana-Farber Cancer Institute, Guardian Research Network, Kettering Health, Mayo Clinic, Sutter Health, and the US Oncology Network.

Our studies include the collection of blood and, as available and as directed by the protocol, tissue samples, demographic data, patient-reported outcomes data, and clinical data from participants. Clinical information, demographics, and medical data relevant to cancer status are collected from participants at time of enrollment and at regular intervals during a follow-up period. We integrate this information with the genomic data created from sequencing the samples and utilize these data to both train and validate our early cancer detection tests. Importantly, these are longitudinal studies and, in many cases, participant medical data will continue accruing for a number of years, facilitating analyses of longer-term outcomes, and further performance improvements of our products. Our studies are conducted by various medical and oncology centers around the country.

Our clinical studies are summarized in the table below:



We were the first to invest in and initiate multiple, large clinical validation studies for multi-cancer early detection. Results from PATHFINDER, our first completed return-of-results study, provided critical data to support launch of Galleri and understand how clinicians implement Galleri into care pathways in clinical practice. We have completed enrollment in five additional studies: NHS-Galleri, Circulating Cell-free Genome Atlas (“CCGA”), SUMMIT, STRIVE, and SYMPLIFY. We are actively enrolling two studies: PATHFINDER 2 and REFLECTION, and will begin enrollment in our Galleri-Medicare Study by the third quarter of 2024.

We have presented data and published results from our clinical studies in leading forums, including multiple major medical conferences, such as AACR, ASCO, and ESMO, and leading journals, such as *The Lancet*, *Nature*, *Nature Medicine*, *Cancer Cell*, and *The Lancet Oncology*. Data from our studies is expected to support regulatory filings as we pursue PMA approval.

Importantly, our clinical program was designed to enable test development for a diverse population, and enrollment was managed to enable diversity across multiple characteristics including diversity in behaviors (such as smoking), non-cancer diseases, environmental exposures, age, gender, race, ethnicity, socio-economic status, and other confounding indications and differences. Understanding and cataloging this diversity has enabled us to develop tests with high-specificity, cancer signal detection across many cancer types, and accurate cancer signal origin prediction. Long-term follow-up in the studies we have launched in years past will continue to yield critical data that we believe can help define the standard of care in early cancer detection.

NHS-Galleri

In 2020, NHS England selected us to assist with the United Kingdom's ambitions for early cancer detection and to assess Galleri for potential population screening on a national scale. In 2021, we initiated the NHS-Galleri Trial, a fully enrolled prospective randomized controlled clinical utility trial of approximately 140,000 participants between the ages of 50 and 77 at the time of enrollment, to evaluate the implementation of Galleri alongside the existing NHS standard of care screenings. Funding for the trial is provided by us. Collaborators include Cancer Research UK, Queen Mary University of London, Kings College London Cancer Prevention Trials Unit, and NHS, and, based on reviews by the Independent Data Monitoring Committee, no serious adverse events have been identified. These collaborations are subject to terms generally consistent with industry sponsored studies, provided that our arrangement with NHS includes the framework for our potential two year commercial implementation pilot. The NHS-Galleri Trial is being conducted pursuant to an FDA-approved investigational device exemption ("IDE") application. The primary objective of the trial is to assess whether implementation of Galleri can reduce the incidence of late-stage cancers through early cancer detection. Secondary objectives include collecting outcomes reported by participants with a cancer signal detected test over several timepoints. These outcomes include an assessment of participants' anxiety, satisfaction with Galleri, and attitudes regarding standard of care screening. The trial aimed to enroll a representative population sample to promote health equity and was fully enrolled in just over 10 months. Results of an early analysis from the first screening test (the prevalent screening round) representing one year of results out of the three-year trial period are expected to be reviewed by the NHS in , and final results from the trial are expected to be available in . We seek to use data from the NHS-Galleri Trial, together with data from our PATHFINDER 2 study, as well as supplemental data from other clinical studies, to support our planned PMA submission for Galleri in the United States.

The trial is designed for participants to provide three blood draws over a two-year period, with the first draw taken at enrollment. As a randomized controlled trial, half of the trial participants will receive the Galleri test, and half will have their blood sample stored for future analysis. Any participant in the interventional arm with a cancer signal detected result will be sent for further diagnostic workup with the NHS. All other participants and their physicians remain blinded as to which arm of the study they are in. The second round of blood draws was completed in July 2023, with over 91% retention of participants from the first round. The final round of blood draws commenced in September 2023 and is expected to conclude in July 2024.

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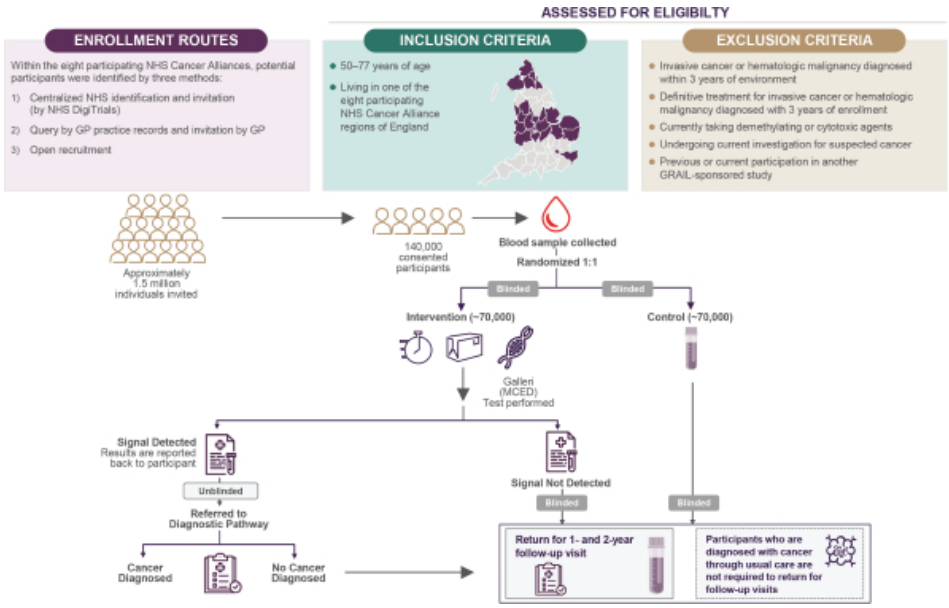
The design of our NHS-Galleri Trial is summarized in the figure below:



PATHFINDER 2

PATHFINDER 2 is a prospective, multi-center, interventional study evaluating the safety and performance of Galleri in a population of individuals aged 50 years and older who are eligible for guideline-recommended cancer screening in the United States. We began enrolling PATHFINDER 2 in December 2021, and the study is expected to enroll approximately 35,000 participants at up to 40 clinical institutions in North America. Funding for PATHFINDER 2 is provided by us. Collaborators include, among others, the Cleveland Clinic, Duke Health, Henry Ford Health System, Mayo Clinic, Memorial Care, Sutter Health, and the US Oncology Network, and based on reviews by the Data Safety Monitoring Committee, no serious adverse events have been identified. These collaborations are subject to terms generally consistent with industry sponsored studies.

PATHFINDER 2 is being conducted pursuant to an FDA-approved IDE application. The primary objectives of the study are to evaluate the safety of Galleri based on the number and type of diagnostic procedures performed in participants who receive a cancer signal detected but do not receive a cancer diagnosis (*i.e., false positive) and to evaluate the performance of Galleri across various measures, including PPV, NPV, sensitivity, specificity, and cancer signal origin prediction accuracy, among others. Participants who receive a cancer signal detected result undergo additional diagnostic testing based on the predicted cancer signal origin to confirm if the participant does in fact have cancer. Secondary objectives include, among others, collecting outcomes reported by participants over several timepoints, including an assessment of participants' anxiety, satisfaction with Galleri, and attitudes regarding standard of care screening. Timepoints for collection will include baseline measurement prior to testing, post-results, and post-diagnostic resolution for positive test results. Interim results from the study are expected to be announced in . We seek to use data from the PATHFINDER 2 study, together with data from the NHS-Galleri Trial, as well as supplemental data from other clinical studies, to support our planned PMA submission for Galleri in the United States.*

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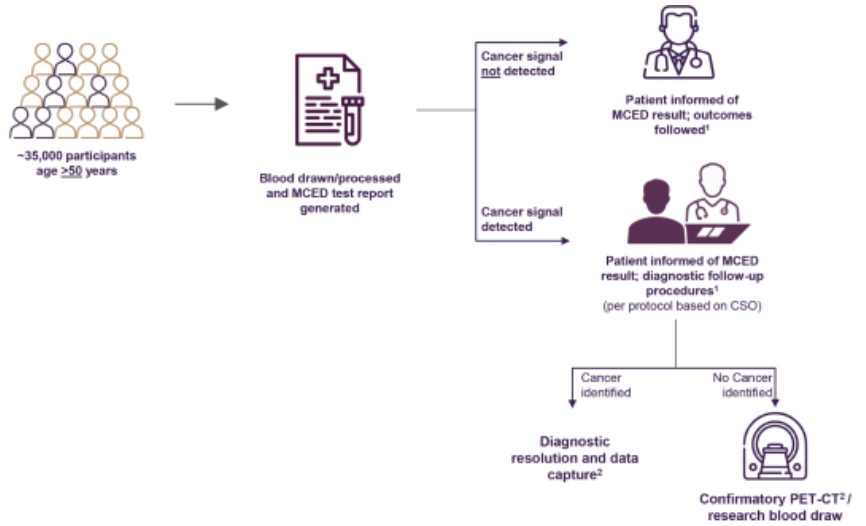
The design of our PATHFINDER 2 study is summarized in the figure below:



[1] Participants will be actively followed by enrolled institution for three years to assess cancer status and collect participant-reported outcomes
[2] Clinical information including but not limited to cancer type, pathologic, imaging and clinical staging information will be captured

PATHFINDER

In December 2019, we initiated PATHFINDER, a prospective, multi-center, interventional study evaluating an earlier version of Galleri in clinical practice. The study enrolled 6,662 participants across several health systems in the United States. Funding for PATHFINDER was provided by us. Collaborators included, among others, the Cleveland Clinic, Dana-Farber Cancer Institute, Intermountain Healthcare, Mayo Clinic, Oregon Health & Science University, Sutter Health, and the US Oncology Network, and no serious adverse events were identified. These collaborations were subject to terms generally consistent with industry sponsored studies. The study evaluated the safety and performance of this earlier version of Galleri in a population of individuals aged 50 years and older divided into two cohorts: participants with elevated cancer risk and participants with non-elevated cancer risk. PATHFINDER was our first study that returned test results to physicians and participants, and evaluated how these test results affected diagnostic and care pathways in a screening population. PATHFINDER was conducted pursuant to an FDA-approved IDE application involving an earlier version of Galleri. Over the course of the study, we made refinements to the test to reduce the detection of pre-malignant hematologic conditions, which are relatively common. Results for the study are reported for both the earlier and refined versions of the test. Initial results from the PATHFINDER study were presented at ESMO in 2022, and full results were published in *The Lancet* in October 2023. These data, in conjunction with the results from our CCGA study, supported our launch of Galleri as a laboratory developed test ("LDT") in the United States.

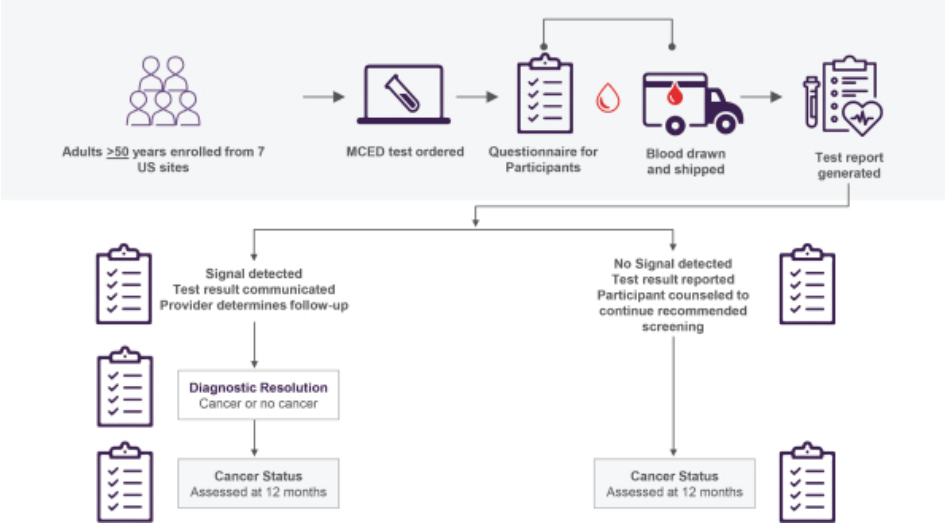
In the study, when added to current standard of care screening, Galleri more than doubled the number of cancers detected from screening. Study results showed that 71% (25/35) of participants that received a cancer signal detected from our MCED test result had types of cancer detected that have no routine cancer screening available. Among participants who received a cancer signal detected result and had a confirmed new cancer diagnosis (true positive), nearly half (48%) of the non-recurrent cancers were detected at an early stage (Stage I or II).

For patients with a cancer signal detected result, the predicted cancer signal origin directed diagnostic workups and helped to resolve cancer diagnosis in less than three months (median 79 days) for most participants

(73%), and in less than two months (57 days) for patients with true positive results. As expected, the median time to diagnostic resolution was longer for false positive results (162 days), with 44% of these participants scheduling follow-up imaging or procedures three or more months later, contributing to the longer time to resolution. Notably, the first workup based on cancer signal origin facilitated a diagnostic resolution in 25 of the 32 participants who had diagnostic resolution (approximately 80%). This group of 32 participants consisted of only those who received a cancer signal detected result from both Galleri and an earlier version of our MCED test also being studied in PATHFINDER.

Study results with the earlier version of the test showed a high PPV of approximately 38%, high (97%) cancer signal origin prediction accuracy, and the test detected 36 cancer cases in 35 patients out of 6,621 participants with analyzable results. A pre-specified retrospective re-analysis of samples with the refined version of the test showed a higher PPV of approximately 43%, which is consistent with our CCGA study, and high (88%) cancer signal origin prediction accuracy. Specificity was 99.1% with the earlier version of the test and 99.5% with the refined version of the test, resulting in a false positive rate of less than 1% for both versions of the test.

The design of our PATHFINDER study is summarized in the figure below:



Circulating Cell-free Genome Atlas Study

CCGA is our foundational observational, case-controlled study with planned five years of longitudinal follow-up. The study was used to discover, train, and validate Galleri, and was used alongside the SYMPLIFY study to analyze performance in the symptomatic patient population to support our DAC offering. The CCGA study enrolled 15,254 participants, 56% of which had newly diagnosed cancer, inclusive of both early-and late-stage disease, and 44% of which did not have a known cancer diagnosis at the time of enrollment. Funding for the CCGA study was provided by us. Collaborators included, among others, the Cleveland Clinic, Dana-Farber Cancer Institute, Lahey Hospital and Medical Center, Mayo Clinic, and the US Oncology Network, and no serious adverse events were identified. These collaborations were subject to terms generally consistent with industry sponsored studies. We completed enrollment of our CCGA study in February 2019, and follow-up with participants is ongoing and expected to continue until 2024. The results of CCGA, in conjunction with the results from our PATHFINDER study, supported our launch of Galleri as an LDT in the United States.

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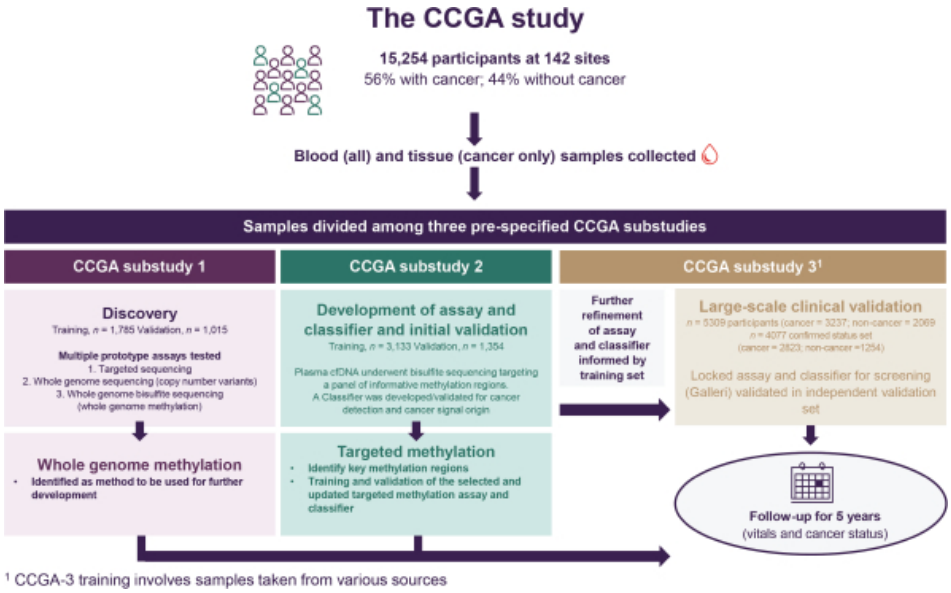
The goals of CCGA included the development and evaluation of classifiers to distinguish cancer cfDNA from non-cancer cfDNA and the identification of classifiers for the cfDNA prediction of cancer signal origin. By enrolling people with and without cancer, we are able to characterize cfDNA profiles by tumor type and tumor stage in participants with cancer, and can compare these signals to participants without cancer. In addition, understanding the signals associated with population diversity is important to our ability to account for biological noise and develop high-specificity tests. For example, our machine learning algorithms are trained to distinguish patterns of cancer from technical and biological noise, which is necessary to distinguish cancer cfDNA from other cfDNA signals that are indicative of non-cancerous conditions but that may be confused with a cancer signal. As a result, we enrolled participants with confounding indications across broad populations, and individuals with varied age, sex, cancer risk factors such as smoking status, body mass index and comorbid conditions, to increase the generalizability of this population.

We evaluated data from the CCGA study in three pre-specified sub-studies, each as described in more detail below. The design of our CCGA study, including the three pre-specified sub-studies, is summarized in the figure below:



CCGA-1

In CCGA-1, our first CCGA sub-study of approximately 2,800 participants, we investigated various comprehensive cfDNA-based approaches for the detection of cancer signals and the prediction of the cancer signal origin, including through targeted sequencing to analyze single nucleotide variants and small insertions and deletions; WGS to analyze copy number variations, fragment lengths, fragment endpoints, and allelic imbalance; and WGBS to analyze methylation patterns. The data demonstrated that WGBS (the methylation-based assay studied) performed as well or better than the other prototype assays we tested, either alone or in combination, at both cancer signal detection and cancer signal origin prediction. After comprehensive analysis of these whole-genome methylation patterns, we discovered highly informative and low-noise methylation regions for cancer signal detection and cancer signal origin prediction, suggesting that the methylation-based assay also had the most room for efficiency improvements. Based on these results, our methylation technology was

advanced into further development, ultimately resulting in a targeted methylation approach that had superior performance and lower costs compared to whole-genome methylation. Data from this sub-study were shared in several oral and poster presentations at multiple major medical conferences, including at AACR, ASCO, and ESMO, and were published in *Cancer Cell*.

CCGA-2

The primary objective of the CCGA-2 sub-study was to train and validate a classifier for cancer detection versus non-cancer detection, and cancer signal origin prediction, utilizing our targeted methylation assay. This pre-specified sub-study included approximately 6,700 total participants across training and validation sets, with 4,487 participants from CCGA and 2,202 from STRIVE. Of the total participants, 2,482 participants had previously untreated cancers and 4,207 participants did not have cancer. More than 50 types of cancer across all clinical stages were represented.

Results from the CCGA-2 sub-study were published in the *Annals of Oncology* in March of 2020 (and reflected on the cover) and demonstrated that Galleri could detect a shared cancer signal across more than 50 different types of cancer, including many types of cancer that do not have recommended screenings, from a simple blood draw with very high specificity. Data was evaluated in both training and test sets, and performance was comparable across the two analyses. At greater than 99% specificity, Stage I-III sensitivity for a pre-specified set of 12 deadly types of cancer, which together account for approximately 63% of cancer deaths in the United States annually, was approximately 67% and for all cancers was approximately 55%. The cancer signal origin prediction was correct in more than 90% of true positive test results.

CCGA-3

CCGA-3, our third CCGA sub-study, was designed to further validate a version of the MCED test refined for use as a screening tool (Galleri) in a large cohort of participants with and without cancer. This pre-specified sub-study included 4,077 participants in an independent validation set (2,823 had cancer and 1,254 did not have cancer). Specificity, sensitivity, and cancer signal origin prediction accuracy were measured.

Results of the CCGA-3 sub-study were published in the *Annals of Oncology* in June of 2021, and confirmed that Galleri detects a shared cancer signal across more than 50 different types of cancer. Specificity for cancer signal detection was 99.5%. Stage I-III sensitivity for a pre-specified set of 12 deadly types of cancer, which together account for approximately 63% of cancer deaths in the United States annually, was approximately 68% and for all cancers was approximately 41%. The overall sensitivity for cancer signal detection was 52%. As expected, and as previously observed, sensitivity increased with stage (stage I: 16.8%, stage II: 40.4%, stage III: 77.0%, stage IV: 90.1%). The cancer signal origin prediction was correct in approximately 89% of true positive test results.

STRIVE

STRIVE is a prospective, observational, longitudinal cohort study in the United States that enrolled 99,481 women without a known cancer at the time of enrollment. Samples from a subset of women will be used to help further validate Galleri in an asymptomatic and intended use population. This study was initiated in February 2017 and completed enrollment in November 2018. Funding for the study is provided by us. Collaborators include, among others, the Cleveland Clinic, Henry Ford Health System, Mayo Clinic, and Sutter Health, and no serious adverse events have been identified. These collaborations are subject to terms generally consistent with industry sponsored studies. Each participant had a blood draw at the time of their regular screening mammogram. Participants diagnosed with any type of cancer had additional blood draws. Participants were followed for 30 months and thereafter, if they developed cancer, through state and national cancer registries. We collected demographic information, such as age, race, and ethnicity, in addition to clinical information, such as cancer diagnoses, treatment, cancer-specific mortality, and overall survival. We utilized 2,202 samples for validation of

an earlier version of Galleri and used 4,891 samples in a training set to support the version of Galleri we launched as an LDT. We have not used other samples to analyze or validate performance in an asymptomatic and intended use population to date, and thus we have not reported any interim findings or results from STRIVE. We plan to leverage the long-term follow up to help us understand how best to optimally use the remaining samples.

SUMMIT

SUMMIT is a prospective, observational, longitudinal cohort study that is being conducted in and around London, United Kingdom. Funding for the study is provided by us. Collaborators include University College London and University College London Hospitals, and no serious adverse events have been identified. These collaborations are subject to terms generally consistent with industry sponsored studies. The study is designed to further validate Galleri as an MCED test, including for lung and other smoking-related cancers, and to assess the feasibility of low-dose computed tomography ("LDCT") lung cancer screening in the United Kingdom. This study was initiated in April 2019 and completed enrollment in May 2023. The study enrolled 13,035 men and women between the ages of 50 and 77 who did not have a cancer diagnosis at the time of enrollment. Participants in the study are individuals at high risk for lung cancer due to significant smoking history based on validated risk scores. Participants provided three serial (annual) blood draws and are being followed annually for three years and then for a further five years through national health registries as well as medical records. The primary objective is to measure cancer incidence, which will be used to assess the test performance for sensitivity, specificity, PPV, and NPV.

Our SUMMIT study may also demonstrate the utility of MCED testing in a high-risk population by comparing performance of Galleri in detecting lung and other smoking-related cancers to that of LDCT. We expect to report interim results from the SUMMIT study in .

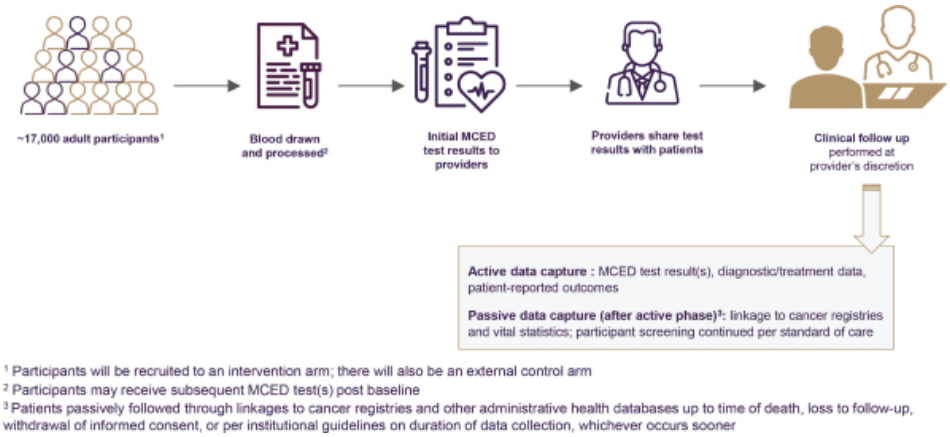
REFLECTION

REFLECTION is a multi-center, prospective, observational cohort study of patients administered Galleri as part of their medical care in a real-world setting in the United States that will enroll approximately 17,000 individuals. The purpose of the study is to evaluate and understand the real-world experience with Galleri in clinical settings. The objectives of the study are to describe cancer signal detection and cancer signal origin prediction within and across sites among participants who opt to receive Galleri in a real-world setting, to assess the feasibility and acceptability of Galleri from the perspective of participants and patient-reported outcomes, and to assess healthcare resource utilization associated with diagnostic workups for participants that receive a cancer signal detected result.

We began enrolling the REFLECTION study August 2021 and enrollment is ongoing at all sites. Funding for the study is provided by us. Collaborators include, or have previously included, Carolina Blood and Cancer Care Associates, Providence, U.S. Department of Veterans Affairs, and Vincere Cancer Center, and no serious adverse events have been identified. These collaborations are subject to terms generally consistent with industry sponsored studies.

We expect that data will be generated over time as enrollment increases across sites.

The design of our REFLECTION study is summarized in the figure below:



[1] Participants will be recruited to an intervention arm; there will also be an external control arm
[2] Participants may receive subsequent MCED test(s) post baseline
[3] Patients passively followed through linkages to cancer registries and other administrative health databases up to time of death, loss to follow-up, withdrawal of informed consent, or per institutional guidelines on duration of data collection, whichever occurs sooner

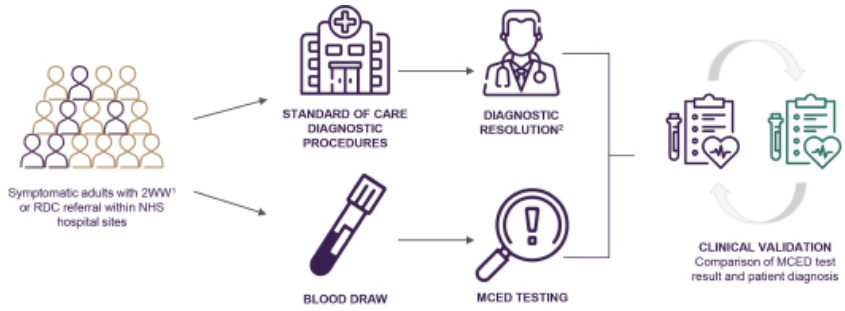
SYMPLIFY

SYMPLIFY evaluated the performance of MCED in symptomatic patients in the United Kingdom that were referred from the primary care setting due to clinical suspicion of cancer. This patient population represents a distinct patient population from Galleri's targeted asymptomatic screening population. This study was initiated in July 2021 and completed enrollment in November 2021. The SYMPLIFY study enrolled 6,238 participants aged 18 years and older in England and Wales. Funding for the study is provided by us. Collaborators includes Oxford University. This collaboration is subject to terms generally consistent with industry sponsored studies. Participants were referred for urgent imaging, endoscopy or other diagnostic modalities to investigate symptoms suspicious for possible gynecological, lung, lower GI or upper GI cancer, or who presented with non-specific symptoms. The most commonly reported symptoms leading to referral were unexpected weight loss (24.1%), change in bowel habit (22.0%), post-menopausal bleeding (16.0%), rectal bleeding (15.7%), abdominal pain (14.5%), pain (10.6%), difficulty swallowing (8.8%), and anemia (7.1%). In the study, the MCED test's cancer signal detected and cancer signal origin prediction results were compared with diagnoses results obtained through standard of care pathways. Data from the study demonstrated strong performance in this symptomatic population, and supported the feasibility of using an MCED test to assist clinicians with decisions regarding referrals from primary care. Data from the SYMPLIFY study were presented at ASCO in 2023 (in a podium presentation) and published in *The Lancet Oncology*, and we are using the results to support the development and launch of DAC.

In the study, 368 (6.7%) of the 5,461 evaluable patients were diagnosed with cancer through standard of care pathways. The most common cancer diagnoses were colorectal (37.2%), lung (22.0%), uterine (8.2%), oesophago-gastric (6.0%) and ovarian (3.8%). Our test detected a cancer signal in 323 participants, and cancer was diagnosed in 244 of these participants. The test demonstrated a PPV of approximately 75%, NPV of approximately 98%, sensitivity of approximately 66%, specificity of approximately 98%, and cancer signal origin prediction accuracy of approximately 90%. Among participants in the study, 6.7% of enrolled participants were eventually diagnosed with cancer, having already been referred by their primary care physician for investigation.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

The design of our SYMPLIFY study is summarized in the figure below:



Note: 2WW, two-week-wait; GI, gastrointestinal; MCED, multi-cancer early detection; NHS, National Health Service; RDC rapid diagnostic center; SOC, Standard of Care
[1] 2WW lung, 2WW upper GI, 2WW GI, 2WW gynecological
[2] Within 3 months of enrollment. Where investigations had not been completed, updated information was sought within 9 months of enrollment

REACH

In November 2023, we initiated the Real-World Evidence to Advance Multi-Cancer Early Detection Health Equity REACH) study following FDA approval of our IDE application and CMS approval for Medicare coverage of the study. While timelines are still under development, the study will enroll approximately 50,000 participants across several health systems, and is designed to generate large-scale real-world evidence of Galleri performance and outcomes in the diverse Medicare population, which we believe represents one of the highest populations of unmet need for early cancer detection. The study seeks to compare up to 50,000 Medicare beneficiaries who have received usual care plus an annual Galleri test with a matched comparator arm of beneficiaries who receive usual care only. The clinical impact measures of interest in the study include reduction in diagnosed stage IV cancers, safety, and healthcare resource utilization associated with diagnostic workup for suspected cancer within the interventional arm compared to usual care. Medicare will fund the costs of Galleri and related and routine items and services for study participants.

Commercialization

Established Commercial Leadership in a Pre-Reimbursement Setting

We launched Galleri in the United States in mid-2021. As of December 31, 2023, we have sold more than 150,000 commercial tests and established over 100 commercial partnerships, including leading healthcare systems, employers, payors, and life insurance providers. We have also established a network of over 9,000 prescribers in the pre-reimbursement setting, with prescribers in private practices across the United States. As of December 31, 2023, our commercial organization included 390 personnel supporting our multi-channel strategy. We believe we currently have the largest share of the market for MCED testing, and we continue to build the key components of our commercial infrastructure and capabilities that are required to support rapid, population-scale testing in a post-reimbursement environment.

Our Commercial Strategy in the United States is Focused on Innovative Value-oriented Partnerships

Our strong commercial adoption is underpinned by our ability to demonstrate clinical utility and economic value even before obtaining broad reimbursement coverage. We are driving adoption in the following key channels:

- **Health systems**. We have partnered with over 40 health systems as of December 31, 2023 that offer Galleri, typically as part of a comprehensive screening program with patient and physician support

services. We believe many of these health systems view Galleri as a key differentiating offering to patients. We have streamlined the implementation of Galleri for these partners, often connecting the health system's electronic medical record system with our software systems. This bolsters our position as the partner of choice for establishing early cancer detection programs. Many health systems are investing in robust programs in population health management and precision medicine, of which Galleri is a key feature, and have developed novel care navigation pathways. With these novel pathways, a positive test result can result in patients being referred within the health system. We believe our experience with these partners will allow us to rapidly scale upon broad reimbursement for Galleri.

- **Employers**. As of December 31, 2023, we have engaged over 80 employers who offer Galleri as a benefit to eligible employees. We target medium and large self-insured employers with compelling and innovative healthcare offerings that are designed to attract and retain employees and to deepen health equity among employees. Cancer treatment costs now represent the highest spend category for self-insured employers according to the most recent Business Group on Health's 2023 Large Employers' Health Care Strategy and Plan Design Survey. Galleri offers earlier cancer detection to help reduce these costs. Our employer customer base includes large tech companies, large life insurance companies, professional services companies, major health systems, and educational institutions, among others.
- **Life insurance providers**. We have partnered with several leading life insurance providers to provide Galleri to their policyholders. Life insurers are committed to helping customers live longer, healthier, better lives and understand that preventative care and early detection are key to that mission. Galleri is offered by these providers as a preventative health benefit and is not used for underwriting, risk assessment or risk pooling.
- **Physician-directed channels**. We believe Galleri is compelling to physicians whose patients are focused on preventive health and wellness as well as to concierge and executive health practices. The physician practices we are targeting are known to offer innovative, cutting-edge health offerings, and market research suggests the members are willing to invest in differentiated healthcare services. We are targeting physicians serving this market segment in all major metropolitan population centers in the United States with our field-based sales team. Concierge medicine has been a key early adopter of Galleri. As our strategy evolves in the physician-directed channel, we are working to educate physicians and patients on the benefits of annual screening.
- **Payors**. We have announced pilot or benefit programs with leading payors and continue to engage with other progressive payors. These programs allow for measurement of the clinical utility and economic value of Galleri. These payors include Medicare Advantage plans, which generally must cover all of the services that traditional Medicare covers, but they have the discretion to offer their enrollees additional or supplemental benefits. This also includes early-adopting commercial payors.
- **First Responders**. We have worked with clinics, fire departments, municipalities, and unions to make Galleri available to firefighters who generally have exposure-related increased risk of cancer and are actively screening their populations and seeking new approaches. To date, thousands of firefighters have been tested with Galleri across more than 40 fire departments nationally.

Reimbursement Landscape for Screening Tests

United States

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 Centers for Medicare and Medicaid Services ("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, an independent, volunteer panel of experts in the field of prevention, evidence-based medicine and primary care, and (c) appropriate for Medicare beneficiaries under Part A or Part B. CMS establishes coverage through a national coverage determination ("NCD") process. In its discretion, the USPSTF generally waits for FDA authorization before it considers undertaking reviews of novel technology.

Because MCED is not expressly authorized for coverage by the Medicare statute, one possible pathway for Medicare reimbursement is to first obtain FDA approval and then obtain a grade of A or B recommendation from USPSTF, to enable CMS to issue an NCD. The last cancer screening test to receive a recommendation from USPSTF with a grade A/B and obtain Medicare coverage was LDCT to screen high-risk smokers for lung cancer in 2015.

Medicare coverage can also be changed by statute, thus a second possible pathway for Medicare reimbursement would be to amend the Medicare statute to cover MCED. 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. Galleri is currently offered as an LDT in our CAP-accredited and CLIA-certified laboratories. We have a Breakthrough Device designation with the FDA and have begun the modular PMA submission process, which we expect to conclude with data from our ongoing pivotal studies. Under our Breakthrough Designation, interactions with the FDA have resulted in a clear timeline to submission, which we anticipate making in . Nonetheless, 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, 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. Following FDA approval and assuming a statutory change in the reimbursement landscape, we plan to pursue broad reimbursement, for example, through Medicare reimbursement, and subsequently pursue inclusion of Galleri in the USPSTF guideline recommendation.

United Kingdom—Commercial agreement with NHS

In November 2020, we established a partnership with NHS England. The NHS-Galleri Trial, which was undertaken as part of the partnership established by our commercial agreement with NHS England, is a large randomized controlled trial taking place across eight regions in England. The trial aims to assist with the United Kingdom's ambitions for early cancer detection and to assess Galleri for potential population screening on a national scale. The primary objective of the trial is to assess whether implementation of Galleri can reduce the incidence of late-stage cancers through early cancer detection.

Subject to results of an early analysis from the first screening test (the prevalent screening round) representing one year of results out of the three-year trial period, the NHS may commence phased commercial implementation in England, beginning with a two-year pilot, and with the potential for further expansion subject to final results from the trial. In the event that we proceed with phased commercial implementation following such results, our partnership with the NHS would be our first national system implementation. Given that the NHS has a reputation for high evidence standards for new technologies, we expect NHS approval and implementation would expand adoption in the United Kingdom and could also facilitate adoption in other single payor systems around the world. The Galleri test is UKCA marked.

Other International

We intend to explore the launch of Galleri in select other geographies, including through distributors.

Operations

Significant Investments for Scale

We have made significant investments for scale in our CAP-accredited and CLIA-certified laboratory facilities in Menlo Park, California and Durham, North Carolina and demonstrated execution with more than

390,000 clinical and commercial individual samples processed through December 31, 2023. We have an established footprint in the United States and United Kingdom, with operations in Durham, North Carolina, Washington, D.C., and London, United Kingdom.

In total we have approximately 65,000 square feet of CAP-accredited, CLIA-certified laboratory space and laboratory support with sufficient capacity to support multiple years of growth. We have made significant investments to our Durham laboratory to improve the automation, including development of a fully automated laboratory testing platform consisting of robotic work cells connected by a central track system to increase efficiencies and reduce costs. Our lab operates 16 hours a day, seven days a week, and uses automation and other technology to reduce staff exposure to complicated, dangerous, repetitive, or injury-prone work. We believe that our current facilities are sufficient to meet our current and anticipated near-term needs.

Supply Chain and Agreements

Our supply chain includes industry leading vendors and we maintain significant supplies on hand of both laboratory consumables and other materials to avoid work stoppages and material delays. We rely on a limited number of suppliers, or in some cases, sole suppliers, to provide certain materials for our products and services. For example, Illumina, Inc. is our primary supplier of sequencers and certain laboratory reagents, Madison (who acquired our blood collection tube manufacturer Streck, Inc. in 2023) is our sole supplier of tubes used for sample collection and Twist is the sole supplier of our DNA probes. We rely on standard commercial carriers for the delivery of samples to our laboratories.

Our supply strategy is to maintain raw material and released reagent supplies at levels that ensure our clinical laboratories can maintain continuous operations 365 days a year. We utilize a risk-based approach such that higher risk materials (e.g, sole-sourced or more vulnerable supply chains) have a higher safety stock and lower risk materials (e.g, multi-sourced) may have lower safety stock levels.

We have entered into supply agreements with various parties, including Illumina, Madison, and Twist. In January 2016, we entered into a supply and commercialization arrangement with Illumina, which agreement was amended and restated in February 2017 and subsequently further amended ("Supply Agreement"). Pursuant to the Supply Agreement, Illumina granted us non-exclusive rights to use certain Illumina know-how and technology with Illumina products purchased under the agreement. Under the terms of the Supply Agreement, regardless of whether our products incorporate any Illumina technology, we were obligated to pay 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. In August 2021, following Illumina's acquisition of us, the Supply Agreement was amended to suspend the perpetual royalty obligation to Illumina as long as we are an affiliate of Illumina or as long as any successor to us or any substantial part of our business is held by Illumina or an affiliate of Illumina. In connection with our separation from Illumina via the Spin-Off, we will no longer be an affiliate of Illumina, and the Supply Agreement will be further amended to extend the suspension of the perpetual royalty agreement until the earlier of two-and-a-half years or any earlier change of control of GRAIL, at which time royalty payments will resume, without retroactive effect. In addition, when the perpetual royalty obligation to Illumina restarts, we may elect to have either Illumina's universal pricing terms applicable to all of its for-profit oncology customers in the United States since March 2021, as updated (the "Open Offer") or the pricing terms we had prior to Illumina's acquisition of us (the "Grandfathered Pricing").

Industry Participants

There are other companies, such as Adela, Inc., DELFI Diagnostics, Inc., Exact Sciences Corporation, 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 are attempting to develop tests to detect certain types of cancer early, including some that will use cfDNA analyses. Some of these companies may have substantially greater financial and other resources than we have, such as larger research and development staff and well-established marketing and sales forces, or may operate in jurisdictions where lower standards of evidence are required to bring

products to market. For example, we are aware that some companies have conducted large-scale clinical studies for single-cancer early detection tests, including Guardant Health, Inc., Exact Sciences Corporation and Freenome Inc. in colon cancer, as well as AnchorDX in lung cancer (pulmonary nodules). In addition, other established diagnostic, medical technology, biotechnology, or pharmaceutical companies may decide in the future to invest to accelerate discovery and development of similar tests. If any tests are developed by these companies and do not perform to expectations or cause harm or injury to patients, it may result in lower confidence in early cancer detection tests in general, which could potentially adversely affect confidence in our products and services.

Given the numerous and rigorous requirements for a successful cancer detection test, we do not believe many companies would have the financial resources to invest in population-scale clinical studies and rigorous analytics to compete with our products. Further, among companies pursuing an early-detection product, we believe we are substantially differentiated by our robust intellectual property portfolio, extensive research, rigorous and objective approach, and multidisciplinary capabilities, which leverage the power of NGS, population-scale clinical studies, and advanced and trained machine learning algorithms and data science. We believe we are further differentiated by the extent of our investment in our facilities and operational workflows, including our high-capacity laboratories, which we built for rapid, automatic processing of samples and to scale as we grow and process more tests.

Additionally, certain of our other products in development, such as DAC, and our precision oncology offerings, could compete against a number of companies that are working to leverage blood-based technologies to improve cancer care. Many companies such as Roche / Foundation Medicine, Inc., Natera, Inc., Guardant, Inc., Tempus Labs, Inc., Invitae Corp., NeoGenomics Laboratories, Personalis, Inc., Twist Bioscience Corp. and Adaptive Biotechnologies Corp., among others, currently provide or are developing technologies focused on improving cancer care after a diagnosis of cancer is made, including enabling selection of therapy, monitoring of therapy, or detection of relapsed disease. Unlike with respect to MCED testing, precision oncology is a very competitive space with many industry participants. However, as DAC and our precision oncology portfolio leverage our methylation platform, we believe we are differentiated by the extent of the quality of our methylation platform and our investments to develop such platform through our population-scale clinical studies, rigorous analytics and machine learning expertise.

Intellectual Property

Our success depends in part on our ability to obtain and maintain intellectual property protection for our products and technology, including by seeking and maintaining patent protection, protecting our trade secrets and other proprietary information, obtaining and maintaining our licenses to use intellectual property owned by third parties, and continually evaluating third-party technologies for further licensing opportunities. We also seek trademark protection where appropriate to protect the names that identify us as the source of our products and services.

We own certain patents, patent applications, and other intellectual property, and also exclusively license certain patents, patent applications, and other intellectual property from third parties, including the Chinese University of Hong Kong. Our patent portfolio broadly relates to methods, techniques, systems, and chemistry used to generate and analyze data using our proprietary bioinformatics and classifiers, including, for example, cfNA sequencing, marker panels, methylation signatures, bioinformatics techniques and biologically directed machine learning classifiers, which are incorporated into or used for Galleri, our precision oncology portfolio, and DAC. We have also entered into certain supply and commercial agreements with various vendors and suppliers, including Illumina, under which we receive rights to their intellectual property for use in our products. Our material licenses and other agreements are described in more detail below.

As of January 23, 2024, we own or co-own more than 120 issued or granted patents and more than 580 pending patent applications globally, including 31 issued U.S. patents, 90 patents granted in Australia, Belgium, Canada, Switzerland, China, Denmark, Germany, Europe, France, the United Kingdom, Hong Kong, Indonesia, Ireland, Italy, Japan, Luxembourg, Malaysia, Netherlands, Norway, Sweden, Spain, Singapore, and Taiwan, and more than 120 pending U.S. non-provisional and provisional patent applications.

We also have exclusive licenses to more than 470 issued or granted patents and more than 210 pending patent applications globally, including 53 issued U.S. patents and 423 patents granted in Albania, Austria, Australia, Belgium, Bulgaria, Brazil, Canada, Switzerland, China, Cyprus, Czechia, Germany, Denmark, Eurasia, Europe, Estonia, Spain, Finland, France, the United Kingdom, Greece, Hong Kong, Croatia, Hungary, Indonesia, Ireland, Israel, India, Iceland, Italy, Japan, South Korea, Lithuania, Luxembourg, Latvia, Monaco, North Macedonia, Macao, Malta, Mexico, Malaysia, Netherlands, Norway, New Zealand, Poland, Portugal, Romania, Serbia, Sweden, Singapore, Slovenia, Slovakia, San Marino, Turkey, Taiwan, and South Africa, and more than 30 pending U.S. non-provisional and provisional patent applications. We believe these patents cover, and that these patent applications upon grant will cover, various aspects of Galleri, DAC, and our precision oncology portfolio.

Of particular importance within our sizable patent portfolio are patents that relate to various aspects of our current commercial products such as Galleri. For example:

- with respect to methylation analysis, which is a foundational technology underlying our current products, we own or exclusively license 79 granted patents directed to systems, software, methods, mixtures, or kits for methylation analysis in Australia, Belgium, Brazil, Canada, Switzerland, Germany, Denmark, Eurasia, Europe, Spain, France, the United Kingdom, Hong Kong, Indonesia, Ireland, Israel, Italy, Japan, Korea, Luxemburg, Mexico, Malaysia, Netherlands, Norway, New Zealand, Poland, Portugal, Sweden, Singapore, Turkey, Taiwan, the United States, and South Africa. These patents are expected to expire between 2033 and 2040, subject to our payment of applicable maintenance fees and annuities;
- with respect to our technology for determining cancer type through identification of cancer signal of origin, we own or exclusively license 17 granted patents directed to systems, software, methods, or kits for determining cancer signal of origin in Australia, China, Israel, Japan, Korea, Mexico, Malaysia, Singapore, Taiwan, and the United States. These patents are expected to expire between 2033 and 2041, subject to our payment of applicable maintenance fees and annuities; and
- with respect to our assay chemistry and techniques for preparing and optimizing patient samples for analysis, we own or exclusively license 32 granted patents directed to methods, assay panels, compositions, or software for assay chemistry and techniques in Belgium, Switzerland, China, Germany, Europe, France, the United Kingdom, Hong Kong, Netherlands, Sweden, and the United States. These patents are expected to expire between 2034 and 2042, subject to our payment of applicable maintenance fees and annuities.

Our patent portfolio also includes granted patents and pending patent applications directed to other technologies that may have varying levels of importance to our current and future products, including, for example:

- systems, methods, kits, mixtures, and probes for sequencing, library preparation and enrichment (20 patent families with 43 granted patents and 38 pending applications; granted patents expected to expire between 2027 and 2040);
- methods and nucleic acid constructs for error correction for identifying somatic variants (23 patent families with 83 granted patents and 72 pending applications; granted patents expected to expire between 2030 and 2034);
- systems and methods for variant based assessment of cancer (18 patent families with 30 granted patents and 56 pending applications; granted patents expected to expire between 2033 and 2038);
- systems, software, and methods for sequencing based assessment of copy number aberrations in cancer (13 patent families with 82 granted patents and 57 pending applications; granted patents expected to expire between 2028 and 2037);
- systems, software, and methods for fragment length assessment in cancer detection (25 patent families with 101 granted patents and 91 pending applications; granted patents expected to expire between 2031 and 2039);

- systems, software, methods, and compositions for fragmentation based assessment of cancer (15 patent families with 38 granted patents and 82 pending applications; granted patents expected to expire between 2030 and 2039); and
- systems, software, and methods for viral based assessment of cancer (10 patent families with 18 granted patents and 55 pending applications; granted patents expected to expire between 2038 and 2040).

The expiration dates described above may not account for all potentially available patent term adjustments and are subject to our payment of applicable issue fees, maintenance fees and annuities. Patent expiration dates are estimates based on our calculations, taking into account terminal disclaimers and patent term adjustments.

Our in-licensed patents and patent applications, if issued as patents, expire or would be expected to expire, at the earliest, in 2027, absent any potentially available patent term adjustment and assuming our timely payment of applicable issue fees, maintenance fees and annuities. Our owned or co-owned patents and patent applications, if issued as patents, expire or would be expected to expire, at the earliest, in 2037, absent any potentially available patent term adjustment and assuming our timely payment of applicable issue fees, maintenance fees and annuities. The term of these patents depends upon the laws of the countries in which they are obtained, and in most countries in which we file, is 20 years from the earliest date of filing of a non-provisional patent application. A provisional patent application 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 provisional patent application. If we do not timely file non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. In the United States, patent term adjustments may be available depending upon the time the United States Patent and Trademark Office takes to examine and eventually issue a patent, and the patent term may be shorter than 20 years if we disclaim a portion of the patent term to overcome double patenting rejections. The protection of patents may vary on a country-by-country and claim-by-claim basis, which can vary the scope of protection afforded by such patents. In addition, we must generally pay fees to maintain our patents annually or at other specified intervals, or risk the patent lapsing. We cannot provide any assurance that any of our current or future owned or licensed patent applications will result in the issuance of patents in any jurisdiction, or that any of our current or future owned or licensed issued patents will effectively protect any of our products or technology or prevent others from commercializing competitive products or technology. Even if any of our current or future owned or licensed patent applications are granted as issued patents, those patents may be challenged, circumvented or invalidated by third parties.

We recently faced an opposition from anonymous challengers against one of our in-licensed European patents. The patent does not relate to aspects of Galleri, DAC or our precision oncology portfolio. The challengers asserted that this granted patent was invalid over prior art, among other arguments. The opposition concluded with the patent claims being maintained in amended form. The challengers have filed an appeal. While we believe that this patent is valid, there is a risk that the patent could be invalidated in its entirety, or certain claims of this patent could be amended and narrowed in scope during the appeal.

License Agreements with the Chinese University of Hong Kong

We have entered into five license agreements with the Chinese University of Hong Kong, each on substantially similar terms and with two dated April 7, 2016 and three dated May 29, 2017. Pursuant to these agreements, the Chinese University of Hong Kong has granted exclusive, worldwide intellectual property licenses to us for the use of certain nucleic acid sequencing and analysis technologies in all fields under one license and in all fields except prenatal diagnostics, prognostications, or analysis under four licenses. The Chinese University of Hong Kong reserves the right to use its technology for internal research and education purposes and for fulfilling governmental contractual obligations (to the extent they exist). Three of the licenses are subject to certain non-exclusive license rights granted by the Chinese University of Hong Kong to a certain third party, solely for such third party's internal research purposes in the field of cancer detection, cancer prognostication and other analysis for the screening and management of cancer.

To the extent our products use the licensed technology, such as our current Galleri, precision oncology and DAC products, we are required to pay the Chinese University of Hong Kong low single-digit percentage royalties on net sales of such products, subject to minimum annual guarantees, which began in 2018. In addition, for any sublicense of the licensed technology, we are obligated to pay the Chinese University of Hong Kong a specified portion of the revenue we receive from sublicensing. Our royalty and sublicense 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. We are additionally obligated to reimburse the Chinese University of Hong Kong for costs and expenses related to the filing, prosecution, maintenance, and defense of the licensed patents and patent applications.

Under these license agreements, we are obligated to use specified efforts to reach milestones relating to the development and sale of products that use the Chinese University of Hong Kong's technology, and our failure to do so could result in termination of the license agreements. The Chinese University of Hong Kong may also terminate the agreements under certain other circumstances, such as our uncured material breach of the agreements or cessation of our business. We may terminate the agreements at any time at our convenience, provided we give the Chinese University of Hong Kong a certain period of notice. We can also terminate the agreements for the Chinese University of Hong Kong's uncured material breach.

Trade Secrets

We also rely on trade secret protection for our confidential and proprietary information. Included in our trade secrets are the data from our genomics studies, various aspects of the operation of our laboratories, and various aspects of the algorithms used to process our data. Trade secrets are difficult to protect. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees, contractors, and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology via unauthorized means, such as hacking by private or state actors. Although state and federal courts in the United States are generally willing to protect trade secrets, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

For further discussion of the risks relating to our intellectual property, see "Risk Factors—Risks Relating to Intellectual Property."

Properties

Our principal office and laboratory is approximately 74,300 square feet and located at 1525 O'Brien Drive, Menlo Park, California. We amended the related lease in June 2017 to add approximately 57,400 square feet at 1605 Adams Drive, Menlo Park, California. Our lease expires in 2026 and we have an option to extend the lease for an additional five years.

In June 2020, we entered into an agreement to lease approximately 200,000 square feet of a building in Durham, North Carolina. Our lease expires in 2033 and we have three separate options to extend the lease, each for an additional five years.

We hold CLIA Certificates of Accreditation Registration from the CMS and accreditations from CAP for our laboratories in Menlo Park, California, and Durham, North Carolina, and a Clinical Laboratory Certificate of Deemed Status from the State of California Department of Public Health. Our Menlo Park, California laboratory also holds a Clinical and Public Health Laboratory License from the California Department of Public Health.

We believe that our facilities are sufficient to meet our current and anticipated near-term needs.

Employees and Human Capital

As of December 31, 2023, we had approximately 1,340 full-time employees, the majority of which are based in the United States. We also engage with contractors, vendors, and consultants. We have invested substantial time and resources into building our team. Our success depends in large part on our collective effort

across our areas of expertise and across sites in Menlo Park, California, Durham, North Carolina, Washington, D.C., and London, United Kingdom. Therefore, it is crucial that we continue to attract and retain high-performing employees from all demographics by providing competitive compensation and benefits, and fostering a diverse, inclusive, and safe workplace, while making opportunities for all employees to grow and develop in their careers. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Since our founding, we have built an entrepreneurial culture, driven to improve outcomes for cancer patients. We are led by a multidisciplinary team with extensive experience across biotechnology, life sciences, public health, genomics, computer science, data science, biostatistics, clinical development, medical affairs, government and regulatory affairs, quality assurance, and laboratory and commercial operations. We believe this confluence of talent from multiple disciplines has enabled us to make significant progress in improving cancer care and will enable us to remain at the forefront of our industry.

Fostering a Culture of Inclusivity and Belonging

We are an innovation-driven company where diversity, inclusion, and equity are critical drivers to our success. We embrace talent from all backgrounds, seek out diverse perspectives, and facilitate and invite open and authentic conversations. Our diverse employee pool includes expertise across the specialties that drive our business. As of December 31, 2023, our workforce was 49% racially/ethnically diverse and 55% female.

We are investing in culture and creating opportunities to build community for our employees. We currently have six employee resource groups ("ERGs"), which are sponsored by members of our executive and senior leadership teams. ERGs are employee-led groups that can help create a more inclusive culture and amplify the voices of employees with shared identities and experiences across the company. We have invested in resources to educate our employees on building an inclusive culture and on recognizing and managing bias. We also regularly survey employees on how effective our leadership has been in creating an equitable and inclusive workplace to discover new opportunities to build an inclusive community.

We believe that our company culture helps us to achieve our mission and is a core driver of our success.

- *Embrace Change*—We operate in a dynamic environment. We need to mirror the external world and be agile, adaptive, and able to adjust course to move in the direction required.
- *Solve Problems Together*—Working together allows us to take on increasingly complex problems.
- *Think BIG*—We are leading BIG changes that require a long runway, and we'll succeed by keeping our mission in sight as we work toward long-term goals.
- *Be Courageous*—We are going up against entrenched ways of thinking, which requires boldness, determination, and courage.
- *Bring an Open Mind*—We seek to improve cancer care, which requires engaging everyone in a conversation around what's needed, what's possible, and how to approach problems in different ways with creative thinking. We're open-minded, curious, and always learning.

Each value has defined behaviors that link to our leadership attributes and our programming to keep our values as the cornerstone for how we show up with one another and support our customers. These values are embedded in our recruiting and hiring practices and performance management. We believe that our focus on our values helps support a culture of inclusivity and belonging. We operate from a place of openness, taking initiative to drive our shared success, while seeking input in order to grow ourselves and our customers.

Compensating and Supporting Our Colleagues

We are committed to providing equitable compensation opportunities to attract and retain accountable, team-oriented, high-performing colleagues with the purpose of driving our mission. We consider external market data as well as internal parity considerations when making compensation decisions using data-informed actions to build desirable programs. To incentivize top performance, we aim to differentiate pay increases and incentive programs in recognition of colleague contributions aligned to the success of the business.

We take a holistic approach to supporting employee well-being through providing eligible colleagues and their eligible dependents with competitive health and wellness benefits, retirement savings plans, and work-life options designed to provide flexibility to thrive. We also provide flexible time off and other opportunities to enable balance. We are also devoted to investing in the development of our colleagues through learning and development opportunities to help them achieve their personal and professional goals.

Government Regulations

We are subject to complex and frequently changing national, state, and local laws and regulations that govern various aspects of our business. In many jurisdictions, including the United States, the clinical laboratory and medical device industries must operate in accordance with extensive and complex legal standards, including laws and regulations related to certification, licensing, development, research, testing, manufacturing, laboratory operations, distribution, ordering and billing practices, advertising, promotion, marketing, sales and pricing practices, anti-markup practices, health information privacy and security, and consumer protection and unfair trade practices.

In the United States, the laws and regulations governing the marketing of diagnostic products are evolving, extremely complex, and in some instances, there are no significant regulatory or judicial interpretations of these laws and regulations. Clinical laboratory tests are regulated under CLIA, as well as by applicable state laws. In addition, the Federal Food, Drug and Cosmetic Act ("FDC Act") defines a medical device to include any instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including a component part or accessory intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals. The tests we are developing and marketing are considered by the FDA to be subject to regulation as medical devices. Among other things, pursuant to the FDC Act and its implementing regulations, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion, and sales and distribution of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. The FDA has statutory authority to assure that medical devices are safe and effective for their intended uses, but the FDA has historically exercised its enforcement discretion and not enforced certain applicable provisions of the FDC Act and regulations with respect to LDTs. However, the FDA recently issued a proposed rule to phase out its enforcement discretion with respect to LDTs, which, if finalized, would make LDTs subject to the FDA's medical device authority.

U.S. Regulation

Clinical Laboratory Improvement Amendments of 1988 (CLIA)

We are required to obtain and hold certain federal and state licenses, certificates, permits and accreditations to offer our products in the United States through our laboratory facilities in Menlo Park, California, and Durham, North Carolina. In 1988, Congress passed CLIA, establishing rigorous quality standards for laboratories in the United States that perform testing on human specimens 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. Such testing may also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.

CLIA requires such laboratories to be certified by the federal government and mandates compliance with ongoing requirements intended to ensure the accuracy, reliability, and timeliness of medical test results. CLIA certification is also a prerequisite to be eligible to bill federal and state healthcare programs, as well as many commercial third-party payors, for laboratory testing services. We hold CLIA Certificates of Accreditation from the CMS and accreditations from CAP for our Menlo Park, California and Durham, North Carolina laboratories, and a Clinical Laboratory Certificate of Deemed Status from the State of California Department of Public Health. Our Menlo Park, California laboratory also holds a Clinical and Public Health Laboratory License from the California Department of Public Health. In order to obtain a CLIA certification, a laboratory must validate the test (ensure and document that the test provides accurate and reliable test results) and add the applicable specialty or subspecialty to the test menu. Before introducing and reporting patient results from an LDT, a laboratory is required to establish the specifications for a variety of performance characteristics, including accuracy, precision, analytical sensitivity, analytical specificity, reportable range, and reference interval. Such analytical validation is based on, among other things, the specific conditions, staff, and equipment of the particular laboratory.

Prior to offering a new test at our laboratories, we must also satisfy certain notification requirements to change our testing menu, such as notifications to regulatory and accrediting bodies, CMS, the California Department of Public Health Laboratory Field Services, and CAP. At their discretion, any of these entities may inspect our clinical laboratory at any time. In connection with a CLIA certification, laboratories are subject to routine survey and inspection every other year, as well as additional random or "for cause" inspections. Under CLIA, a survey is generally conducted every two years by CMS, a CMS agent (typically a state agency), or, if the laboratory holds a CLIA Certificate of Accreditation, a CMS-approved accreditation organization (for example, CAP). The routine biennial survey includes review of the laboratory's analytical validation of any LDTs performed by the laboratory.

Penalties for non-compliance with CLIA requirements include a range of enforcement actions, including suspension, limitation or revocation of the laboratory's CLIA certificate, as well as directed plan of correction, state on-site monitoring, civil monetary penalties, civil injunctive suit or criminal penalties.

CLIA provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and a number of states have implemented their own more stringent laboratory regulatory requirements. State laws may require that laboratory personnel meet certain qualifications and obtain licenses, specify certain quality control procedures and facility requirements, or prescribe record maintenance requirements. For more information on state licensing and other requirements, see "—State Licensing Laws."

State Licensing Laws

In addition to the federal certification requirement for laboratories under CLIA, many states require licensure for laboratories under state law. For example, both California and North Carolina require laboratories to maintain in-state licenses to conduct testing in the state. In addition to in-state licensing requirements, certain states require licensing of out-of-state laboratories when specimens are collected or received from patients in such states. The state laboratory licensure requirements establish standards for the day-to-day operation of a clinical laboratory, including the training and qualifications required of personnel, quality control, and proficiency testing. Moreover, certain states, such as New York, require state approval of certain tests, including certain tests that have not been cleared or approved by the FDA (such as LDTs), through a premarket submission containing, among other information, documentation relating to device analytical and clinical performance data. The New York Department of Health also mandates proficiency testing for laboratories granted a permit under New York State law, regardless of whether or not such laboratories are located in New York. Clinical laboratory licensing laws in certain states, however, do not apply to laboratories operated for research purposes that do not return patient-specific results for the purpose of diagnosis or treatment.

Non-compliance with state laboratory licensure requirements may cause the state agency to suspend, restrict, or revoke a license to operate the clinical laboratory, disapprove a licensure application, assess

substantial civil money penalties, require onsite monitoring or impose specific corrective action plans. Certain statutory or regulatory noncompliance may also result in misdemeanor charges under state law. CLIA does not preempt state laws that have established laboratory quality standards that are at least as stringent as the federal law requirements under CLIA.

In addition to laboratory licensing, certain states, including California, impose registration and/or licensing requirements on companies that manufacture medical devices. These laws can apply to a manufacturer before its products are commercialized, including when a company is evaluating its product candidates in clinical trials. 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.

U.S. Food and Drug Administration

In the United States, laboratory tests, such as Galleri and DAC, are subject to regulation by the FDA under the FDC Act and its implementing regulations, and other federal and state statutes and regulations. The laws and regulations govern, among other things, medical device development, testing, manufacture, labeling, storage, premarket clearance or approval, advertising and promotion, export, import, and product sales and distribution.

Laboratory Developed Tests

Under the FDA's regulatory framework, *in vitro* diagnostic devices ("IVDs"), such as Galleri and DAC, are a type of medical device, including tests that can be used in the diagnosis or detection of diseases, such as cancer, or other conditions. The FDA considers LDTs to be a subset of IVDs that are intended for clinical use and are designed, manufactured, and used within a single laboratory. Although the FDA has statutory authority to assure that medical devices, including IVDs, are safe and effective for their intended uses, the FDA has historically exercised its enforcement discretion and not enforced certain applicable provisions of the FDC Act and regulations with respect to LDTs, with certain exceptions such as in the case of tests for public health emergencies or where the tests are offered directly to the consumer. Even under its current enforcement discretion policy, the FDA has issued warning letters to and safety communications about *in vitro* diagnostic 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 that, if finalized, would 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. 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 establish 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. 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. Pending the FDA's issuance of the final rule or Congress's enactment of legislation governing LDTs, LDTs remain subject to the FDA's existing policy of enforcement discretion.

PMA Pathway

The FDA categorizes medical devices into one of three classes—class I, II, or III—based on the risks presented by the device and the regulatory controls necessary to provide a reasonable assurance of the device's safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation ("QSR") facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Special controls are established by the FDA for a specific device type and often include specific labeling provisions, performance metrics, and other types of controls that mitigate risks of the device (usually incorrect results for an IVD). Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. Some pre-amendment devices are unclassified, but are subject to the FDA's premarket notification and clearance process in order to be commercially distributed.

Class III devices generally require PMA approval before they can be marketed. Obtaining PMA approval requires the submission of "valid scientific evidence" to the FDA to support a finding of a reasonable assurance of the safety and effectiveness of the device. A PMA must provide complete analytical and clinical performance data and also information about the device and its components regarding, among other things, device design, manufacturing, and labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDC Act to complete its review of a PMA, although in practice, the FDA's review often takes significantly longer, and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. As part of the FDA's review of a PMA, the FDA will typically inspect the manufacturer's facilities for compliance with QSR requirements, which impose requirements related to design controls, manufacturing controls, documentation, and other quality assurance procedures. The user fee costs and the length of the FDA review time for obtaining PMA approval are significantly higher than for a 510(k) notification or a *de novo* classification.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new

PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

510(k) Notification Pathway. To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating to the FDA's satisfaction that the proposed device is "substantially equivalent" to another legally marketed device that itself does not require PMA approval (a predicate device). A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to 12 months, but often takes longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, the FDA collects user fees for certain medical device submissions and annual fees for medical device establishments.

If the FDA agrees that the device is substantially equivalent to a lawfully marketed predicate device, it will grant 510(k) clearance to authorize the device for commercialization. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the *de novo* process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device. Once a *de novo* petition is reviewed and approved, it results in the device having a Class II status, and future devices from the company or a third party may use the company *de novo*-classified device as a 510(k) predicate.

After a device receives 510(k) clearance or *de novo* classification, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval or new *de novo* classification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Modifications that do not rise to the level of requiring a new 510(k) are accomplished through a "letter to file" in which the company documents the rationale for the change and why a new 510(k) is not required. However, if the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until new marketing authorization for the change is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in September 2023, the FDA issued three draft guidance documents to strengthen and modernize the 510(k) program, and the FDA noted that in light of increasing technical complexity, clinical data are increasingly being required to support substantial equivalence determinations.

De Novo Classification Pathway. If no legally marketed predicate can be identified for a new device to enable use of the 510(k) pathway, the device is automatically classified under the FDC Act into class III, which generally requires PMA approval. However, the FDA can reclassify or use "*de novo* classification" for a device that meets the FDC Act standards for a class I or class II device, permitting the device to be marketed without PMA approval. To grant such a reclassification, the FDA must determine that the FDC Act's general controls alone, or general controls and special controls together, are sufficient to provide a reasonable assurance of the device's safety and effectiveness. The *de novo* classification route is generally less burdensome than the PMA approval process.

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Investigational Device Exemption Process. Clinical trials are almost always required to support a PMA and are sometimes required to support a 510(k) submission. All clinical investigations of investigational devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption ("IDE") regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting, and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety, or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board ("IRB") for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping, and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Expedited Development and Review Programs. The FDA has established programs to support and expedite the development of devices that meet criteria for Breakthrough Device designation, which can be voluntarily requested by sponsors. The program offers manufacturers of certain devices an opportunity to interact with the FDA more frequently and efficiently as they develop their products with the goal of expediting commercialization of such products to help patients have more timely access, as well as use of post-market data collection, when scientifically appropriate, to facilitate expedited and efficient development and review of the device, opportunities for efficient and flexible clinical study design, and priority review of premarket submissions. The program is available to medical devices that meet certain eligibility criteria, including that the device provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, and constitutes a device (i) that represents a breakthrough technology, (ii) for which no approved or

cleared alternatives exist, (iii) that offer significant advantages over existing approved or cleared alternatives, or (iv) the availability of which is in the best interest of patients.

Postmarket Regulation. After a device is cleared or approved by the FDA for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of "off-label" uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDC Act that may present a risk to health;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Device manufacturing processes subject to FDA oversight are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation, and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. Manufacturers are subject to periodic scheduled or unscheduled inspections by the FDA. A failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and the recall or seizure of products. The discovery of previously unknown problems with products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

FDA Enforcement Powers. The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a manufacturer has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, including the following:

- issuance of warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- requesting or requiring recalls, withdrawals, or administrative detention or seizure of our products;
- imposing operating restrictions or partial suspension or total shutdown of production;

- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approvals for our products; or
- criminal prosecution.

Federal and State Physician Self-Referral Prohibitions

We are subject to the federal physician self-referral prohibitions, commonly known as the Stark Law. The Stark Law generally prohibits us from billing, presenting, or causing to be presented a claim for any clinical laboratory services or other designated health services payable by the Medicare or Medicaid programs when the physician ordering the service, or any member of such physician's immediate family, has an ownership interest in, or compensation arrangement with, us, unless the arrangement meets an exception to the prohibition. The Stark Law contains several exceptions, including an exception for compensation paid to a physician for personal services rendered by the physician provided that several conditions are met, including that the payment is set at fair market value for the services furnished and the terms of the arrangement be set out in writing and signed by the parties. These prohibitions apply regardless of the reasons for the financial relationship and the referral. The Stark Law is a strict liability statute, and thus no finding of intent is required for a violation.

Sanctions for a violation of the Stark Law include the following:

- denial of payment for the services provided in violation of the prohibition;
- refunds of amounts collected by an entity in violation of the Stark Law;
- monetary penalties; and
- exclusion from federal healthcare programs, including Medicare and Medicaid.

In addition, violations of the Stark Law may also serve as the basis for liability under the Federal False Claims Act, which prohibits knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to the federal government.

Many states, including California, also have laws restricting physicians from referring persons for certain services to entities in which the referring physician has a financial interest, which may apply regardless of whether the payor for such claims is Medicare or Medicaid. For example, we are subject to the California Physician Ownership and Referral Act of 1993 ("PORA"). PORA, which applies regardless of payor type, generally prohibits physicians from referring individuals for certain services, including laboratory or diagnostic services, if the physician or his or her immediate family has a financial interest in the entity receiving the referral. PORA would generally prohibit us from billing an individual or any governmental or private payor for any laboratory or diagnostic services when the physician ordering the service, or any member of such physician's immediate family, has an investment interest in, or compensation arrangement with, us, unless the arrangement falls under one of the statutory exceptions. Further, certain violations of PORA are a misdemeanor, and violations generally could result in civil penalties, criminal fines, and disciplinary action by the applicable governmental agency. Finally, other states have self-referral restrictions with which we have to comply, which may differ from those imposed by federal and California law.

Healthcare Fraud and Abuse

If and when we commercially launch a product in the United States, our business operations, including any relationship we may form with physicians, healthcare providers or other potential customers or business partners, will need to comply with various healthcare fraud and abuse laws.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

The federal healthcare program Anti-Kickback Statute makes it a felony for a person or entity, including a laboratory, to knowingly and willfully offer, pay, solicit, or receive remuneration, directly or indirectly, in order to induce business that is reimbursable under any federal healthcare program, including 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. The Anti-Kickback Statute contains certain statutory exceptions and regulatory safe harbors that protect certain interactions if specific requirements are met. If an arrangement meets the provisions of a safe harbor, it is deemed not to violate the Anti-Kickback Statute. An arrangement must fully comply with each element of an applicable safe harbor in order to qualify for protection. The failure of a transaction or arrangement to fit within a specific safe harbor, however, does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued if the arrangement is determined by the government not to be abusive. A violation of the Anti-Kickback Statute may result in imprisonment, fines and possible exclusion from Medicare, Medicaid, and other federal healthcare programs. Actions that violate the Anti-Kickback Statute or any similar laws may also incur liability under the Federal False Claims Act.

Although the Anti-Kickback Statute applies only to federal healthcare programs, a number of states have passed statutes substantially similar to the Anti-Kickback Statute. For example, California has enacted the PORA (see "—Federal and State Physician Self-Referral Prohibitions" above) and a Medi-Cal Anti-Kickback Statute, Welfare and Institutions Code Section 14107.2, that prohibit conduct similar to that prohibited by the Anti-Kickback Statute. Violations of PORA and Section 14107.2 are both punishable by imprisonment and fines. Many other states have all-payor statutes that extend the provisions of the state anti-kickback statute to not only governmental payors, but also private payors and self-pay patients.

Federal and state law enforcement authorities scrutinize arrangements between healthcare providers and potential referral sources to ensure that the arrangements are not designed as a mechanism to induce healthcare referrals or induce the purchase, prescribing or ordering of particular products or services. Law enforcement authorities and the courts have also demonstrated a willingness to look behind the formalities of a transaction to determine the underlying purpose of any remuneration exchanged between healthcare providers and actual or potential referral sources. Generally, courts have taken a broad interpretation of the scope of the Anti-Kickback Statute, holding that the statute may be violated if merely one purpose of a payment arrangement is to induce referrals or purchases. Investigation or challenge under the federal Anti-Kickback Statute and analogous state laws of any relationship we may form with physicians, healthcare providers or other potential customers or business partners could lead to sanctions that could have a negative effect on our business.

In addition, other healthcare fraud and abuse laws could have an effect on our business. For example, 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.

The federal Civil Monetary Penalties law prohibits, among other things, offering or transferring remuneration to a federal healthcare program beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by a federal healthcare program from a particular provider or supplier. Penalties for violating the Civil Monetary Penalties law may include exclusion from federal healthcare programs and substantial fines.

The Federal False Claims Act prohibits a person from knowingly submitting (or causing to be submitted) a claim, making a false record or statement in order to secure payment, or retaining an overpayment by the federal government. Moreover, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party known as the "relator" who has knowledge of the

alleged fraud. These types of actions are also known as qui tam or "whistleblower" lawsuits. Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government is ultimately successful in obtaining redress in the matter or if the plaintiff succeeds in obtaining redress without the government's involvement, then the plaintiff will receive a percentage of the recovery. It is not uncommon for qui tam lawsuits to be filed by employees, third parties or consultants of healthcare providers, including clinical laboratories. Several states have also enacted similar false claims laws.

Further, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created two federal crimes: healthcare fraud and false statements relating to healthcare matters, in addition to the privacy and security regulations described below under "—Privacy Regulation." The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from government-sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact, or making any materially false, fictitious, or fraudulent statement in connection with the delivery of, or payment for, healthcare benefits, items, or services. Similar to the U.S. federal Anti-Kickback Statute, 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. A violation of this statute is a felony and may result in fines or imprisonment.

Similar foreign laws and regulations may apply to us if we offer our products in foreign jurisdictions in the future.

While we intend fully to comply with applicable federal and state fraud and abuse laws, and similar laws of other states and countries as we commercialize products, it is possible that some of our arrangements or arrangements we may enter into in the future could become subject to regulatory scrutiny, and we cannot provide assurance that we will be found to be in compliance with these laws following any such regulatory review.

Transparency Laws

The Sunshine Act was enacted by Congress in 2010 as part of the Affordable Care Act ("ACA") and was amended in 2018 by the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. The Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS certain data on payments and other transfers of value made to U.S.-licensed physicians (as defined by statute), teaching hospitals, and certain non-physician practitioners, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse-midwives. The data are sent to CMS for public disclosure on the Open Payments.

Additional International Regulation and Product Approval

We may have to obtain or submit approvals, markings, notifications, certifications or satisfy other premarket requirements from regulatory authorities in non-U.S. jurisdictions prior to marketing our products in those countries and territories. The laws and regulations in other jurisdictions vary from those in the United States and may be easier or more difficult to satisfy, and they are subject to change, in some cases frequently. Certain regulatory authorities regulate LDTs and IVDs differently than the United States, and our products may need to satisfy additional requirements to be offered commercially within the jurisdictions.

Foreign Regulation

Medical devices (including IVDs) are subject to extensive regulation, such as premarket review, marketing authorization or certification, by similar agencies or notified bodies in other countries. Regulatory requirements

and approval or certification processes are not harmonized and vary from one country to another. International regulators and notified bodies are independent and not bound by the findings of the FDA.

Regulation of In Vitro Diagnostic Medical Devices in the European Union

We are or may become subject to new laws, regulations, and industry standards concerning medical devices proposed and enacted in various foreign jurisdictions, including the European Union ("EU"). The EU has adopted specific directives and regulations regulating the design, manufacture, clinical investigation, conformity assessment, labeling, and adverse event reporting for IVDs. Until May 25, 2022, IVDs were regulated by Directive 98/79/EC ("EU IVDD"), which has been repealed and replaced by Regulation (EU) No 2017/746 ("EU IVDR"). The EU IVDR became effective on May 26, 2022. However, to prevent disruption in the supply of IVDs on the EU market, a regulation adopted by the European Parliament and the Council on December 15, 2021 enacted a "progressive" roll-out of the EU IVDR and provided for a tiered grace period for most devices depending on the risk classification of the device. Galleri currently benefits from the grace period applicable to Class C IVDs, and therefore must only be fully compliant with the EU IVDR requirements by May 26, 2026. Galleri has been assessed in accordance with the EU IVDD whose regime is described below. However, as of May 26, 2022 and regardless of the tiered grace period, some of the EU IVDR requirements apply in place of the corresponding requirements of the EU IVDD with regard to registration of economic operators and of devices, post-market surveillance and vigilance requirements. Pursuing marketing of IVDs in the EU will notably require that our devices be certified under the new regime set forth in the EU IVDR when our current certificates expire.

In Vitro Diagnostic Medical Devices Directive

Under the EU IVDD, an IVD may be placed on the market only if it conforms the essential requirements set out in the EU IVDD including the requirement that an IVD must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter as it creates a rebuttable presumption that the device satisfies that essential requirement.

As a general rule, demonstration of conformity of IVDs and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence.

In Vitro Diagnostic Medical Devices Regulation

The regulatory landscape related to IVDs in the EU recently evolved. On April 5, 2017, the EU IVDR was adopted with the aim of ensuring better protection of public health and patient safety. The EU IVDR establishes a uniform, transparent, predictable and sustainable regulatory framework across the EU for IVDs and ensures a high level of safety and health while supporting innovation. Unlike the EU IVDD, the EU IVDR is directly applicable in EU member states without the need for member states to implement it into national law. This aims at increasing harmonization across the EU.

The EU IVDR became effective on May 26, 2022. IVDs lawfully placed on the market pursuant to the EU IVDD prior to May 26, 2022 may generally continue to be made available on the market or put into service, provided that the requirements of the transitional provisions are fulfilled. However, even in this case,

manufacturers must comply with a number of new or reinforced requirements set forth in the EU IVDR, in particular the obligations described below.

All manufacturers placing medical devices into the market in the EU must comply with the EU medical device vigilance system. Under this system, serious incidents and Field Safety Corrective Actions ("FSCAs") must be reported to the relevant authorities of the EU member states. Manufacturers are required to take FSCAs defined as any corrective action for technical or medical reasons to prevent or reduce a risk of a serious incident associated with the use of a medical device that is made available on the market. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device.

The aforementioned EU rules are generally applicable in the European Economic Area ("EEA"), which consists of the 27 EU member states plus Norway, Liechtenstein, and Iceland.

Regulations Related to Clinical Laboratories in the European Union

The EU does not have an overarching law or regulation that governs the legal framework surrounding the operations of clinical laboratories in a way that would be analogous to CLIA in the United States. However, EU member states' laws may affect how our business as a diagnostic testing service provider is carried out.

Other laws and guidelines that impact clinical laboratories' work include the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, the Declaration of Helsinki adopted by the World Medical Association and related codes of conduct and guidelines issued by the relevant research ethics committees.

The aforementioned EU rules are generally applicable in the EEA.

Regulation of In Vitro Diagnostic Medical Devices in the United Kingdom

Following Brexit, EU laws no longer apply directly in Great Britain. The regulations on IVDs in Great Britain continue to be based largely on the EU IVDD, which preceded the EU IVDR, as implemented into national law by the Medical Devices Regulation 2002 ("UK MDR"). However, under the terms of the Protocol on Ireland/Northern Ireland, the EU IVDR does apply to Northern Ireland. Consequently, there are currently different regulations in place in Great Britain as compared to both Northern Ireland and the EU, respectively. The United Kingdom government has passed a new Medicines and Medical Devices Act 2021, which introduces delegated powers in favor of the Secretary of State or an "appropriate authority" to amend or supplement existing regulations in the area of medicinal products and medical devices. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices.

Under the powers granted by the Medicines and Medical Devices Act 2021, the United Kingdom is currently drafting amendments to the UK 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 United Kingdom-approved body in order to be lawfully placed on the market. The United Kingdom has stated that the core elements of the future regime are expected to apply from July 1, 2025, but that IVDs in compliance with either the EU IVDD or IVDR can continue to be placed on the Great Britain market until the sooner of certificate expiration or June 30, 2030. Following these transitional periods, it is expected that all IVDs will require a United Kingdom Conformity Assessment ("UKCA") mark. Manufacturers may choose to use the UKCA mark on a voluntary basis prior to the regulations coming into force. However, from July 2025, it is expected that products which do not have existing and valid CE certification will be required to carry the UKCA mark if they are to be sold into the market in Great Britain. UKCA marking will not be recognized in the EU.

Since January 1, 2021, the Medicines and Healthcare Products Regulatory Agency ("MHRA") has become the sovereign regulatory authority responsible for Great Britain. All IVDs are required to be registered with the MHRA, and since January 1, 2022, manufacturers based outside the UK have been required to appoint a UK responsible person that has a registered place of business in the UK to register devices with the MHRA.

Coverage and Reimbursement

We are pursuing payment for our products through a diverse and broad range of channels, including sales to self-insured employers, integrated health systems, healthcare providers, life insurance companies, and patients, as well as, where available, through coverage and reimbursement by government healthcare programs and commercial third-party payors.

United States

In the United States, there is no uniform coverage for clinical laboratory tests. The extent of coverage and rate of payment for covered services varies from payor to payor. Obtaining coverage for tests like ours that involve genomic sequencing can be particularly challenging.

Medicare is the single largest healthcare payor in the United States, and a particularly significant payor for many cancer-related laboratory services given the demographics of the Medicare population, a large portion of which includes elderly individuals. Many other U.S. payors look to the Medicare policies as a benchmark and model for their own. Medicare provides two main forms of insurance coverage: traditional Medicare fee-for-service, administered by the federal government and its contractors, and Medicare Advantage, where coverage is provided by private insurers approved by CMS that must follow federal rules and guidelines.

Generally, Medicare will not cover screening tests, which are considered preventive services, that are performed in the absence of signs or symptoms of illness or injury, except if explicitly authorized by statute. CMS, the agency responsible for administering the Medicare program, authorizes certain additional preventive services including certain screening tests that are not expressly covered by 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, an independent, volunteer panel of experts in the field of prevention, evidence-based medicine and primary care, and (c) appropriate for Medicare beneficiaries under Part A or Part B. CMS establishes coverage through an NCD process. In making the NCD determination, CMS may also consider, among other things, the relationship between predicted outcomes and expenditures for such services, and take into account the results of such an assessment in making such determination. In its discretion, the USPSTF generally waits for FDA authorization before it considers undertaking review of novel technology.

Galleri could be considered a screening test under Medicare and, accordingly, is unlikely to be covered by Medicare without pursuing the CMS NCD-related measures described above. These processes may take multiple years to complete as currently, coverage decisions for preventive services are not made prior to FDA authorization. Even if we pursue these processes, it is possible that Galleri will never become eligible for Medicare coverage and reimbursement. We are evaluating opportunities for nearer-term reimbursement through Medicare Advantage plans, while generating evidence to meet the requirements of the traditional Medicare path. Medicare Advantage plans generally must cover all of the services that traditional Medicare covers (except hospice care), but they have the discretion to offer their enrollees additional, or supplemental, benefits not otherwise covered under traditional Medicare, including those benefits referred to as optional supplemental benefits, for which enrollees may elect to pay extra to receive coverage. Obtaining such coverage may, however, involve lengthy negotiations with individual Medicare Advantage plans, and there is no guarantee that we will receive such coverage. We also intend to continue to pursue coverage and reimbursement from private payors for our products. Many of these private payors must cover certain services required by federal and state laws, such as preventive health services that have received a rating of A or B by the USPSTF. Like Medicare Advantage plans, private payors have discretion to extend greater coverage than recognized under traditional Medicare, but

obtaining coverage from such payors generally involves lengthy negotiations, and there is no guarantee that we will receive such coverage. State Medicaid programs make individual coverage decisions for diagnostic tests and have taken steps to control the cost, utilization and delivery of healthcare services, meaning that, even if Galleri receives coverage through private payors, there is no guarantee that it will be covered by individual state Medicaid programs.

DAC is intended to be a diagnostic product, and we believe we could obtain Medicare coverage and reimbursement of DAC as a medical benefit in the next several years, although there are no assurances that we will be successful in doing so. We may explore Medicare local coverage of DAC by Medicare Administrative Contractors ("MACs") by demonstrating utility of our product in a clinical study. MACs administer the Medicare program in their respective designated regions and have some discretion in determining coverage. We may seek FDA clearance or approval, which, if obtained, would help us obtain coverage and reimbursement for DAC.

If eligible for reimbursement, laboratory tests such as ours generally are 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 an HCPCS or CPT code applicable to our tests, the submission and payment 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 April 2014, Congress passed the Protecting Access to Medicare Act of 2014 ("PAMA"), which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA (as amended by the Further Consolidated Appropriations Act, 2020), laboratories that receive the majority of their Medicare revenue from payments made under the CLFS and Physician Fee Schedule and receive at least $12,500 in Medicare revenues for CLFS services during a data collection period are subject to certain reporting requirements. CMS uses the data reported, which includes certain private payor payment rates for each test the laboratory performs, the volume of tests paid at each rate, and the HCPCS code associated with the test, to calculate a weighted median payment rate for each test, which is used to establish revised Medicare CLFS reimbursement rates for clinical diagnostic laboratory tests ("CDLTs"). If the test is an advanced diagnostic laboratory test ("ADLT"), the test will be paid based on an actual list charge for an initial period of three quarters before being shifted to the weighted median private payor rate reported by the laboratory performing the ADLT. Laboratories offering ADLTs are subject to recoupment if the actual list charge exceeds the weighted median private payor rate by a certain amount. Accordingly, if our tests receive Medicare coverage in the future, the reimbursement rate we receive for such tests may be affected by payment rates made by private payors for such tests.

The revised reimbursement methodology described above generally results in relatively lower reimbursement amounts under Medicare for clinical laboratory services than has been historically reimbursed. Any reductions to reimbursement rates resulting from the new methodology are limited to 0% in 2023 and 15% per test per year in each of 2024 through 2026.

In addition, PAMA codified Medicare coverage rules for laboratory tests by requiring any local coverage determination to be made following the local coverage determination process. PAMA also authorizes CMS to consolidate coverage policies for clinical laboratory tests among one to four laboratory-specific MACs. These same contractors may also be designated to process claims if CMS determines that such a model is appropriate. It is unclear whether CMS will proceed with contractor consolidation under this authorization.

General Coverage and Reimbursement Considerations

Across jurisdictions, a decision to provide coverage for a product from a government payor, such as Medicare, or other third-party payor does not imply that an adequate reimbursement rate will be approved. Further, coverage and reimbursement for products, and services that utilize such products, can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance or at all.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, including clinical laboratory tests, in addition to their safety and efficacy. In certain foreign markets, the government controls the coverage and pricing of many healthcare products, including IVDs and clinical laboratory tests. In order to obtain coverage and reimbursement for any product that might be cleared or approved by regulators for sale (or certified by a notified body), or for any procedure that utilizes such product, it may be necessary to conduct health economic studies in order to demonstrate the medical necessity and cost-effectiveness of the products. The cost of such studies would be in addition to the costs required to obtain regulatory approvals or certifications. If third-party payors do not consider a product to be cost-effective compared to other available products, they may not cover the product after approval (or certification) as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. Tests such as ours that will cover a large population and could potentially generate a significant number of false-positive results on an absolute basis may face incremental scrutiny in obtaining reimbursement from third-party payors given the additional costs of further diagnostic workup.

The marketability of Galleri and DAC may suffer if government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased, and we expect will continue to increase the pressure on medical products and services pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for our tests, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system. Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our products, decrease our revenue and adversely impact sales of, and pricing of and reimbursement for, our products. For example, in March 2010, the ACA was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. The ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments, and fraud and abuse changes.

The implementation of the ACA in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The ACA included, among other things, provisions governing enrollment in federal and state healthcare programs, reimbursement matters, and fraud and abuse. Since its enactment, there have been judicial, U.S. Congressional and executive branch challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. It is unclear how other healthcare reform measures, if any, will impact our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, resulted in reductions in payments to Medicare providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced CMS payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover Medicare overpayments to providers from three to five years.

In the EU, 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.

We believe that there will continue to be proposals by legislators at both the federal and state levels and in foreign jurisdictions, regulators and third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. Changes in healthcare policy could increase our costs, decrease our revenue and impact sales of and reimbursement for our products.

Data Privacy and Security Regulation

Data Privacy and Security Laws

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing. For additional information, see the section entitled "Risk Factors" beginning on page 30 of this Information Statement.

Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time, we are and may become involved in legal proceedings or investigations. For example, we are currently involved in various lawsuits and claims with respect to employment matters. Lawsuits or other legal proceedings could have an adverse impact on our reputation, business, financial condition, results of operations, or cash flows, and could divert the attention of our management from the operation of our business.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

Emerging Growth Company Status

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 Securities Exchange Act of 1934, which refer to as the "Exchange Act," for at least one year (and have 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.

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 in the assessment of our internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act of 2002, 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 stockholder approval on golden parachute compensation not previously approved. We may choose to take advantage of some or all of these reduced burdens. For example, we have taken advantage of the reduced disclosure obligations regarding executive compensation in this Information Statement. For as long as we take advantage of the reduced reporting obligations, the information we provide stockholders 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 the price of our common stock.

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 included in this Information Statement, as well as 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.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

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 consolidated financial statements, which we refer to as the "Consolidated Financial Statements," and the notes thereto included under the section entitled "Index to Consolidated Financial Statements" beginning on page F-1 of this Information Statement, as well as the discussion in the sections entitled "Unaudited Pro Forma Condensed Consolidated Financial Statements" and "Business" beginning on pages 114 and 115, respectively, of this Information Statement. 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 the midstream industry and our business and financial results. Our actual results could differ materially from the results contemplated by these forward-looking statements due to a number of factors, including those discussed in the sections entitled "Risk Factors" and "Cautionary Statement Concerning Forward-Looking Statements" beginning on pages 30 and 97, respectively, of this Information Statement.

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

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

Prior to the Closing Date, and unless the context otherwise requires, references to "GRAIL," "we," and "us" within this Information Statement refer to GRAIL, Inc., and its consolidated subsidiaries, while references to "GRAIL," "we," and "us" on or after the Closing Date refer to GRAIL, LLC and its consolidated subsidiaries unless the context otherwise requires.

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 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, which can help guide next steps for diagnosis, and yield high positive predictive values and low false positive rates, all from a simple blood draw. We launched Galleri in the United States in mid-2021. As of December 31, 2023, we have sold more than 150,000 commercial tests and established over 100 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. Our net losses were $1.5 billion for fiscal year 2023 (which includes $718.5 million of goodwill and intangible impairment), $5.4 billion for fiscal year 2022 (which includes $4.7 billion in goodwill impairment), $911.5 million for the 2021 successor period and $336.2 million for 2021 predecessor period (see "Basis of Presentation" below for a description of applicable fiscal periods). Adjusted EBITDA was $(523.9) million for fiscal year 2023, $(500.1) million for fiscal year 2022, $(158.1) million for the 2021 successor period and $(216.5) million for the 2021 predecessor period. 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 impairment, amortization of intangible assets, as well as our research and development programs, G&A costs associated with our operations and sales and marketing costs associated with commercializing our products. Additionally, due to the application of pushdown accounting, our balance sheet includes goodwill and 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 , 2024, Illumina announced plans for the separation of GRAIL from Illumina via the Spin-Off.

To effect the Spin-Off, Illumina will distribute at least 85.5% of the shares of GRAIL's common stock owned by Illumina to Illumina's stockholders on a pro rata basis, and GRAIL will become an independent, publicly traded company. Immediately after the Distribution becomes effective, Illumina may retain up to 14.5% of GRAIL's common stock.

Prior to completion of the Spin-Off, we intend to enter into a Separation and Distribution Agreement and several other agreements with Illumina related to the Spin-Off. These agreements will govern the relationship between Illumina and us up to and after completion of the Spin-Off and allocate between Illumina and us various assets, liabilities, and obligations, including tax-related assets and liabilities. See the section entitled "Certain Relationships and Related Party Transactions" beginning on page 217 of this Information Statement for more detail. No approval of Illumina's stockholders is required in connection with the Spin-Off, and Illumina's stockholders will not have any appraisal rights in connection with the Spin-Off.

Completion of the Spin-Off is subject to the satisfaction, or the waiver by Illumina's board of directors (the "Illumina Board") of a number of conditions.

In addition, Illumina has the right not to complete the Spin-Off if, at any time, the Illumina Board determines, in its sole and absolute discretion, that the Spin-Off is not in the best interests of Illumina or its stockholders or is otherwise not advisable. If the Spin-Off is not completed for any reason, Illumina and GRAIL will have incurred significant costs related to the Spin-Off, including fees for consultants, financial and legal advisors, accountants, and auditors, that will not be recouped. Total one-time transaction costs associated with the Spin-Off are preliminarily estimated to range from $[ ] to $[ ] if the Spin-Off is completed. If the Spin-Off is not completed for any reason, the one-time transaction costs will generally be limited to the transaction costs incurred for services rendered as of the date the Spin-Off is abandoned, which will be less than the range noted above. Our management will also have devoted significant time to manage the Spin-Off process, which will decrease the time they will have to manage our business. See the section entitled "The Spin-Off—Conditions to the Spin-Off" beginning on page 108 of this Information Statement for more detail.

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Pursuant to 17 C.F.R. Section 200.83

Basis of Presentation

The accompanying consolidated financial statements have been prepared on a stand-alone basis using the consolidated financial statements and accounting records of Illumina. These consolidated financial statements reflect GRAIL's consolidated historical financial position, results of operations and cash flows as historically managed, in accordance with GAAP. The Consolidated Financial Statements may not be indicative of GRAIL's 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. 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.

GRAIL's fiscal year is the 52 or 53 weeks ending the Sunday closest to December 31, so the exact year-end date may change from year to year. Upon the closing of the Spin-Off, GRAIL will have a fiscal year end of December 31. References herein to (i) the "2021 predecessor period" refer to the period from January 1, 2021 through August 18, 2021 and reflect the pre-Acquisition activity of GRAIL, (ii) the "2021 successor period" refer to the period from August 19, 2021 through January 2, 2022 and reflect the post-Acquisition activity of GRAIL, (iii) "fiscal year 2022" refer to the period from January 2, 2022 through January 1, 2023, and (iv) "fiscal year 2023" refer to the period from January 2, 2023 to December 31, 2023.

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

Subsequent to the separation from Illumina, 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;
- Personnel costs, including compensation-related expenses for additional headcount 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, legal and other professional services fees, annual report and proxy statement costs, SEC filing fees, transfer agent fees, and stock exchange listing fees.

These additional costs are expected to increase our general and administrative ("G&A") expenses. Certain factors could impact the nature and amount of these separate public company costs, including the finalization of our staffing and infrastructure needs.

We also expect Illumina to continue providing us with some of the services related to certain functions on a transitional basis. Costs associated with services provided by Illumina on a transitional basis are expected to be immaterial. We also expect to provide certain services to Illumina on a transitional basis in exchange for agreed-upon fees.

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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:

- ***Continued development of the market for MCED testing***. Multi-cancer early detection is a relatively novel concept and the market for MCED tests is rapidly 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 and our other products 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 well as other at-risk populations. 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 December 31, 2023, we have entered into over 100 commercial partnerships, including with leading healthcare systems, employers, payors, and life insurance providers, and have established a network of over 9,000 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.
- ***Regulatory approval and reimbursement***. Our performance will be impacted by the extent to which we can secure reimbursement and coverage for our products. 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 an 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 tests in the United States. We plan to complete a PMA submission with the FDA in to support broad access for Galleri. 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 believe that FDA approval, if obtained, could unlock large commercial payors in the United States and we are working with stakeholders to advance and shape the public reimbursement landscape in the United States to enable coverage of FDA-approved MCED tests by Medicare. Following 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. Subject to results of an early analysis from the first screening test (the prevalent screening round) representing one year of results out of the three-year trial period, the NHS may commence phased commercial implementation with the potential for further expansion subject to final results from the trial. 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.

- ***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, including the development of new and improved products, and the ongoing evidence generation supporting the clinical 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, and REFLECTION. 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 our investments to continue. In addition, we have invested heavily in the development of our methylation platform and extensive technological infrastructure. We expect to increase our research and development expenses as we continue to develop new technologies and launch innovative products across the cancer care continuum.
- ***Leverage our operational infrastructure***. We have made significant investments to build a scalable infrastructure capable of meeting significant demand while satisfying stringent certification parameters. 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 addition, we may invest significant amounts in infrastructure to support new products resulting from our research and development activities.
- ***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, and we expect to launch Galleri in the United Kingdom through our partnership with NHS England. We continue to evaluate international expansion opportunities and expect to expand into additional select geographies over time, including through distributors.

While each of these areas presents significant opportunities for us, they also pose significant risks and challenges that we must address. See "Risk Factors" 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 health systems, employers, payors, and life insurance providers. Galleri is not currently broadly reimbursed. The test price is based on the negotiated contractual rate with our contracted customers, otherwise our standard list price applies. We identify each sale of our test to our customer as a single performance obligation; therefore, revenue is recognized at the point of time when the test result report is delivered. For

self-pay patients, we have concluded that an implied contract exists, however the transaction price for the implied contract represents variable consideration as there are situations in which we do not expect to collect the full invoiced amounts from self-pay patients due to price concessions. We utilize the expected value approach to estimate the transaction price and apply a constraint for such variable consideration, on a portfolio basis. We monitor the estimated amounts to be collected at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required.

Development Services Revenue

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

Cost of Screening Revenue (Exclusive of Amortization of Intangible Assets), 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 DAC that is being designed to accelerate diagnostic resolution for patients for whom there is a clinical suspicion of cancer. 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 8 to our audited Consolidated Financial Statements included elsewhere in this Information Statement. 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 plateau over the coming years as our existing clinical studies and development of our automated platform conclude. We will continue our research and development activities for new products, to enhance existing products, and initaite and conduct additional clinical studies to provide the evidence to support our products.

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 in the successor periods also includes amortization of the tradename intangible asset that was recognized upon the Acquisition, which has been recorded in our financial statements as a result of the application of pushdown accounting. The cost of identifiable intangible assets with finite lives, such as trade names, are amortized on a straight-line basis over the assets' respective estimated useful lives of 9 years. We expect our sales and marketing expenses to continue to increase as we continue to invest in building brand awareness of our current products and services, as well as additional product marketing and sales functions.

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, and management information systems personnel. Also included are professional fees, legal costs, including patent and trademark-related expenses. The related party amount represents allocated audit fees and stock administration expenses from Illumina. We expect our G&A expenses to increase as we become a standalone public company and continue to grow our business. 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 also expect to increase our administrative headcount as a standalone public company.

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.

On July 13, 2022, the European General Court ruled that the European Commission has jurisdiction under the European Union Merger Regulation to review the Acquisition. Additionally, on September 6, 2022, the European Commission issued a decision prohibiting the Acquisition. These decisions constituted substantive changes in circumstances that would more likely than not reduce the fair value of goodwill. We recognized a goodwill impairment for $4.7 billion in 2022. In the third quarter of 2023, we concluded the sustained decrease in Illumina's stock price and overall market capitalization during the quarter was a triggering event indicating the fair value of GRAIL might be less than its carrying amount that led us to test goodwill for impairment. We recognized an additional goodwill impairment of $608.5 million in 2023 primarily due to changes to expected timing of revenue and a higher discount rate. 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.

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 entity of Illumina, we were no longer subject to U.S. income tax for the successor periods ended December 31, 2023, January 1, 2023 and January 2, 2022 on a standalone basis and U.S. income tax is combined into Illumina's consolidated income tax return as a division 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. 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 GRAIL is not a separate taxpayer and merely a division 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 a standalone GRAIL entity on its income tax returns in the future.

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Pursuant to 17 C.F.R. Section 200.83

Results of Operations

Comparisons of Fiscal Year 2023 to Fiscal Year 2022

The following table summarizes our results of operations for fiscal year 2023 and fiscal year 2022.

(in thousands)	Year Ended December 31, 2023	Year Ended January 2, 2022	Change $	Change %
Revenue:				
Screening revenue	$ 74,347	$ 39,123	$ 35,224	90%
Screening revenue—related parties	652	694	(42)	(6)%
Development services revenue	18,106	15,733	2,373	15%
Total revenue	93,105	55,550	37,555	68%
Costs and operating expenses:				
Cost of screening revenue (exclusive of amortization of intangible assets)	39,284	27,998	11,286	40%
Cost of screening revenue—related parties	8,682	4,142	4,540	110%
Cost of development services revenue	6,623	5,741	882	15%
Cost of development services revenue—related parties	238	227	11	5%
Cost of revenue—amortization of intangible assets	133,889	133,889	—	— %
Research and development	318,088	310,431	7,657	2%
Research and development—related parties	20,657	19,145	1,512	8%
Sales and marketing	162,292	122,328	39,964	33%
General and administrative	200,062	173,494	26,568	15%
General and administrative—related parties	206	614	(408)	(66)%
Goodwill and intangible impairment	718,466	4,700,431	(3,981,965)	(85)%
Total costs and operating expenses	1,608,487	5,498,440	(3,889,953)	(71)%
Loss from operations	(1,515,382)	(5,442,890)	3,927,508	(72)%
Other income (expense):				
Interest income	7,954	1,740	6,214	357%
Other income (expense), net	(208)	(238)	30	(13)%
Total other income (expense), net	7,746	1,502	6,244	416%
Loss before income taxes	(1,507,636)	(5,441,388)	3,933,752	(72)%
Benefit from income taxes	41,951	42,290	(339)	(1)%
Net loss	$ (1,465,685)	$ (5,399,098)	$ 3,933,413	(73)%

Comparison of Fiscal Year 2023 to Fiscal Year 2022:

Revenue

Screening Revenue and Screening Revenue—Related Parties

The increase in screening revenue of $35.2 million was primarily attributable to an increase in Galleri sales volume.

Development Services Revenue

The increase in development services revenue of $2.4 million was primarily due to new pilots initiated with biopharmaceutical partners in fiscal year 2023.

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

The increase in cost of screening revenue (exclusive of amortization of intangible assets) and cost of screening revenue—related parties of $15.8 million was primarily attributable to the 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 fiscal year 2023 primarily due to improved efficiency of Galleri testing process, primarily due to increased Galleri sales volume.

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

The increase in cost of development services revenue and cost of development services revenue—related parties was overall inline with the increase in development services revenue, primarily driven by labor costs for development services projects.

Cost of Revenue—Amortization of Intangible Assets

Cost of revenue—amortization of intangible assets remained consistent period over period.

Research and Development and Research and Development—Related Parties

Research and development and research and development—related parties expenses for fiscal years 2023 and 2022 were as follows:

	Year Ended		Change	
(in thousands)	December 31, 2023	January 2, 2022	$	%
Compensation expenses	$ 174,469	$ 154,739	$ 19,730	13%
Clinical studies and research collaboration expenses	56,934	69,938	(13,004)	(19)%
Laboratory supplies and expenses	39,599	32,487	7,112	22%
Cloud computing expenses	8,897	10,465	(1,568)	(15)%
Depreciation and impairment expenses	12,058	8,163	3,895	48%
Allocated and other expenses	46,788	53,784	(6,996)	(13)%
Total research and development and research and development—related parties expenses	$ 338,745	$ 329,576	$ 9,169	3%

The increase in the compensation expenses of $19.7 million was primarily attributable to increased headcount and employee long-term incentive awards. The decrease in clinical studies and research collaboration expenses of $13.0 million was primarily attributable to a reduction in clinical study expenses related to the clinical studies which previously completed enrollment and decreased study activity maintenance costs. The increase in the laboratory supplies and expenses of $7.1 million was primarily due to increased research and development and clinical study sample processing and cost optimization efforts. The decrease of $1.6 million in cloud computing expenses was primarily due to a decrease in clinical trial data processing. The increase of $3.9 million in depreciation and impairment expenses was attributable to a full year of depreciation on laboratory equipment placed into service in 2022. Allocated and other expenses decreased as a result of lower software, IT, and facilities expenses being allocated to the research and development function, in addition to decreases in the use of contractors and temporary labor.

Sales and Marketing

The increase in sales and marketing expenses of $40.0 million was primarily attributable to an increase of $34.5 million in compensation expenses, primarily due to increased headcount in our dedicated sales team hired to support Galleri. Third-party marketing and professional services expenses increased by $2.7 million primarily due to a 2023 marketing event. Additionally, our corporate overhead allocations increased as a result of our increased headcount.

General and Administrative

The increase in general and administrative expenses of $26.2 million was primarily attributable to an increase of $24.1 million in compensation expenses due to increased headcount and employee long-term incentive awards. Legal and professional services increased by $1.6 million primarily related to legal and professional services costs associated with the Acquisition and corresponding antitrust litigation. Corporate IT expenses increased by $2.0 million to support the increase in headcount. Facilities and depreciation increased by $1.1 million primarily due to an impairment charge taken on the right of use asset for a office building due to a change in management's plan of use. These increases were partially offset by decreases in allocated and other expenses as well as a decrease in the use of contractors and temporary labor.

Goodwill and Intangible Impairment

As a result of an impairment assessment performed, a goodwill impairment charge of $608.5 million was recorded in the fiscal year 2023 which represents the amount by which the carrying value of GRAIL exceeded the fair value of GRAIL upon performing a quantitative test, primarily due to changes to expected timing of revenue and a higher discount rate. In conjunction with the 2023 impairment assessment, an impairment charge of $110.0 million was recorded to the IPR&D intangible asset. As a result of an impairment assessment performed, an impairment charge of $4.7 billion was recorded in 2022 which represents the amount by which the carrying value of GRAIL exceeded the fair value of GRAIL upon performing a quantitative test.

Interest Income

The increase in interest income of $6.2 million was primarily attributable to an increase in interest earned on our money market accounts primarily due to higher interest rates.

Other Expense

The decrease in other expense was primarily a result of foreign currency gains in the fiscal year 2023.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

Comparisons of Fiscal Year 2022 to the 2021 Successor Period and the 2021 Predecessor Period

The following table summarizes our results of operations for fiscal year 2022, the 2021 successor period and the 2021 predecessor period. Results between periods presented are not comparable and thus, percentage change has been omitted for presentation purposes.

(in thousands)	(Successor) Year Ended January 1, 2023	(Successor) August 19, 2021 to January 2, 2022	(Predecessor) January 1, 2021 to August 18, 2021
Revenue:			
Screening revenue	$ 39,123	$ 7,074	$ 1,953
Screening revenue—related parties	694	381	46
Development services revenue	15,733	4,978	180
Total revenue	55,550	12,433	2,179
Costs and operating expenses:			
Cost of screening revenue (exclusive of amortization of intangible assets)	27,998	4,664	4,965
Cost of screening revenue—related parties	4,142	662	227
Cost of development services revenue	5,741	624	261
Cost of development services revenue—related parties	227	133	—
Cost of revenue—amortization of intangible assets	133,889	44,630	—
Research and development	310,431	309,781	138,366
Research and development—related parties	19,145	1,475	10,590
Sales and marketing	122,328	100,512	24,814
General and administrative	173,494	478,071	160,140
General and administrative—related parties	614	35	4
Goodwill impairment	4,700,431	—	—
Total costs and operating expenses	5,498,440	940,587	339,367
Loss from operations	(5,442,890)	(928,154)	(337,188)
Interest income	1,740	19	313
Other income (expense), net	(238)	(884)	642
Total other income (expense), net	1,502	(865)	955
Loss before income taxes	(5,441,388)	(929,019)	(336,233)
Benefit from income taxes	42,290	17,477	—
Net loss	**$ (5,399,098)**	**$ (911,542)**	**$ (336,233)**

Comparison of Fiscal Year 2022 to the 2021 Successor Period, and the 2021 Predecessor Period:

Revenue

Screening Revenue and Screening Revenue—Related Parties

The increase in screening revenue in fiscal year 2022 as compared to all prior periods presented is a direct result of the commercial launch of Galleri in mid-2021. Screening revenue increased from $2.0 million in the 2021 predecessor period, to $7.4 million in the 2021 successor period. In fiscal year 2022, screening revenue increased to $39.8 million, which was driven by an increased volume of Galleri tests sold and having a full year of commercialized sales compared to seven months of sales in calendar year 2021.

Development Services Revenue

Development services revenue increased from $0.2 million in the 2021 predecessor period, to $5.0 million in the 2021 successor period, primarily due to pilot and research services performed for biopharmaceutical

customers. In fiscal year 2022, development services revenue increased to $15.7 million. The increase in development services revenue in fiscal year 2022 was primarily due to services performed for a large biopharmaceutical partner, as well as new pilots initiated with other biopharmaceutical partners.

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

The increase in cost of screening revenue (exclusive of amortization of intangible assets) and cost of screening revenue—related parties corresponded to the increase in screening revenue. Cost of screening revenue and cost of screening revenue—related parties were $5.2 million in the 2021 predecessor period, $5.3 million in the 2021 successor period and $32.1 million in fiscal year 2022. Cost of screening revenue (exclusive of amortization of intangible assets) and cost of screening revenue—related parties as a percent of revenue decreased in fiscal year 2022 primarily due to improved efficiency of Galleri testing process, primarily due to increased volume following the commercial launch of Galleri in mid-2021.

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

The increase in cost of development services revenue and cost of development services revenue—related parties was overall inline with the increase in development services revenue, primarily driven by labor costs for development services projects. Cost of development services revenue and cost of development services revenue—related parties were $0.3 million in the 2021 predecessor period, $0.8 million in the 2021 successor period and $6.0 million in fiscal year 2022.

Cost of Revenue—Amortization of Intangible Assets

The increase of the amortization of intangible assets is a result of the amortization of definite-lived developed technology intangible assets resulting from the Acquisition and the recognition of a full year of amortization as compared to the shorter successor period. Prior to the Acquisition, we did not have intangible assets.

Research and Development and Research and Development—Related Parties

Research and development and research and development—related parties expenses for the predecessor and successor periods were as follows:

	(Successor)		(Predecessor)
(in thousands)	Year Ended January 1, 2023	August 19, 2021 to January 2, 2022	January 1, 2021 to August 18, 2021
Compensation expenses	$ 154,739	$ 256,823	$ 63,499
Clinical studies and research collaboration expenses	69,938	23,784	24,366
Laboratory supplies and expenses	32,487	4,523	25,340
Cloud computing expenses	10,465	4,196	6,719
Depreciation and impairment expenses	8,163	2,248	2,630
Allocated and other expenses	53,784	19,682	26,402
Total research and development and research and development—related parties expenses	**$ 329,576**	**$ 311,256**	**$ 148,956**

The increase in the compensation expenses from the 2021 predecessor period to the 2021 successor period is primarily due to non-recurring compensation of $201.2 million incurred as a result of the Acquisition, primarily consisting of accelerated vesting of stock-based compensation expenses in connection with the Acquisition,

which resulted in $615.0 million of expense recognized immediately upon closing of the Acquisition in August 2021, of which $177.7 million was allocated to research and development, and retention incentives of $23.5 million. The decrease from the 2021 successor period to fiscal year 2022 was a result of no non-recurring transaction related compensation expenses in the 2021 successor period, which was offset by increased headcount year over year and the introduction of new employee long-term incentive programs in the post transaction period.

Clinical studies and research collaboration expenses increased in 2022 as compared to other periods presented, primarily due to increased clinical study activity. The majority of the increase in our clinical studies and research collaboration expenses relate to the NHS-Galleri Trial which enrolled its first patient in August 2021, and the PATHFINDER 2 clinical study, which began enrollment in the fourth quarter of 2021, as a result of active enrollment and a full year of expenses in 2022. These increases were partially offset by a reduction in expenses related to the SUMMIT and STRIVE clinical studies as enrollment completed in the predecessor period and thus study activity decreased.

The decrease in the laboratory supplies and expenses from the 2021 predecessor period to the 2021 successor period is a result of a decrease in clinical study sample processing, a decrease in general research and development sample processing, and a $0.9 million reduction in expenses due to renegotiation of a previously accrued purchase commitment. The increase of laboratory supplies and expenses in 2022 as compared to other periods presented is primarily due to increased research and development and clinical study sample processing.

Cloud computing expenses remained relatively unchanged period over period.

Depreciation and impairment expenses increased in 2022 compared to all other periods presented as $20 million of equipment was placed into service at our laboratory locations.

Allocated and other expenses increased as a result of higher software, IT, and facilities expenses being allocated to the research and development function, in addition to increases in the use of contractors and temporary labor.

Sales and Marketing

Sales and marketing expenses in fiscal year 2022 were $122.3 million, compared to $100.5 million in the 2021 successor period and $24.8 million in the 2021 predecessor period. The increase of sales and marketing expense from the 2021 predecessor period to the 2021 successor period was primarily due to the accelerated vesting of stock-based compensation expenses in connection with the Acquisition, which resulted in $615 million of expense recognized immediately upon closing of the Acquisition in August 2021, $71.8 million of which was allocated to sales and marketing. The increase of sales and marketing expenses in fiscal year 2022 compared to all periods presented was primarily attributable to an increase of compensation expenses, primarily due to increased headcount in our dedicated sales team initially hired to support the commercial launch of Galleri in 2021. Headcount increased 205% from the end of the 2021 successor period to the end of fiscal year 2022, contributing to higher wages, employer payroll taxes, bonuses, long-term incentive compensation, and other personnel related costs in 2022 compared to previous periods presented. Additionally, we incurred higher travel expenses in fiscal year 2022 as a result of fewer COVID-19 related travel restrictions and more sales-based travel as compared to other periods. Third-party marketing and professional services expenses increased from $6.4 million in the 2021 successor period to $28.0 million in fiscal year 2022 to support efforts to market our newly commercialized product. Additionally, our corporate overhead allocations increased as a result of our increased headcount. Trade name intangible assets amortization expense increased from $1.5 million in the 2021 successor period to $4.4 million in fiscal year 2022 as a result of a full year of amortization as compared to the shorter 2021 successor period. These increases from the 2021 successor period to 2022 were offset by the one-time stock-based compensation expense being incurred in the 2021 successor period with no comparable expense in 2022.

General and Administrative

The 2021 predecessor period includes non-recurring transaction related professional services fees and insurance premiums of $51.0 million and $4.5 million, respectively. The increase in G&A expense in the 2021 successor period compared to the 2021 predecessor period was primarily due to the accelerated vesting of stock-based compensation expenses in connection with the Acquisition, which resulted in $615.0 million of expense recognized immediately upon closing of the Acquisition in August 2021, $365.5 million of which was allocated to G&A. Non-recurring retention bonuses of $12.4 million and severance related costs of $7.2 million were also incurred in the 2021 successor period. The corresponding decrease from the 2021 successor period to fiscal year 2022 was primarily a result of these non-recurring transactions not being incurred in fiscal year 2022 and a reduction in legal expenses. This decrease was partially offset by an increase in facilities expenses in fiscal year 2022.

Goodwill Impairment

As a result of an impairment assessment performed, an impairment charge of $4.7 billion was recorded in 2022 which represents the amount by which the carrying value of GRAIL exceeded the fair value of GRAIL upon performing a quantitative test.

Interest Income

The decrease in interest income from the 2021 predecessor period to the 2021 successor period was primarily a result of the sale of our marketable securities upon consummation of the transaction. The increase from the 2021 successor period to fiscal year 2022 was primarily attributable to an increase in interest earned on our money market account primarily due to the increase in length of the period, and higher interest rates.

Other Income (Expense), Net

The increase in other income (expense), net from the 2021 successor period to fiscal year 2022 primarily related to foreign currency gains, offset slightly by losses on asset retirements. The decrease from the 2021 predecessor period to the 2021 successor period was a result of foreign currency gains in the 2021 predecessor period converting to foreign currency losses in the 2021 successor period.

Non-GAAP Financial Measures

In addition to our results provided throughout this Information Statement that are determined in accordance with GAAP, this Information Statement also includes the following non-GAAP financial measures for the 2021 predecessor period, 2021 successor period, fiscal year 2022, and fiscal year 2023, which information should be read in conjunction with our audited Consolidated Financial Statements and the related notes and accompanying notes included elsewhere in this Information Statement:

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 indirect costs associated with our sales and marketing, product development, general and administrative activities, and depreciation and amortization, and the impact of our financing methods and income taxes.

We calculate Adjusted Gross Profit/(Loss) as gross profit/(loss) (as defined below) adjusted to exclude amortization of intangible assets and stock-based compensation allocated to cost of revenue. Adjusted Gross

Profit/(Loss) should be viewed as a measure of operating performance that is a supplement to, and not a substitute for, operating income or loss from operations, net earnings or loss and other GAAP measures of income (loss) or profitability. The following table presents a reconciliation of gross profit, the most directly comparable financial measure calculated in accordance with GAAP, to Adjusted Gross Profit/(Loss).

	(Successor)			(Predecessor)
(in thousands)	Year Ended December 31, 2023	Year Ended January 1, 2023	August 19, 2021 to January 2, 2022	January 1, 2021 to August 18, 2021
Gross loss (1)	$ (95,611)	$(116,447)	$(38,280)	$ (3,274)
Amortization of intangible assets	133,889	133,889	44,630	—
Stock-based compensation	1,970	957	150	88
Adjusted Gross Profit/(Loss)	$ 40,248	$ 18,399	$ 6,500	$ (3,186)

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

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 amortization of intangible assets, which represent intangible assets resulting from pushdown accounting. 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.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

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 payments, tax payments, and debt service requirements. 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 income (loss), the most directly comparable financial measure calculated in accordance with U.S. GAAP, to Adjusted EBITDA on a consolidated basis.

	(Successor)			(Predecessor)
(in thousands)	Year Ended December 31, 2023	Year Ended January 1, 2023	August 19, 2021 to January 2, 2022	January 1, 2021 to August 18, 2021
Net loss	$ (1,465,685)	$ (5,399,098)	$ (911,542)	$ (336,233)
Adjusted to exclude the following:				
Interest income	(7,954)	(1,740)	(19)	(313)
Benefit from income tax expense	(41,951)	(42,290)	(17,477)	—
Amortization of intangible assets (1)	138,333	138,333	46,111	—
Depreciation	20,364	16,430	5,422	6,916
Goodwill and intangible impairment(2)	718,466	4,700,431	—	—
Illumina/GRAIL merger legal and professional services costs (3)	17,320	12,127	10,750	81,470
Stock-based compensation (4)	97,235	75,729	650,260	31,647
Non-recurring transaction related compensation and payroll taxes (5)	—	—	58,346	—
Adjusted EBITDA	$ (523,872)	$ (500,078)	$ (158,149)	$ (216,513)

(1) Represents amortization of intangible assets, including developed technology and tradenames.
(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.
(4) Represents all stock-based compensation recognized on our standalone financial statements for the periods presented.
(5) Represents various one-time cash retention bonuses and related payroll taxes directly attributable to the contractual agreement terms related to Illumina's acquisition of the Company, as well as payroll taxes paid on total merger consideration including cash, equity, and contingent value rights distributed to employee award holders in accordance with the terms of the Merger Agreement. Retention bonuses represented $35.6 million and $0.6 million of related payroll taxes whereas payroll taxes on merger consideration amounted to $22.1 million.

Liquidity and Capital Resources

Sources of Liquidity

From inception through the Closing Date, we had funded our operations primarily through the sale and issuance of our redeemable convertible preferred stock and receipt of continuation payments from Illumina. Post- Acquisition, we received funding on a quarterly basis directly from Illumina. As of December 31, 2023, our cash and cash equivalents totaled $97.3 million, and our cash and cash equivalents together with our pro forma cash and cash equivalents would have been $ [ ] million.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

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, we have incurred net losses of $7.8 billion which include charges for impairment of goodwill 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, in addition to the funding that Illumina is required to provide pursuant to the EC Divestment Decision, 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 Information Statement. However, we anticipate that we will need to raise additional financing in the future to fund our operations. Our future capital requirements will depend on many factors, including the timing and extent of spending to support commercialization, market acceptance of our products prior to broad reimbursement, the timing of broad reimbursement, and launch of pipeline products. We are subject to typical risks associated with an early-stage commercial company and are developing the market for multi-cancer early detection. We may encounter complications with executing our business plans that may cause unforeseen expenses and adversely affect our business.

We may in the future enter into arrangements to acquire or invest in complementary businesses, services, technologies, and intellectual property rights. We may be required to seek additional capital through equity or debt financing. In the event that additional financing is required, we may not be able to raise it on terms acceptable to us or at all. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders, increased fixed payment obligations, and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations. We 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):

	(Successor)			(Predecessor)
	Year Ended December 31, 2023	Year Ended January 1, 2023	August 19, 2021 to January 2, 2022	January 1, 2021 to August 18, 2021
Net cash used by operating activities	$ (595,800)	$ (561,313)	$ (485,870)	$ (202,260)
Net cash provided by (used by) investing activities	(12,887)	(22,859)	(7,976)	352,788
Net cash provided by financing activities	463,766	604,817	143,931	250,811
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	305	(511)	(135)	(64)
Net increase (decrease) in cash and cash equivalents and restricted cash	**$ (144,616)**	**$ 20,134**	**$ (350,050)**	**$ 401,275**

Net Cash Used by Operating Activities

During the 2021 predecessor period, net cash used by operating activities consisted of a net loss of $336.2 million, adjusted by non-cash charges of $38.4 million, and cash provided by changes in our operating assets and liabilities of $95.5 million. The non-cash charges primarily consisted of stock-based compensation expense of $31.6 million, depreciation of $6.9 million, and amortization of premium on marketable securities of $0.5 million. Cash provided by operating assets and liabilities was primarily a result of an increase in accounts

payable of $62.5 million, an increase in accrued and other liabilities of $13.3 million, and an increase in operating lease liabilities which was primarily due to tenant inducements received from our landlord of $18.2 million, respectively.

During the 2021 successor period, net cash used by operating activities consisted of a net loss of $911.5 million, adjusted by non-cash charges of $684.6 million, $185.0 million of cash payments for equity awards and cash used by changes in our operating assets and liabilities of $74.0 million. The non-cash charges primarily consisted of stock-based compensation expense of $650.3 million and depreciation and amortization of $51.5 million, which was partially offset by a non-cash benefit of $17.5 million relating to deferred income tax. The main driver of changes in our operating assets and liabilities was an increase in accounts receivable of $6.1 million, an increase in supplies and supplies—related parties of $3.7 million, and a decrease of accounts payable and accounts payable-related parties of $63.2 million.

During fiscal year 2022, net cash used by operating activities consisted of a net loss of $5.4 billion, adjusted by non-cash charges of $4.9 billion, $41.0 million cash payments for equity awards, and cash used by changes in our operating assets and liabilities of $14.5 million. The non-cash adjustments consisted of goodwill impairment of $4.7 billion, depreciation and amortization of $154.8 million, and stock-based compensation expense of $75.7 million, which was partially offset by a non-cash benefit of $39.1 million relating to deferred taxes. The changes in operating assets and liabilities was predominantly driven by increases in accounts receivable of $8.6 million, an increase in prepaids and other current assets of $11.3 million, an increase in supplies and supplies—related parties of $14.1 million, partially offset by an increase in accrued and other liabilities of $14.0 million.

During fiscal year 2023, net cash used by operating activities consisted of a net loss of $1.5 billion, adjusted by non-cash charges of $939.1 million, $76.9 million cash payments for equity awards, and cash provided by changes in our operating assets and liabilities of $7.7 million. The non-cash adjustments primarily consisted of goodwill and intangible impairment of $718.5 million, depreciation and amortization of $158.7 million, and stock-based compensation expense of $97.2 million, which was partially offset by a non-cash benefit of $38.2 million relating to deferred taxes. Changes in operating assets and liabilities was predominantly driven by a decrease in operating lease assets and liabilities of $6.7 million, an increase in accounts payable of $2.9 million, and an increase in accrued and other liabilities of $2.4 million, partially offset by an increase in supplies and supplies —related parties of $1.9 million, an increase in accounts receivable of $1.4 million, and an increase in prepaids and other current assets of $0.9 million.

Net Cash Provided by Investing Activities

During the 2021 predecessor period, net cash provided by investing activities consisted of $574.1 million in proceeds from the sale of and the maturities of marketable securities, partially offset by $159.4 million in purchases of marketable securities and $62.0 million of capital expenditures. Capital expenditures were primarily related to purchases of machinery and equipment for use in our laboratories.

During the 2021 successor period, net cash used by investing activities consisted of $8.0 million for capital expenditures primarily related to purchases of machinery and equipment for use in our laboratories.

During fiscal year 2022, net cash used by investing activities primarily consisted of $22.9 million for capital expenditures primarily related to purchases of machinery and equipment for use in our laboratories.

During fiscal year 2023, net cash used by investing activities primarily consisted of $12.9 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 2021 predecessor period, net cash provided by financing activities consisted of $245.0 million in funding from Illumina and $6.0 million of proceeds from the exercise of stock options and the early exercise of unvested stock options, partially offset by $0.2 million of repurchases of early exercised stock options.

During the 2021 successor period, net cash provided by financing activities primarily consisted of $774.0 million in funding received from Illumina, offset by $625.7 million cash payments for acquisition consideration on behalf of Illumina, and by $4.3 million of taxes paid related to net share settlement of equity awards.

During the 2022 successor period, net cash provided by financing activities primarily consisted of $609.0 million in funding received from Illumina, offset by $4.2 million of taxes paid related to net share settlement of equity awards.

During fiscal year 2023, net cash provided by financing activities primarily consisted of $464.0 million in funding received from Illumina, offset by $0.2 million of taxes paid related to net share settlement of equity awards.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements.

Material Cash Requirements

Our material cash requirements include the following contractual and other obligations as of December 31, 2023:

Leases

Historically, we have entered into operating leases for facilities and equipment used for research and development. Operating leases have remaining lease terms which range from 1 year to 10 years, and often include one or more options to renew. These renewal terms can extend the lease term from 5 to 15 years and are included in the lease term when it is reasonably certain that the option will be exercised. The exercise of lease renewal and termination options are at the sole discretion of GRAIL. We also have variable lease payments that are primarily comprised of common area maintenance and utility charges. As of December 31, 2023, we had undiscounted operating lease payment obligations of $105.2 million, with $17.9 million payable within twelve months of December 31, 2023.

Purchase Commitments

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude purchase orders for goods and services that are cancellable. Our non-cancelable purchase orders represent authorizations to purchase rather than binding agreements. The Company's contractual commitment amounts are associated with agreements that are enforceable and legally binding and that specify all significant terms, including: fixed or minimum services to be used; fixed, minimum, or variable price provisions; and the approximate timing of the transaction. The purchase commitments primarily relate to contractual commitments for future use of web services, laboratory supplies and marketing events in the normal course of business. As of December 31, 2023, we had non-cancelable purchase obligations of $74.8 million, with $19.3 million payable within twelve months of December 31, 2023.

Minimum Royalties

Minimum royalty commitments are associated with licensing agreements related to research efforts. Minimum annual royalty payments do not include royalties that would be payable on net sales of Galleri or any future products, pursuant to existing agreements and licenses with Illumina, The Chinese University of Hong Kong, and other third parties in excess of minimum annual royalty payments. As of December 31, 2023, we had minimum royalties of $7.8 million, with $1.0 million payable within twelve months of December 31, 2023.

Critical Accounting Estimates

This discussion and analysis of our financial condition and results of operations is based on our audited Consolidated Financial Statements, which have been prepared in accordance with U.S. GAAP. The preparation of these audited 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 audited 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 elsewhere in this Information Statement, 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.

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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.

Cash-Based Equity Awards

We compensate our employees through a long-term incentive program that includes GRAIL cash-based equity incentive awards ("Cash-Based Equity Awards"). As these awards are indexed to the value of GRAIL and settled in cash, they are 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 have 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 results 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 do not have an actively traded standalone stock, GRAIL's stand-alone value calculation is estimated by the Company based on its analysis and on input from independent valuation advisors. To estimate the value of GRAIL, various assumptions may be used, such as our long-range financial projections, as well as the discount rate and terminal growth rate. 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.

Goodwill and Indefinite-Lived Intangible Impairment

Goodwill represents the costs in excess of the fair value of net assets of GRAIL acquired by Illumina. 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 one reporting unit.

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 our most recent analysis, we selected a discount rate of 24.0% for the goodwill assessment and 19.0% for the intangible assets assessment. 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. 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.

On July 13, 2022, the European General Court ruled that the European Commission had jurisdiction under the European Union Merger Regulation to review the Acquisition. Additionally, on September 6, 2022, the European Commission issued a decision prohibiting the Acquisition. These decisions constituted substantive changes in circumstances and led us to test goodwill for impairment. Based on our analysis, we concluded that our reporting unit's carrying value exceeded its estimated fair value. As a result, we recorded $4.7 billion of goodwill impairment, primarily due to the negative impact of capital market conditions and a higher discount rate selected for the fair value calculation of our business.

In the third quarter of 2023, we concluded that the sustained decrease in Illumina's stock price and overall market capitalization during the quarter was a triggering event indicating the fair value of GRAIL might be less than its carrying amount that led us to test goodwill for impairment. Based on our analysis, we concluded that the carrying value exceeded its estimated fair value. The Company recognized a goodwill impairment of $608.5 million as a result of the impairment assessment, primarily due to changes to expected timing of revenue and a higher discount rate selected for the fair value calculation of GRAIL. In conjunction with the 2023 goodwill impairment assessment, the IPR&D intangible asset was evaluated for potential impairment. 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 impairment of $110.0 million, primarily due to a decrease in projected cash flows and a higher discount rate selected for the fair value calculation.

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, upon completion of this offering, 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 audited Consolidated Financial Statements included elsewhere in this Information Statement for details of recent accounting pronouncements.

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 $97.3 million as of December 31, 2023, 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 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 Consolidated Financial Statements.

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MANAGEMENT

Executive Officers of GRAIL Following the Spin-Off

The following table and accompanying narrative present information, as of , 2023, regarding the individuals who are expected to serve as executive officers of GRAIL following the completion of the Spin-Off, including a five-year employment history. We are in the process of identifying any other persons who may be expected to serve as executive officers following the completion of the Spin-Off and will include information concerning those persons in an amendment to this Information Statement.

Name	Age	Position with GRAIL
Robert Ragusa	64	Chief Executive Officer
Aaron Freidin	45	Chief Financial Officer
Josh Ofman	59	President

Executive Officers

Robert Ragusa has served as our Chief Executive Officer since October 2021. Mr. Ragusa was previously Chief Operations Officer for Illumina from December 2013 until October 2021, where he was responsible for the company's operations serving clinical and research customers. Prior to joining Illumina, Mr. Ragusa was Executive Vice President of Engineering and Global Operations at Accuray Incorporated, a radiation oncology company, where he and his team were responsible for the development, manufacturing and distribution of innovative precision treatment solutions. Mr. Ragusa also previously served as Senior Vice President of Global Operations for Applied Biosystems from 1997 until 2005. Mr. Ragusa currently serves on the Board of Directors for Twist Bioscience Corporation, a publicly-held synthetic biology company, since December 2016. Mr. Ragusa holds a B.S. in electrical engineering and an M.B.A. from the University of Connecticut as well as an M.S. in biomedical and electrical engineering from Carnegie Mellon University.

Aaron Freidin has served as our Chief Financial Officer since November 2021 and previously served in various roles at GRAIL since 2018, including Senior Vice President of Finance from January 2021 until November 2021, Vice President of Finance from June 2018 until January 2021, and Corporate Controller from August 2016 until June 2018. Mr. Freidin previously served as VP, Corporate Controller at Counsyl, where he led the Accounting, Reporting, Facilities and Procurement functions. Before this, Mr. Freidin led the SEC Reporting and Revenue functions at Cepheid, and managed multinational and cross-functional client service teams at PricewaterhouseCoopers LLP. Mr. Freidin has over 20 years of finance and accounting experience. Mr. Freidin is a Certified Public Accountant (Inactive) and holds a B.A. in business management from the University of California, Santa Cruz.

Josh Ofman, M.D., MSHS, has served as our President since June 2021 and previously served as our Chief Medical Officer from November 2021 until June 2022, as our Chief Medical Officer and Head of External Affairs from June 2020 until August 2021, and as Chief of Corporate Strategy and External Affairs from June 2019 until January 2020. Mr. Ofman has served on the Board of Directors of Cell BT, Inc., a privately-held immuno-therapy company focused on the discovery and development of innovative cancer therapeutics, since July 2019. Previously, Mr. Ofman spent more than 15 years at Amgen, where he most recently held the role of Senior Vice President, Global Value, Access and Policy. Prior to that, Mr. Ofman was a faculty member in the Department of Medicine and Health Services Research at University of California, Los Angeles ("UCLA") School of Medicine, Cedars-Sinai Medical Center, as well as Senior Vice President of Zynx Health Inc. Mr. Ofman holds a B.A. in history and philosophy of science from the University of California, Berkeley, an M.D. from the University of California, Irvine, School of Medicine, and an MSHS from the UCLA School of Public Health.

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Board of Directors of GRAIL Following the Spin-Off

The following table and accompanying narrative present information, as of , 2023, regarding the individuals who are expected to serve on our Board of Directors (the "Board") following the completion of the Spin-Off and until their respective successors are duly elected and qualified, including a five-year employment history and any directorships held by our directors in public companies. We are in the process of identifying the persons who are expected to serve as directors following the completion of the Spin-Off and will include information concerning those persons in an amendment to this Information Statement.

Name	Age	Position with GRAIL

Director Nomination Process

Our initial Board will be selected through a process involving Illumina and us. The initial directors who will serve after the Spin-Off are expected to begin their terms at the time of the Distribution, except as noted below.

Board Structure and Composition

Upon completion of the Spin-Off, our Board will consist of members. Our board has determined that each of and is independent under the applicable Nasdaq Global Select Market rules.

Our directors will be divided into three classes serving staggered three-year terms. Class I, Class II, and Class III directors will serve until our annual meetings of stockholders in 2024, 2025, and 2026, respectively. The Class I directors will consist of , , and . The Class II directors will consist of , , and . The Class III directors will consist of , , and . At each annual meeting of stockholders, directors will be elected to succeed the class of directors whose terms have expired. This classification of our Board could have the effect of increasing the length of time necessary to change the composition of a majority of the Board. In general, at least two annual meetings of stockholders will typically be necessary for stockholders to effect a change in a majority of the members of the Board.

Executive Sessions

We expect that the independent directors will meet in executive session in which independent directors meet without the presence or participation of management at most regular Board meetings and meet in executive session at other times whenever they believe it appropriate. We expect that will chair the executive sessions of the independent directors.

Compensation Committee Interlocks and Insider Participation

During the fiscal year ended January 1, 2023, GRAIL did not have a compensation committee (or any other committee serving a similar function). Decisions as to the compensation of those who served as our executive officers for that fiscal year required agreement with Illumina (including its compensation committee) on a mutually acceptable and workable approach.

Committees of the Board

Effective immediately prior to the commencement of "when issued" trading, the Board will have a standing Audit Committee, and upon the completion of the Spin-Off, our Board is expected to have three additional standing committees: the Compensation Committee, the Nominating and Governance committee, and the Science, Medicine, and Technology Committee. Each committee is governed by a charter that will be available on our website following completion of this Spin-Off.

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Audit Committee

Following the completion of the Spin-Off, the members of our Audit Committee will consist of , , and and will be the chairperson of our Audit Committee. The composition of our Audit Committee meets the requirements for independence under the current listing standards of the Nasdaq Global Select Market and Rule 10A-3 of the Exchange Act. Each member of our Audit Committee is financially literate. In addition, our Board has determined that is an "audit committee financial expert" within the meaning of the SEC rules. This designation does not impose on such directors any duties, obligations, or liabilities that are greater than are generally imposed on members of our Audit Committee and our Board. Our Audit Committee is directly responsible for, among other things:

- appointing, retaining, compensating, and overseeing the work of our independent registered public accounting firm;
- assessing the independence and performance of the independent registered public accounting firm;
- reviewing with our independent registered public accounting firm the scope and results of the firm's annual audit of our financial statements;
- overseeing the financial reporting process and discussing with management and our independent registered public accounting firm the financial statements that we will file with the SEC;
- pre-approving all audit and permissible non-audit services to be performed by our independent registered public accounting firm;
- reviewing policies and practices related to risk assessment and management;
- reviewing our accounting and financial reporting policies and practices and accounting controls, as well as compliance with legal and regulatory requirements;
- reviewing, overseeing, approving, or disapproving any related-person transactions;
- reviewing with our management the scope and results of management's evaluation of our disclosure controls and procedures and management's assessment of our internal control over financial reporting, including the related certifications to be included in the periodic reports we will file with the SEC; and
- establishing procedures for the confidential anonymous submission of concerns regarding questionable accounting, internal controls, or auditing matters, or other ethics or compliance issues.

Compensation Committee

Following the completion of the Spin-Off, the members of our Compensation Committee will consist of , , and and will be the chairperson of our Compensation Committee. Each of , , and is a non-employee director, as defined by Rule 16B-3 of the Exchange Act and meet the requirements for independence under the current Nasdaq Global Select Market listing standards. Our Compensation Committee is directly responsible for, among other things:

- reviewing and approving the compensation of our executive officers, including reviewing and approving corporate goals and objectives with respect to compensation;
- authority to act as an administrator of our equity incentive plans;
- reviewing and approving, or making recommendations to our Board with respect to, incentive compensation and equity plans;
- reviewing and recommending that our Board approve the compensation for our non-employee board members; and
- establishing and reviewing general policies relating to compensation and benefits of our employees.

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Nominating and Governance Committee

Following the completion of the Spin-Off, the members of our Nominating and Governance Committee will consist of , , and and will be the chairperson of our Nominating and Governance Committee. , , and meet the requirements for independence under the current Nasdaq Global Select Market listing standards. Our Nominating and Governance Committee is responsible for, among other thing:

- identifying and recommending candidates for membership on our Board, including the consideration of nominees submitted by stockholders, and on each of the Board's committees;
- reviewing and recommending our corporate governance guidelines and policies;
- reviewing proposed waivers of the code of business conduct and ethics for directors and executive officers;
- overseeing the process of evaluating the performance of our Board; and
- assisting our Board on corporate governance matters.

Science, Medicine, and Technology Committee

Following the completion of the Spin-Off, the members of our Science, Medicine, and Technology Committee will consist of , , and and will be the chairperson of our Science, Medicine, and Technology Committee. Our Science, Medicine, and Technology Committee is responsible for, among other thing:

- advising our Board on key scientific, medical, and technological issues;
- reviewing, evaluating, and advising our Board regarding our performance in achieving long-term strategic goals and objectives and the quality and direction of our research and development programs; and
- assisting our Board with recruitment and retention of scientific and technological talent to advance our research and development programs.

Code of Business Conduct and Ethics

In connection with the Spin-Off, we will adopt a code of business conduct and ethics that applies to all of our employees, officers, and directors, including our Chief Executive Officer, Chief Financial Officer, and other executive and senior financial officers. Upon completion of the Spin-Off, the full text of our code of business conduct and ethics will be posted on the investor relations section of our website. We intend to disclose future amendments to our code of business conduct and ethics, or any waivers of such code, on our website or in public filings if required.

Director Compensation

We are currently in the process of determining the composition of our Board and of developing the details regarding the compensation packages of the directors who will comprise our Board. This is an ongoing process and we will include the relevant disclosure in an amendment to this Information Statement.

We did not have a board of directors in 2023 and we have not established a compensation program for our non-employee directors. In connection with the Spin-Off, we expect to approve and implement a compensation program for our non-employee directors that we expect will consist of annual retainer fees and long-term equity awards. We expect that directors who are also full-time officers or employees of our company will receive no additional compensation for serving as directors.

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EXECUTIVE COMPENSATION

This section discusses the material components of the executive compensation program for our named executive officers (NEOs) who are named in the "2023 Summary Compensation Table" below. In 2023, our NEOs and their positions were as follows:

- Robert Ragusa, Chief Executive Officer;
- Aaron Freidin, Chief Financial Officer; and
- Josh Ofman, President.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs and policies. Actual compensation programs and policies that we implement following the completion of the Spin-Off may differ materially from the currently planned programs and policies summarized in this discussion.

Summary Compensation Table

The following table sets forth information concerning the compensation awarded to or earned by our NEOs during our fiscal years ended December 31, 2023 and December 31, 2022.

2023 SUMMARY COMPENSATION TABLE

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)(2)	All Other Compensation ($)(3)	Total ($)
Robert Ragusa	2023	779,615	—	8,400,000	—	19,660	9,199,275
Chief Executive Officer	2022	746,154	1,000,000	2,100,000	875,000	—	4,721,154
Aaron Freidin	2023	556,154	—	2,800,000	—	3,000	3,359,154
Chief Financial Officer	2022	533,461	—	1,400,000	291,575	—	2,225,036
Josh Ofman	2023	654,154	—	3,300,000	—	99,118	4,053,272
President	2022	625,385	—	1,475,000	343,350	169,453	2,613,188

(1) The amounts shown in this column represent the grant date fair values of Cash-Based Equity Awards granted in 2022 or 2023, as applicable, as computed in accordance with Financial Accounting Standards Board (FASB) Accounting Standard Codification (ASC) Topic 718, rather than the amounts paid to or realized by the named individual. For a discussion of the assumptions used to determine the grant date fair value of these awards made to our NEOs in 2023, see Note 7—Stock Incentive Awards in the notes to our audited consolidated financial statements included elsewhere in this prospectus.

(2) With respect to 2023, amounts represent annual bonuses earned by each named executive officer in 2023 and payable in cash in 2024 under our VCP (discussed below under "2023 Annual Bonuses (Non-Equity Incentive Plan Awards)"), based on the attainment of pre-determined individual and company performance metrics. The amount of compensation payable under the VCP in respect of 2023 has not yet been determined; it is anticipated that any compensation under the VCP in respect of 2023 will be determined in the first quarter of 2024 and will be disclosed in a subsequent amendment to this Information Statement.

(3) Amounts in this column include the following for 2023: (i) for Mr. Ragusa: $3,000 in 401(k) plan matching contributions, $8,400 in GRAIL-provided dues for a membership in connection with a 2023 marketing event, $8,260 in payments made to offset taxes imposed on Mr. Ragusa with respect to his GRAIL-provided dues; (ii) for Mr. Freidin: $3,000 in 401(k) plan matching contributions; (iii) for Mr. Ofman: $3,000 in 401(k) plan matching contributions, $72, 079 in payments made to Mr. Ofman to offset his rent expense in 2023 (as contemplated by his initial offer of employment, GRAIL provides Mr. Ofman with a housing

allowance to enable him to spend significant time at GRAIL's headquarters in Menlo Park) and $24,039 in payments made to Mr. Ofman to offset taxes imposed on him with respect to his GRAIL-paid housing benefit.

2023 Salaries

The annual base salaries for Robert Ragusa, Aaron Freidin, and Josh Ofman for 2023 were $785,000 (increased from $750,000 in 2022), $560,000 (increased from $535,000 in 2022), and $655,000 (increased from $630,000 in 2022), respectively. Increases in base salary were approved following an analysis of market positioning against peers in alignment with our overall compensation philosophy.

2023 Annual Bonuses (Non-Equity Incentive Plan Awards)

Our annual Variable Compensation Program ("VCP") provides the opportunity to eligible employees, including our NEOs, to earn annual cash bonuses based on the achievement of pre-established corporate and individual performance goals for the applicable fiscal year. Individual VCP targets are determined by salary grade and expressed as a percentage of base pay—2023 target bonuses for Messrs. Ragusa, Freidin, and Ofman have not been changed since 2022 and were 100%, 50%, and 50% of applicable base salary, respectively. The payment of any annual bonus, if earned, is contingent upon the applicable participant's (i) continued employment or other service with the company through the applicable payment date, (ii) employment start date commencing on or prior to October 1 of the applicable fiscal year and (iii) continued compliance with company policy and applicable law.

Equity-Linked Compensation

Each of our NEOs currently holds Cash-Based Equity Awards representing dollar-denominated, long-term incentive awards which increase or decrease in value based on corresponding changes in our equity value. The Cash-Based Equity Awards generally vest and are paid out incrementally over a four-year period with twenty-five percent (25%) of the award vesting and paid (based on value as of the applicable vesting date) on or shortly after each of the first four anniversaries of the vesting commencement date, subject to continued employment through the applicable vesting date. If we experience a "change in control" (as provided in the Cash-Based Equity Award agreements), the Cash-Based Equity Awards will continue on their terms unless the Cash-Based Equity Awards are not assumed/continued or substituted for in connection with such change in control, in which case the Cash-Based Equity Awards will vest and be paid upon such change in control. The Cash-Based Equity Awards are generally paid in cash, but may be converted into Illumina restricted stock units at Illumina's election, in which case the converted awards would entitle the applicable holder to awards denominated in Illumina common shares and would be valued based on the fluctuation in value of Illumina shares.

For additional information about these awards, please see the sections titled "—Outstanding Equity Awards at Fiscal Year End" and "—Executive Compensation Arrangements" below. For information regarding their treatment in connection with the Spin-Off, see "The Spin-Off—Treatment of Outstanding Equity Incentive Awards" beginning on page 103 of this Information Statement.

We intend to adopt a 2024 Incentive Award Plan, referred to below as the 2024 Plan, in order to facilitate the grant of cash and equity incentives to directors, employees (including our NEOs) and consultants of our company and certain of our subsidiaries and to enable our company and certain of our subsidiaries to obtain and retain services of these individuals following the Spin-Off, which we view as essential to our long-term success. We expect that the 2024 Plan will become effective in connection with the Spin-Off, subject to approval of such plan by Illumina, in its capacity as our sole stockholder, as required by applicable listing requirements. For additional information about the 2024 Plan, please see the section titled "—Executive Compensation Arrangements—2024 Equity Incentive Plan" below.

Other Elements of Compensation

Retirement Plans

We maintain a tax-qualified 401(k) retirement savings plan for our employees, including our NEOs, who satisfy certain eligibility requirements. Our NEOs are eligible to participate in the 401(k) plan on the same terms generally as other eligible, full-time employees. The Code allows eligible employees to defer a portion of their compensation, within prescribed limits, on a pre-tax basis through contributions to the 401(k) plan. In 2023, we made matching contributions under our 401(k) plan, including for the NEOs, up to a specified percentage of employee contributions and a maximum of $3,000. These matching contributions vest in full after one year of service. We believe that providing a vehicle for tax-deferred retirement savings through our 401(k) plan adds to the overall desirability of our executive compensation package and further incentivizes our employees, including our NEOs, in accordance with our compensation policies.

Employee Benefits and Perquisites

Health/Welfare Plans. All of our full-time employees, including our NEOs, are eligible to participate in our health and welfare plans, including:

- medical, dental, and vision benefits;
- medical and dependent care flexible spending accounts;
- short-term and long-term disability insurance;
- wellbeing benefits (including mental health, back-up care and family forming benefits); and
- life insurance.

In addition, GRAIL made payments to Mr. Ofman and Mr. Ragusa to offset their rent expense and GRAIL-provided membership expense, respectively, in 2023.

We believe the benefits described above are in-line with market practice and necessary and appropriate to provide a competitive compensation package to our NEOs. There are no executive perquisites.

No IRC Section 280G "Golden Parachute" Tax Gross-Ups

Except for tax gross up payments (i) in the amount of $24,039 in 2023 paid to Mr. Ofman to offset taxes imposed on him with respect to his GRAIL-paid housing benefit and (ii) in the amount of $8,260 in 2023 paid to Mr. Ragusa to offset taxes imposed on him with respect to his GRAIL-paid dues, we do not make gross-up payments to cover our NEOs' personal income taxes that may pertain to any of the compensation or perquisites paid or provided by our company. Without limiting the foregoing, we have not paid, and have no obligation to pay, any tax gross-ups with respect to any excise taxes imposed under or by operation of the Internal Revenue Code Section 280G "golden parachute" rules.

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Outstanding Equity Awards at Fiscal Year End

The following table sets forth information concerning the number of shares of common stock underlying outstanding equity incentive awards for each NEO as of December 31, 2023.

		Option Awards (1)				Stock Awards(2)	
Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Price ($)(3)	Option Expiration Date	Number of shares or units of stock that have not vested (#)(4)	Market value of shares or units of stock that have not vested ($)(5)
Robert Ragusa	March 6, 2023(6)	—	—	—	—	NA	8,400,000
	March 4, 2022(6)	—	—	—	—	NA	1,651,979
	October 14, 2021(6)	—	—	—	—	NA	8,698,512
Aaron Freidin	March 6, 2023(6)	—	—	—	—	NA	2,800,000
	March 4, 2022(6)	—	—	—	—	NA	1,101,320
	November 16, 2021(6)	—	—	—	—	NA	2,036,993
	October 6, 2021(6)	—	—	—	—	NA	1,046,024
	February 17, 2018(7)	71	—	18.25	2/17/2028	—	—
Josh Ofman	March 6, 2023(6)	—	—	—	—	NA	3,300,000
	March 4, 2022(6)	—	—	—	—	NA	1,160,319
	October 6, 2021(6)	—	—	—	—	NA	4,954,849
	— (8)	—	9,786	90.77	3/6/2030	—	—

(1) Amounts disclosed in these columns represent options to purchase Illumina's common stock. These options were originally granted as options to purchase our Class A common stock and were converted to options to purchase Illumina's common stock in connection with GRAIL's acquisition by Illumina.

(2) Amounts disclosed in these columns represent Cash-Based Equity Awards awarded by GRAIL.

(3) The exercise price per share of each option granted was equal to the fair market value of our Class A common stock on the applicable grant date. The exercise price reflected in this column represents the price following the option's conversion into options to purchase Illumina's common stock.

(4) The Cash-Based Equity Awards disclosed here are dollar-denominated, cash-settled awards, the value of which fluctuates with, and is ultimately determined by reference to, the aggregate equity value of GRAIL at the time of settlement as compared to the aggregate equity value of GRAIL at the time of grant (in each case, as determined in accordance with the applicable award agreement). Accordingly, these awards do not cover a discernable number of shares of GRAIL common stock.

(5) Amounts in this column represent the aggregate estimated value of the outstanding Cash-Based Equity Awards as of December 31. 2023.

(6) These Cash-Based Equity Awards vest and are paid out incrementally over a four-year period with twenty-five percent (25%) of the award vesting and paid (based on value as of the applicable vesting date) on or shortly after each of the first four anniversaries of the vesting commencement date, subject to continued employment through the applicable vesting date.

(7) Represents Mr. Freidin's stock option award, which vested in full on November 6, 2022 based on the achievement of applicable performance metrics.

(8) Represents Mr. Ofman's stock option award with respect to Illumina's common stock, which is eligible to vest as to one thirty-sixth (1/36th) of the shares subject thereto on each monthly anniversary of the date on which GRAIL determines that it has delivered at least 250,000 GRAIL multi-cancer early detection blood tests for commercial use, in accordance with the terms and conditions set forth in the award agreement (the "Ofman performance condition"), subject to Mr. Ofman's continued service through the applicable vesting date; provided that (i) if Mr. Ofman's employment with GRAIL is terminated by GRAIL without cause or he resigns for good reason (each as defined in his award agreement) the stock option will vest as to the portion of the option that would have vested over the twelve month period immediately following the

termination date (provided that the Ofman performance condition has been satisfied prior to the termination date) and (ii) the stock option will vest in full in the event that Mr. Ofman's employment is terminated without cause or he resigns for good reason, in either case, during the period commencing three months before the announcement of the signing of a definitive agreement to consummate a change in control and ending twelve months following the consummation of such change in control. This option is early-exercisable, meaning that it can be exercised before it vests for restricted shares subject to the same vesting provisions as apply to the underlying option.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

EXECUTIVE COMPENSATION ARRANGEMENTS

Below is a description of the material terms of each employment contract, agreement, plan, or arrangement that provides for the employment of, and payments to, our NEOs (including such payments to be made at, following or in connection with the resignation, retirement, or other termination of an NEO, or following a change in control).

Offer Letters and Separation and General Release Agreement

Robert Ragusa Offer Letter

We have entered into an employment offer letter with Robert Ragusa, dated October 14, 2021, pursuant to which Mr. Ragusa serves as our Chief Executive Officer. Mr. Ragusa's employment pursuant to the offer letter is "at-will" and is terminable by either party with or without notice or cause.

Pursuant to his offer letter, Mr. Ragusa was entitled to receive an initial base salary of $725,000 (increased to $785,000 in 2023). In addition, pursuant to his offer letter, Mr. Ragusa is eligible to participate in our VCP with a target bonus of 100% of his base salary. In connection with his entry into his offer letter, Mr. Ragusa was granted a Cash-Based Equity Award with an initial award value of $15,800,000 (subject to adjustment based on changes in our equity value) vesting in annual increments as to 25% of the award on each of the first four anniversaries of grant, and received a signing bonus in the amount of $4,000,000, of which 50% was subject to clawback in the event of a voluntary resignation or termination by us without cause within 12 months of commencing employment with us. The offer letter also provides that Mr. Ragusa will be entitled to receive standard benefits in accordance with our policies.

Pursuant to the offer letter, if Mr. Ragusa's employment is terminated by us without cause or Mr. Ragusa resigns with good reason (each as defined in the offer letter), then, in addition to any accrued benefits and subject to his timely execution of an effective separation and release agreement in a form prescribed by us, Mr. Ragusa will be entitled to receive the following severance payments and benefits: (i) a lump-sum cash payment in an amount equal to the sum of (x) 12 months of base salary and (y) 100% of Mr. Ragusa's target bonus under the VCP, (ii) reimbursement for the cost of health benefits under COBRA for up to 12 months, and (iii) accelerated vesting of any outstanding equity award(s) (or portion thereof) that would have vested over 12 months following such termination had Mr. Ragusa's service not terminated (with performance-vesting awards being deemed vested at target).

In the event of a change in control transaction, if outstanding and unvested equity awards are not assumed by the acquirer or successor, Mr. Ragusa's outstanding and unvested equity awards shall accelerate in full as of immediately prior to the closing of the change in control transaction. In addition, pursuant to his offer letter, if Mr. Ragusa's employment is terminated by us without cause or he resigns for good reason, in either case, within 24 months following or within 3 months preceding a change in control, then Mr. Ragusa will instead be entitled to receive the following severance payments and benefits (subject to the same separation and release agreement requirements and in lieu of the amounts described above): (i) a lump-sum cash payment in an amount equal to 24 months of base salary, (ii) a lump-sum cash payment in an amount equal to 200% of Mr. Ragusa's target bonus under the VCP, (iii) reimbursement for the cost of health benefits under COBRA for up to 24 months, and (iv) full accelerated vesting of outstanding and unvested equity awards (including Cash-Based Equity Awards, and with performance vesting awards vesting based on target performance).

Aaron Freidin Letter Agreement

We have entered into a letter agreement with Aaron Freidin, dated July 5, 2018, pursuant to which Mr. Freidin's employment is "at-will" and terminable by either party with or without notice or cause. The letter agreement provides that if Mr. Freidin's employment is terminated by us without cause or Mr. Freidin resigns for

good reason (each as defined in the letter agreement), then, in addition to accrued benefits and subject to his timely execution of an effective separation and release agreement in a form prescribed by us, Mr. Freidin will be entitled to receive the following severance payments and benefits: (i) a lump-sum cash payment in an amount equal to nine months of base salary and (ii) reimbursement for the cost of health benefits under COBRA for up to nine months.

In addition, pursuant to Mr. Freidin's letter agreement, if Mr. Freidin's employment is terminated by us without cause or Mr. Freidin resigns for good reason, in either case, within 12 months following or 3 months preceding a change in control, then Mr. Freidin will instead be entitled to receive the following severance payments and benefits (subject to the same separation and release agreement requirements and in lieu of the amounts described above): (i) a lump-sum cash payment in an amount equal to 12 months of base salary, (ii) a lump-sum cash payment in an amount equal to 100% of Mr. Freidin's target bonus under the VCP, (iii) reimbursement for the cost of health benefits under COBRA for up to 12 months, and (iv) full accelerated vesting of outstanding and unvested equity awards (including Cash-Based Equity Awards and with performance vesting awards vesting based on target performance).

Josh Ofman Offer Letter

We have entered into an employment offer letter with Josh Ofman, dated May 13, 2019, pursuant to which Mr. Ofman serves as our President. Mr. Ofman's employment under the offer letter is "at-will" and is terminable by either party with or without notice or cause.

Pursuant to his offer letter, Mr. Ofman was entitled to receive an initial base salary of $500,000 (in 2023, Mr. Ofman's base salary was $655,000) and is eligible to participate in our VCP with a target bonus of 50% of his base salary. In connection with his entry into the offer letter, Mr. Ofman was granted an option to purchase 2,340,000 shares of Grail common stock, vesting as to one-fourth of the shares subject thereto on the first anniversary of the vesting commencement date and thereafter as to one-forty-eighth of the shares subject thereto on each monthly anniversary of the vesting commencement date, subject to continued service on the applicable vesting date, and received a signing bonus in the amount of $750,000, subject to clawback in the event of termination by us for cause or resignation by Mr. Ofman without good reason, in either case, within 12 months of commencing employment with us, and reimbursement for relocation expenses, also subject to clawback in the event of termination by us for cause or resignation by Mr. Ofman without good reason, in either case, within 12 months of the payment date. Mr. Ofman's relocation has not yet occurred and GRAIL has continued to reimburse Mr. Ofman for the cost of rental housing. Effective as of December 15, 2023, GRAIL committed to reimburse Mr. Ofman for up to 50% of Mr. Ofman's monthly housing rental cost, up to a maximum of $4,438 per month until February 28, 2025 and to pay an additional amount to Mr. Ofman to offset the amount of taxes payable by Mr. Ofman as a result of such reimbursement.

Pursuant to the offer letter, in the event that Mr. Ofman's employment is terminated by us without cause or Mr. Ofman resigns for good reason (each as defined in the offer letter), then, in addition to accrued benefits and subject to his timely execution of an effective separation and release agreement in a form prescribed by us, Mr. Ofman will be entitled to receive the following severance payments and benefits: (i) a lump-sum cash payment in an amount equal to nine months of base salary and (ii) reimbursement for the cost of health benefits under COBRA for up to nine months.

In addition, pursuant to the offer letter, in the event that Mr. Ofman's employment is terminated by us without cause or Mr. Ofman resigns for good reason, in either case, within 12 months following or 3 months preceding a change in control, then Mr. Ofman will instead be entitled to receive the following severance payments and benefits (subject to the same separation and release agreement requirements and in lieu of the amounts described above): (i) a lump-sum cash payment in an amount equal to 12 months of base salary, (ii) a lump-sum cash payment in an amount equal to 100% of Mr. Ofman's target bonus under the VCP, (iii) reimbursement for the cost of health benefits under COBRA for up to 12 months, and (iv) full accelerated

vesting of outstanding and unvested equity awards (including Cash-Based Equity Awards and with performance vesting awards vesting based on target performance).

2024 Equity Incentive Plan

We intend to adopt the 2024 Incentive Award Plan, or the 2024 Plan, subject to approval by Illumina, in its capacity as our sole stockholder, as required by applicable listing requirements, under which we may grant cash and equity incentive awards to eligible service providers in order to attract, motivate, and retain the talent for which we compete. The material terms of the 2024 Plan, as it is currently contemplated, are summarized below. Our board of directors is still in the process of developing the 2024 Plan and, accordingly, this summary is subject to change.

Eligibility and Administration. Our employees, consultants, and directors, and employees, consultants, and directors of our subsidiaries, will be eligible to receive awards under the 2024 Plan, however, only our employees will be eligible to receive incentive stock options ("ISOs"). Following the Spin-Off, the 2024 Plan will be administered by our board of directors with respect to awards to non-employee directors and by our compensation committee with respect to other participants, each of which may delegate its duties and responsibilities to committees of our board of directors and/or officers (referred to, collectively, as the plan administrator below), subject to certain limitations that may be imposed under the 2024 Plan, Section 16 of the Exchange Act, and/or stock exchange rules, as applicable. The plan administrator will have the authority to make all determinations and interpretations under, prescribe all forms for use with, and adopt rules for the administration of, the 2024 Plan, subject to its express terms and conditions. The plan administrator will also set the terms and conditions of all awards under the 2024 Plan, including any vesting and vesting acceleration conditions.

Shares Available. An aggregate of shares of our common stock will be available for issuance under awards granted pursuant to the 2024 Plan, which shares may be authorized but unissued shares or shares purchased in the open market. Notwithstanding anything to the contrary in the 2024 Plan, no more than shares of our common stock may be issued pursuant to the exercise of ISOs under the 2024 Plan.

The number of shares available for issuance will be increased annually on the first day of each calendar year beginning January 1, 2025 and ending on and including January 1, 2034, equal to the lesser of (A) % of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (B) such smaller number of shares as is determined by our board of directors.

If an award under the 2024 Plan expires, lapses, or is terminated, exchanged for, or settled in cash, surrendered, repurchased, canceled without having been fully exercised, or forfeited, any shares subject to such award may, to the extent of such forfeiture, expiration or cash settlement, be used again for new grants under the 2024 Plan. Further, shares delivered to us to satisfy the applicable exercise or purchase price of an award under the 2024 Plan and/or to satisfy any applicable tax withholding obligations (including shares retained by us from such award being exercised or purchased and/or creating the tax obligation) will become or again be available for grants under the 2024 Plan. The payment of dividend equivalents in cash in conjunction with any awards under the 2024 Plan will not reduce the shares available for grant under the 2024 Plan. However, the following shares may not be used again for grant under the 2024 Plan: (i) shares subject to SARs that are not issued in connection with the stock settlement of the stock appreciation rights ("SAR") on exercise and (ii) shares purchased on the open market with the cash proceeds from the exercise of options.

Awards granted under the 2024 Plan upon the assumption of, or in substitution for, awards authorized or outstanding under a qualifying equity plan maintained by an entity with which we enter into a merger or similar corporate transaction, or the conversion or substitution of the Cash-Based Equity Awards for awards under the 2024 Plan, in each case, will not reduce the shares available for grant under the 2024 Plan but will count against the maximum number of shares that may be issued upon the exercise of ISOs.

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The 2024 Plan provides that the sum of any cash compensation and the aggregate grant date fair value (determined as of the date of the grant under ASC Topic 718, or any successor thereto) of all awards granted to a non-employee director as compensation for services as a non-employee director during any calendar year may not exceed the amount equal to $, increased to $, in the fiscal year of a non-employee director's initial service as a non-employee director.

Awards. The 2024 Plan provides for the grant of stock options, including ISOs and non-qualified stock options ("NSOs"), SARs, restricted stock, dividend equivalents, restricted stock units ("RSUs"), and other stock- or cash-based awards. Certain awards under the 2024 Plan may constitute or provide for a deferral of compensation, subject to Section 409A of the Code, which may impose additional requirements on the terms and conditions of such awards. All awards under the 2024 Plan will be evidenced by award agreements, which will detail all terms and conditions of the awards, including any applicable vesting and payment terms and post-termination exercise limitations. Awards other than cash awards generally will be settled in shares of common stock, but the plan administrator may provide for cash settlement of any award. A brief description of each award type follows.

- *Stock Options and SARs*. Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, in contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Code are satisfied. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The exercise price of a stock option or SAR may not be less than 100% of the fair market value of the underlying share on the grant date (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute awards granted in connection with a corporate transaction. The term of a stock option or SAR may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders).
- *Restricted Stock*. Restricted stock is an award of nontransferable shares of our common stock that are subject to certain vesting conditions and other restrictions.
- *RSUs*. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met and may be accompanied by the right to receive the equivalent value of dividends paid on shares of common stock prior to the delivery of the underlying shares (i.e., dividend equivalent rights). The plan administrator may provide that the delivery of the shares underlying RSUs will be deferred on a mandatory basis or at the election of the participant. The terms and conditions applicable to RSUs will be determined by the plan administrator, subject to the conditions and limitations contained in the 2024 Plan.
- *Other Stock- or Cash-Based Awards*. Other stock- or cash-based awards are awards of cash, fully vested shares of our common stock and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock. Other stock- or cash-based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of compensation to which a participant is otherwise entitled.
- *Dividend Equivalents*. Dividend equivalents represent the right to receive the equivalent value of dividends paid on shares of our common stock and may be granted alone or in tandem with awards other than stock options or SARs. Dividend equivalents are credited as of the dividend record dates during the period between the date an award is granted and the date such award vests, is exercised, is distributed, or expires, as determined by the plan administrator. Dividend equivalents are only paid out to the extent that the vesting conditions of the underlying award are subsequently satisfied.

Certain Transactions. The plan administrator has broad discretion to take action under the 2024 Plan, as well as make adjustments to the terms and conditions of existing and future awards, to prevent the dilution or enlargement of intended benefits and facilitate necessary or desirable changes in the event of certain transactions

and events affecting our common stock, such as stock dividends, stock splits, mergers, acquisitions, consolidations, and other corporate transactions. In addition, in the event of certain non-reciprocal transactions with our stockholders known as "equity restructurings," the plan administrator will make equitable adjustments to the 2024 Plan and outstanding awards. In the event of a change in control of our Company (as defined in the 2024 Plan), to the extent that the surviving entity declines to continue, convert, assume, or replace outstanding awards, then all such awards will become fully vested and exercisable in connection with the transaction. If, however, the surviving entity assumes outstanding awards and, on or within 12 months of such change in control, a participant's employment or service is involuntarily terminated by the Company (or the surviving entity or its affiliates) other than for cause (as defined in the 2024 Plan) and other than due to death or disability (as defined in the 2024 Plan), then all such awards will become fully vested and exercisable as of the date of such termination. Awards under the 2024 Plan are generally non-transferrable, except by will or the laws of descent and distribution, or, subject to the plan administrator's consent, pursuant to a domestic relations order, and are generally exercisable only by the participant.

Foreign Participants, Claw Back Provisions, Transferability, and Participant Payments. The plan administrator may modify award terms, establish subplans and/or adjust other terms and conditions of awards, subject to the share limits described above, in order to facilitate grants of awards subject to the laws and/or stock exchange rules of countries outside of the United States. All awards will be subject to the provisions of any claw back policy implemented by our Company to the extent set forth in such claw back policy and/or in the applicable award agreement. With regard to tax withholding, exercise price, and purchase price obligations arising in connection with awards under the 2024 Plan, the plan administrator may, in its discretion, accept cash or check, shares of our common stock that meet specified conditions, a "market sell order," or such other consideration as it deems suitable.

Plan Amendment and Termination. The plan administrator may amend or terminate the 2024 Plan at any time; however, no amendment, other than an amendment that increases the number of shares available under the 2024 Plan, may materially and adversely affect an award outstanding under the 2024 Plan without the consent of the affected participant, and stockholder approval will be obtained for any amendment to the extent necessary to comply with applicable laws or to increase the director limit. The plan administrator will have the authority, without the approval of our stockholders, to "reprice" any stock option or SAR, or cancel any stock option or SAR in exchange for cash or another award when the option or SAR price per share exceeds the fair market value of the underlying shares. The 2024 Plan will remain in effect until the tenth anniversary of the date the board of directors adopted the 2024 Plan, unless earlier terminated by our board of directors.

2024 Employee Stock Purchase Plan

In connection with the Spin-Off, we intend to adopt the 2024 Employee Stock Purchase Plan, or the 2024 ESPP, subject to approval of such plan by Illumina, in its capacity as our sole stockholder, as required by applicable listing requirements. The material terms of the 2024 ESPP as it is currently contemplated are summarized below. Our board of directors is still in the process of developing the 2024 ESPP and, accordingly, this summary is subject to change.

The 2024 ESPP is comprised of two distinct components in order to provide increased flexibility to grant options to purchase shares under the 2024 ESPP to our U.S. and non-U.S. employees. Specifically, the 2024 ESPP authorizes (i) the grant of options to U.S. employees that are intended to qualify for favorable U.S. federal tax treatment under Section 423 of the Code (the "Section 423 Component") and (ii) the grant of options that are not intended to be tax qualified under Section 423 of the Code to facilitate participation for employees located outside of the U.S. who do not benefit from favorable U.S. federal tax treatment and to provide flexibility to comply with non-U.S. law and other considerations (the "Non-Section 423 Component"). Where permitted under local law and custom, we expect that the Non-Section 423 Component will generally be operated and administered on terms and conditions similar to the Section 423 Component.

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Shares Available for Awards; Administration. A total of shares of our common stock will initially be reserved for issuance under the 2024 ESPP. In addition, the number of shares available for issuance under the 2024 ESPP will be annually increased on January 1 of each calendar year beginning in 2025 and ending in and including 2034, by an amount equal to the lesser of (A) percent of the shares of our common stock outstanding on the final day of the immediately preceding calendar year and (B) such smaller number of shares as is determined by our board of directors. Our board of directors or a committee of our board of directors will administer and will have authority to interpret the terms of the 2024 ESPP and determine the eligibility of participants. We expect that the compensation committee will be the initial administrator of the 2024 ESPP.

Eligibility. We expect that our employees and the employees of certain of our subsidiaries participating in the 2024 ESPP from time to time, or our designated subsidiaries, will be eligible to participate in the 2024 ESPP if they meet the eligibility requirements under the 2024 ESPP established from time to time by the plan administrator, consistent with Section 423 of the Code, as applicable. However, an employee may not be granted rights to purchase stock under our 2024 ESPP if the employee, immediately after the grant, would own (directly or through attribution) stock possessing 5% or more of the total combined voting power or value of all classes of our common or other class of stock. Neither non-employee directors nor consultants are eligible to participate in the 2024 ESPP. Employees who choose not to participate, or who are not eligible to participate at the start of an offering period but who become eligible thereafter, may enroll in any subsequent offering period.

Grant of Rights. Stock will be offered under the 2024 ESPP during offering periods. The length of the offering periods under the 2024 ESPP will be determined by the plan administrator and may be up to twenty-seven months long. Employee payroll deductions will be used to purchase shares on each purchase date during an offering period. The purchase dates for each offering period will be the final trading day in the purchase period (or, if no purchase period is specified, the final day of the offering period). The number of purchase periods within, and purchase dates during, each offering period will be established by the plan administrator. Offering periods under the 2024 ESPP will commence when determined by the plan administrator. We expect the initial offering period under the 2024 ESPP to commence on the pricing date of our common stock in the Spin-Off. The plan administrator may, in its discretion, modify the terms of future offering periods.

The 2024 ESPP will permit participants to purchase shares of our common stock through payroll deductions of up to a specified percentage of their eligible compensation, which will include a participant's gross cash compensation for services to us, including prior-week adjustments, overtime payments, compensation paid by the company or an designated subsidiary during any leaves of absence, commissions, incentive compensation, and bonuses, but excluding education or tuition reimbursements, travel expenses, business and moving reimbursements, income received in connection with any compensatory equity awards, fringe benefits, other special payments, and all contributions made by the company or any designated subsidiary for the participant's benefit under any employee benefit plan. In any non-U.S. jurisdictions where participation in the 2024 ESPP through payroll deductions is prohibited (if any), the plan administrator may provide that an eligible employee may elect to participate through contributions to his or her account under the 2024 ESPP in a form acceptable to the plan administrator in lieu of or in addition to payroll deductions. The plan administrator will establish a maximum number of shares that may be purchased by a participant during any offering period or purchase period, which, in the absence of a contrary designation, will be 20,000 shares. In addition, no participant will be permitted to accrue the right to purchase stock under the Section 423 Component at a rate in excess of $25,000 worth of shares during any calendar year during which such a purchase right is outstanding (based on the fair market value per share of our common stock as of the first day of the offering period).

On the first trading day of each offering period, each participant will automatically be granted an option to purchase shares of our common stock. The option will be exercised on the applicable purchase date(s) during the offering period, to the extent of the payroll deductions (or contributions, as applicable) accumulated during the applicable purchase period. The purchase price of the shares, in the absence of a contrary designation by the plan administrator, will be 85% of the lower of the fair market value of our common stock on the first trading day of the offering period or on the applicable purchase date (which will be the final trading day of the applicable purchase period), whichever is lower. Participants may voluntarily end their participation in the 2024 ESPP at

any time at least two weeks prior to the end of the applicable offering period (or such longer or shorter period specified by the plan administrator in the applicable offering terms), and will be paid their accrued payroll deductions (and contributions, if applicable) that have not yet been used to purchase shares of common stock. If a participant withdraws from the 2024 ESPP during an offering period, the participant cannot rejoin until the next offering period. Participation ends automatically upon a participant's termination of employment.

A participant may not transfer rights granted under the 2024 ESPP other than by will or the laws of descent and distribution, and such rights are generally exercisable only by the participant.

Certain Transactions. In the event of certain non-reciprocal transactions or events affecting our common stock, the plan administrator will make equitable adjustments to the 2024 ESPP and outstanding rights. In the event of certain unusual or non-recurring events or transactions, including a change in control, the plan administrator may provide for (i) either the replacement of outstanding rights with other rights or property or termination of outstanding rights in exchange for cash, (ii) the assumption or substitution of outstanding rights by the successor or survivor corporation or parent or subsidiary thereof, if any, (iii) the adjustment in the number and type of shares of stock subject to outstanding rights, (iv) the use of participants' accumulated payroll deductions to purchase stock on a new purchase date prior to the next scheduled purchase date and termination of any rights under ongoing offering periods, or (v) the termination of all outstanding rights.

Plan Amendment. The plan administrator may amend, suspend, or terminate the 2024 ESPP at any time. However, stockholder approval will be obtained for any amendment that increases the aggregate number or changes the type of shares that may be sold pursuant to rights under the 2024 ESPP.

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Pursuant to 17 C.F.R. Section 200.83

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

As of the date of this Information Statement, Illumina beneficially owns all the outstanding shares of our common stock. After the Spin-Off, Illumina may own up to 14.5% of our common stock.

The following tables provide information regarding the anticipated beneficial ownership of our common stock at the time of the Distribution. Except as otherwise noted below, we based the share amounts on each person's beneficial ownership of Illumina common stock on , 2024, giving effect to a distribution ratio pursuant to which, for every share[s] of Illumina common stock he, she, or it held, share[s] of our common stock will be distributed. Immediately following the Spin-Off, we estimate that of our common stock will be issued and outstanding, based on the approximately shares of Illumina common stock outstanding on , 2024. The actual number of shares of our common stock outstanding following the Spin-Off will be determined on the Record Date, , 2024.

To the extent our directors and executive officers own Illumina common stock at the Record Date of the Spin-Off, they will participate in the Distribution on the same terms as other holders of Illumina common stock.

Share Ownership Information for Directors and Officers

The following table shows the number of shares of GRAIL common stock expected to be beneficially owned by our current directors, named executive officers and directors and executive officers as a group immediately following the Distribution based on the assumptions set forth above. None of these individuals, or the group as a whole, would be expected to beneficially own more than 1 percent of our common stock immediately following the Distribution. Except as otherwise noted in the footnotes below, each person or entity identified in the table has sole voting and investment power with respect to the securities he, she, or it holds.

Certain Beneficial Owners

The following table shows all holders known to GRAIL that are expected to be beneficial owners of more than 5 percent of the outstanding shares of GRAIL common stock immediately following the completion of the Distribution based on the assumptions set forth above.

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CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Agreements with Illumina

Following the Spin-Off, we and Illumina will operate independently. Immediately after the Distribution becomes effective, Illumina may retain up to 14.5% of our common stock and we will not have any ownership interest in Illumina. Illumina expects that the IRS private letter ruling will require that all retained shares be sold or otherwise disposed of by Illumina as soon as warranted consistent with the business reasons for the retention of those shares, but in no event later than five years after the Distribution. Such dispositions could include a sale of its shares for cash, distributions of GRAIL common stock to Illumina stockholders or securityholders as dividends, or in exchange for outstanding shares of Illumina common stock, indebtedness, or other securities, or any combination thereof. In order to govern the ongoing relationships between us and Illumina after the Spin-Off and to facilitate an orderly transition, we intend to enter into a series of agreements with Illumina to effect the Spin-Off, to provide a framework for the relationship between GRAIL and Illumina after the separation and to provide for various rights and obligations following the Spin-Off, in each case, pursuant to which we and Illumina will agree to indemnify each other against certain liabilities arising from our respective businesses. The following summarizes the terms of the material agreements we expect to enter into with Illumina. The summaries of these agreements are qualified in their entirety by reference to the full text of the applicable agreements, which will be filed as exhibits to our Registration Statement on Form 10, of which this Information Statement is a part.

Separation and Distribution Agreement

We and Illumina intend to enter into a Separation and Distribution Agreement that will set forth our agreements with Illumina regarding the principal actions to be taken in connection with the Spin-Off. It will also set forth other agreements that govern aspects of our relationship with Illumina following the Spin-Off.

The Distribution

The Separation and Distribution Agreement will govern Illumina's and our respective rights and obligations regarding the proposed Distribution. On or prior to the Distribution, Illumina will deliver at least 85.5% of the issued and outstanding shares of our common stock to the distribution agent. Following the Distribution Date, the distribution agent will electronically deliver the shares of our common stock to Illumina stockholders based on the distribution ratio. The Illumina Board will have the sole and absolute discretion to determine the terms of, and whether to proceed with, the Distribution.

Conditions

The Separation and Distribution Agreement will also provide that several conditions must be satisfied or waived by Illumina in its sole and absolute discretion before the Distribution can occur. For further information about these conditions, see the section entitled "The Spin-Off—Conditions to the Spin-Off" beginning on page 108 of this Information Statement. The Illumina Board may, in its sole and absolute discretion, determine the Record Date, the Distribution Date and the terms of the Spin-Off and may at any time prior to the completion of the Spin-Off decide to abandon or modify the Spin-Off.

Termination

The Illumina Board, in its sole and absolute discretion, may terminate the Separation and Distribution Agreement at any time prior to the Distribution.

Indemnification

We and Illumina will each agree to indemnify the other and each of the other's former and current directors, officers, and employees, and each of the heirs, executors, successors, and assigns of any of them, against certain

liabilities incurred in connection with the Spin-Off and our and Illumina's respective businesses. The amount of either Illumina's or our indemnification obligations will be reduced by any insurance proceeds the party being indemnified receives. The Separation and Distribution Agreement will also specify procedures regarding claims subject to indemnification.

Tax Matters Agreement

We and Illumina intend to enter into a tax matters agreement (the "Tax Matters Agreement") prior to the Distribution that will govern the parties' respective rights, responsibilities, and obligations after the Distribution with respect to all tax matters (including tax liabilities, tax attributes, tax returns, and tax contests). The material terms of this agreement will be described in a subsequent amendment to this Information Statement.

Stockholder and Registration Rights Agreement

We and Illumina intend to enter into a stockholder and registration rights agreement (the "Stockholder and Registration Rights Agreement") pursuant to which we will grant to Illumina certain registration rights with respect to the shares of our common stock owned by Illumina. Illumina may transfer these rights in certain limited circumstances, including in connection with an equity-for-debt exchange to a third-party lender (a "Permitted Transferee" and, collectively with Illumina, "Holders"), and such Holders will thereafter be bound by the terms of the Stockholder and Registration Rights Agreement.

Demand Registration

Holders will be able to request registration under the Securities Act of all or any portion of their shares of our common stock covered by the Stockholder and Registration Rights Agreement, and we will be obligated, subject to limitations on minimum offering size and certain other limited exceptions, to register such shares as requested by such Holders. Holders will be able to designate the terms of each offering effected pursuant to a demand registration, which may take the form of a shelf registration, and will be able to request that we complete up to demand registrations in any 12-month period.

We will not be required to honor a demand registration if we have effected a registration within the preceding days. In addition, if we reasonably determine in good faith that filing a registration statement would be significantly disadvantageous to us, we may, no more than during any 12-month period, delay filing such registration statement until the earlier of days after we make such determination or days after the disadvantageous condition no longer exists.

Piggy-Back Registration

If we at any time intend to file on our behalf or on behalf of any of our other security holders a registration statement in connection with a public offering of any of our securities on a form and in a manner that would permit the registration for offer and sale of shares of our common stock held by Holders, Holders will have the right to include their shares of our common stock in that offering, subject to certain limitations.

Indemnification

The Stockholder Registration Rights Agreement will contain customary indemnification and contribution provisions by us for the benefit of Holders and, in limited situations, by Holders for the benefit of us with respect to the information provided by such Holders included in any registration statement, prospectus, or related document.

Ongoing Commercial Agreements

In addition to the above agreements, we are also currently party to, or intend to enter into, various other agreements with Illumina and its subsidiaries, including a supply and commercialization agreement and license agreements.

In January 2016, we entered into a supply and commercialization agreement with Illumina. The agreement was amended and restated in February 2017, and subsequently amended in September 2017 and December 2019. Under the terms of the agreement, we agreed to pay to Illumina a high single-digit royalty, subject to certain reductions, on net sales generated by our products or revenues otherwise generated or received by us regardless of whether these products incorporate any Illumina intellectual property, subject to certain exceptions, in the field of oncology in perpetuity. In August 2021, following Illumina's acquisition of GRAIL, the agreement was further amended to suspend the royalty as long as GRAIL is an affiliate of Illumina. The Divestment Plan (as defined in the section entitled "The Spin-Off—Background" beginning on page 98 of this Information Statement) permits Illumina to maintain the royalty arrangement with GRAIL. In connection with the separation of GRAIL from Illumina via the Spin-Off, GRAIL will no longer be an affiliate of Illumina, and the Supply Agreement will be further amended to extend the suspension of the perpetual royalty agreement until the earlier of two-and-a-half years or any earlier change of control of GRAIL, at which time royalty payments will resume, without retroactive effect. In addition, when the perpetual royalty obligation to Illumina restarts, we may elect to have either the Open Offer or the Grandfathered Pricing.

Under the agreement, Illumina granted us non-exclusive rights to use certain Illumina know-how and technology with Illumina products purchased under the agreement, and we granted Illumina an irrevocable, perpetual, worldwide, fully paid-up, and royalty-free license covering improvements to certain Illumina know-how and technology. Pursuant to the agreement, we were also required to develop a small-variant targeted plasma assay and deliver it to Illumina, which we have done. We retain ownership of the intellectual property generated by the development of this assay, and we have granted Illumina an irrevocable, perpetual, non-exclusive license to use any of the intellectual property embodied in this assay, with certain limitations on sublicensing.

The term of the agreement is 10 years, subject to two-year automatic renewal periods unless one of the parties terminates prior to such renewal period; however, the term is limited to a maximum term of 20 years. The agreement may also be terminated by either party for uncured material breach or bankruptcy or insolvency of the other party. Illumina may terminate the agreement if it is notified by any regulatory authority that our performance under the agreement materially violates an applicable law or due to a change of control of GRAIL involving a competitor of Illumina. Upon the termination of the agreement for any reason, the licenses granted to us by Illumina under the agreement would terminate but our licenses to Illumina survive the termination of the agreement. Our royalty payment obligations also survive the termination of this agreement. In February 2019, pursuant to the terms of the supply and commercialization agreement with Illumina, we entered into two separate non-exclusive and non-sublicensable license agreements with Illumina. Under these license agreements, Illumina is required to pay us (i) initial aggregate licensing fees of $50,000, (ii) annual minimum aggregate royalties of $50,000, increasing by $10,000 annually to a maximum of $100,000, and (iii) running royalties in the low percentages of net sales of products utilizing in-licensed technology. In addition, one of the license agreements includes a milestone of $50,000 tied to the first commercial sale of a product covered by a licensed patent.

Other Arrangements

Prior to the Spin-Off, we have had various other arrangements with Illumina, including arrangements whereby (i) pursuant to the binding Hold Separate Commitments put in place by Illumina and the Transitional Measures imposed by the European Commission, GRAIL has been held and operated separately and independently from Illumina and Illumina funded GRAIL's operations and (ii) in connection with Illumina's acquisition of GRAIL in 2021 (the "Acquisition"), Illumina issued to the then-holders of GRAIL common stock

and preferred stock, at each holder's election in lieu of cash consideration otherwise payable in the Acquisition, contingent value rights ("CVRs") representing the right to receive future cash payments from Illumina on a quarterly basis representing a pro rata portion of certain GRAIL-related revenues. Subject to the terms of the Divestment Plan to be approved by the European Commission, Illumina may (i) conduct a tender offer to acquire all issued and outstanding CVRs and, if permitted under the terms of the CVR Agreement, redeem all remaining outstanding CVRs or (ii) retain the CVR liability and continue its obligation to make payments following the Spin-Off. GRAIL does not currently have, and following the Spin-Off, will not have any obligation to make payments in respect of the CVRs.

Policy and Procedures Governing Related Person Transactions

We have a written Related-Persons Transaction Policy, to be effective upon the completion of the Spin-Off, that applies to our executive officers, directors, director nominees, holders of more than five percent of any class of our voting securities, and any member of the immediate family of, and any entity affiliated with, any of the foregoing persons. Such persons will not be permitted to enter into a related person transaction with us without the prior consent of our Audit Committee, or other independent members of our Board in the event it is inappropriate for our Audit Committee to review such transaction due to a conflict of interest. Any request for us to enter into a transaction with an executive officer, director, director nominee, principal stockholder, or any of their immediate family members or affiliates, in which the amount involved exceeds $120,000, must first be presented to our Audit Committee for review, consideration, and approval. In approving or rejecting any such proposal, our Audit Committee will consider the relevant facts and circumstances available and deemed relevant to our Audit Committee, including, but not limited to, the commercial reasonableness of the terms of the transaction and the materiality and character of the related person's direct or indirect interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

DESCRIPTION OF OUR CAPITAL STOCK

General

Prior to the Distribution Date, our Board of Directors (the "Board"), will approve and adopt our Certificate of Incorporation and our Bylaws. The following summarizes information concerning our capital stock, including material provisions of our Certificate of Incorporation and our Bylaws that will be in effect at the time of the Distribution and certain provisions of Delaware law. You are encouraged to read the forms of our Certificate of Incorporation and our Bylaws, which will be filed as exhibits to our Registration Statement on Form 10, of which this Information Statement is part, for greater detail with respect to these provisions.

Authorized Capital Stock

Immediately following the Spin-Off, our authorized capital stock will consist of shares of common stock, par value $0.001 per share and shares of preferred stock, par value $0.001 per share.

Common Stock

Shares Outstanding. Immediately following the Spin-Off, we estimate that approximately shares of our common stock will be issued and outstanding, based in part on approximately shares of Illumina common stock outstanding as of , 2024. The actual number of shares of our common stock outstanding immediately following the Spin-Off will depend, in part, on the actual number of shares of Illumina common stock outstanding on the Record Date, and will reflect any issuance of new shares or exercise of outstanding options pursuant to Illumina's equity-based incentive compensation plans on or prior to the Record Date. There will be no shares of preferred stock outstanding.

Dividend Rights. Holders of shares of our common stock will be entitled to receive dividends when, as and if declared by our Board at its discretion out of funds legally available for that purpose, subject to the preferential rights of any preferred stock that may be outstanding. See the sections entitled "Dividend Policy" and "Risk Factors—Risks Relating to Our Common Stock—We do not expect to pay any dividends for the foreseeable future" beginning on pages 110 and 90 respectively, of this Information Statement.

Voting Rights. Each share of common stock is entitled to one vote upon any matter submitted to a vote of our stockholders, including the election of directors. Holders of our common stock will vote as a single class on all matters submitted to a stockholder vote, subject to any voting rights granted to holders of any preferred stock. Holders of the common stock are not entitled to any cumulative voting rights.

Liquidation. In the event of our liquidation, dissolution, or winding up, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities, subject to prior distribution rights of preferred stock, if any, then outstanding.

Other Rights. The holders of our common stock have no preemptive rights or other subscription rights.

There are no redemption or sinking fund provisions applicable to our common stock.

Preferred Stock

Our Board has the authority to issue the preferred stock in one or more series and to fix the rights, preferences, privileges, and restrictions thereof, including dividend rights, dividend rates, conversion rights, voting rights, terms of redemption, redemption prices, liquidation preferences, and the number of shares constituting any series or the designation of such series, without further vote or action by the stockholders. The issuance of preferred stock may have the effect of delaying, deterring, or preventing a change in control of our company without further action by the stockholders and may adversely affect the voting and other rights of the holders of common stock. At present, we have no plans to issue any of the preferred stock.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

Certain Provisions of Delaware Law, Our Certificate of Incorporation and Bylaws

Election and Removal of Directors; Vacancies

Our Board will consist of between five and fifteen directors. The exact number of directors will be fixed from time to time by resolution of the Board. Directors will be elected by a plurality of the votes of the shares of our capital stock present in person or represented by proxy at the meeting and entitled to vote on the election of directors.

No director may be removed except for cause, and directors may be removed for cause only by an affirmative vote of shares representing not less than a majority of the shares then entitled to vote at an election of directors.

Any vacancy occurring on the Board and any newly created directorship may be filled only by a majority of the remaining directors in office.

Staggered Board

Immediately after the Spin-Off, our Board will be divided into three classes serving staggered three-year terms. Class I, Class II, and Class III directors will serve until our annual meetings of stockholders in 2024, 2025 and 2026, respectively. At each annual meeting of stockholders, directors will be elected to succeed the class of directors whose terms have expired. This classification of our Board could have the effect of increasing the length of time necessary to change the composition of a majority of the Board. In general, at least two annual meetings of stockholders will typically be necessary for stockholders to effect a change in a majority of the members of the Board.

Limitation on Action by Written Consent

Our Certificate of Incorporation and our Bylaws provide that holders of our common stock will not be able to act by written consent without a meeting.

Stockholder Meetings

Our Certificate of Incorporation and our Bylaws provide that special meetings of our stockholders may be called only by a majority of the directors. Our Certificate of Incorporation and our Bylaws specifically deny any power of any other person to call a special meeting.

Amendment of Certificate of Incorporation

The provisions of our Certificate of Incorporation described under "—Election and Removal of Directors; Vacancies," "—Stockholder Meetings," "—Limitation on Action by Written Consent," "—Limitation of Liability of Directors and Officers," "—Common Stock—Voting Rights," and "—Forum Selection" and provisions relating to amendments to our Certificate of Incorporation may be amended only by the affirmative vote of holders of at least 66-2/3% of the voting power of our outstanding shares of voting stock. The affirmative vote of holders of at least a majority of the voting power of our outstanding shares of stock will generally be required to amend other provisions of our Certificate of Incorporation.

Amendment of Bylaws

Certain provisions of our Bylaws may generally be altered, amended, or repealed, and new bylaws may be adopted, with the affirmative vote of a majority of directors present at any regular or special meeting of the Board called for that purpose, provided that any alteration, amendment, or repeal of, or adoption of any bylaw inconsistent with specified provisions of the bylaws, including those related to special and annual meetings of

stockholders, action of stockholders by written consent, nomination of directors, transfers of capital stock and dividends requires the affirmative vote of at least 66-2/3% of all directors in office at a meeting called for that purpose.

All other provisions of our Bylaws may generally be altered, amended, or repealed, and new bylaws may be adopted, with the affirmative vote of holders of 66-2/3% of the voting power of our outstanding shares of voting stock.

Other Limitations on Stockholder Actions

Our Bylaws impose some procedural requirements on stockholders who wish to:

- make nominations in the election of directors;
- propose that a director be removed;
- propose any repeal or change in our Bylaws; or
- propose any other business to be brought before an annual or special meeting of stockholders.

Under these procedural requirements, in order to bring a proposal before a meeting of stockholders, a stockholder must deliver timely notice of a proposal pertaining to a proper subject for presentation at the meeting to our corporate secretary along with the following:

- a description of the business or nomination to be brought before the meeting and the reasons for conducting such business at the meeting;
- the stockholder's name and address;
- any material interest of the stockholder in the proposal;
- the number of shares beneficially owned by the stockholder and evidence of such ownership; and
- the names and addresses of all persons with whom the stockholder is acting in concert and a description of all arrangements and understandings with those persons, and the number of shares such persons beneficially own.

To be timely, a stockholder must generally deliver notice:

- in connection with an annual meeting of stockholders, not less than 120 nor more than 150 days prior to the date on which the annual meeting of stockholders was held in the immediately preceding year, but in the event that the date of the annual meeting is more than 30 days before or more than 70 days after the anniversary date of the preceding annual meeting of stockholders, a stockholder notice will be timely if received by us not later than the close of business on the later of (1) not less than 70 nor more than 120 days prior to the date of the annual meeting and (2) the 10th day following the day on which we first publicly announce the date of the annual meeting; or
- in connection with the election of a director at a special meeting of stockholders, during the period not less than 120 nor more than 150 days prior to the date of the special meeting, or the 10th day following the day on which a notice of the date of the special meeting was mailed to the stockholders or the public disclosure of that date was made.

In order to submit a nomination for our Board, a stockholder must also submit all information with respect to the nominee that would be required to be included in a proxy statement, as well as other information. If a stockholder fails to follow the required procedures, the stockholder's proposal or nominee will be ineligible and will not be voted on by our stockholders.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

Indemnification of Directors and Officers and Limitation of Liability of Directors and Officers

Section 145 of the Delaware General Corporation Law provides that a corporation may indemnify directors and officers as well as other employees and agents against expenses (including attorneys' fees), judgments, fines, and amounts paid in settlement actually and reasonably incurred by such person in connection with any threatened, pending, or completed actions, suits, or proceedings in which such person is made a party by reason of such person being or having been a director, officer, employee, or agent to the registrant. The Delaware General Corporation Law provides that Section 145 is not exclusive of other rights to which those seeking indemnification may be entitled under any bylaw, agreement, vote of stockholders or disinterested directors or otherwise.

Our Certificate of Incorporation provides that, to the fullest extent permitted by law, we will indemnify any officer or director of our company against all damages, claims, and liabilities arising out of the fact that the person is or was our director or officer, or served any other enterprise at our request as a director or officer. Amending this provision will not reduce our indemnification obligations relating to actions taken before an amendment. GRAIL has entered into indemnification agreements with each of its current directors, executive officers, and certain other officers to provide these directors and officers additional contractual assurances regarding the scope of the indemnification set forth in our Certificate of Incorporation and our Bylaws and to provide additional procedural protections. There is no pending litigation or proceeding involving a director or executive officer of GRAIL for which indemnification has been sought.

Our Certificate of Incorporation also provides that no director or officer will be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director or officer, except as required by applicable law, as in effect from time to time. Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director or officer of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director or officer, except for liability of:

- a director or officer for any breach of the director's or officer's duty of loyalty to our company or our stockholders;
- a director of officer for any act or omission not in good faith or which involved intentional misconduct or a knowing violation of law;
- a director for unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law;
- a director or officer for any transaction from which the director or officer derived an improper personal benefit; and
- an officer in any action by or in the right of our company.

As a result, neither we nor our stockholders have the right, through stockholders' derivative suits on our behalf, to recover monetary damages against a director or officer for breach of fiduciary duty as a director or officer, including breaches resulting from grossly negligent behavior, except in the situations described above.

Forum Selection

Our Certificate of Incorporation provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on behalf of us; (ii) any action asserting a claim of breach of fiduciary duty owed by any director, officer, or other employee of our company to us or our stockholders; (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or our Certificate of Incorporation and bylaws; or (iv) any action asserting a claim governed by the internal affairs doctrine. This provision would not apply to claims brought to enforce a duty or liability created by the Securities

Exchange Act of 1934, as amended, or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, our Certificate of Incorporation will also provide 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 of 1933, as amended. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock shall be deemed to have notice of and have consented to the foregoing forum selection provisions.

Our exclusive forum provision will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations.

The enforceability of similar federal court choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find this type of provision to be inapplicable or unenforceable. If a court were to find either of the choice of forum provisions contained in our Certificate of Incorporation or Bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

The choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with the company or its directors, officers or other employees, which may discourage such lawsuits against the company and its directors, officers, and other employees and result in increased costs for investors to bring a claim.

Delaware Business Combination Statute

We have elected to be subject to Section 203 of the Delaware General Corporation Law. Section 203 prevents an "interested stockholder," which is defined generally as a person owning 15% or more of a corporation's voting stock, or any affiliate or associate of that person, from engaging in a broad range of "business combinations" with the corporation for three years after becoming an interested stockholder unless:

- the Board of the corporation had previously approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, that person owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, other than statutorily excluded shares; or
- following the transaction in which that person became an interested stockholder, the business combination is approved by the Board of the corporation and holders of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

Under Section 203, the restrictions described above also do not apply to specific business combinations proposed by an interested stockholder following the announcement or notification of designated extraordinary transactions involving the corporation and a person who had not been an interested stockholder during the previous three years or who became an interested stockholder with the approval of a majority of the corporation's directors, if such extraordinary transaction is approved or not opposed by a majority of the directors who were directors prior to any person becoming an interested stockholder during the previous three years or were recommended for election or elected to succeed such directors by a majority of such directors.

Section 203 may make it more difficult for a person who would be an interested stockholder to effect various business combinations with a corporation for a three-year period. Section 203 also may have the effect of preventing changes in our management and could make it more difficult to accomplish transactions that our stockholders may otherwise deem to be in their best interests.

Anti-Takeover Effects of Some Provisions

Certain provisions of our Certificate of Incorporation and Bylaws could make the following more difficult:

- acquisition of control of us by means of a proxy contest, tender offer, or otherwise; or
- removal of our incumbent officers and directors.

These provisions, as well as our ability to issue preferred stock, are designed to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our Board. We believe that the benefits of increased protection give us the potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us, and that the benefits of this increased protection outweigh the disadvantages of discouraging those proposals, because negotiation of those proposals could result in an improvement of their terms.

Registration Rights

We and Illumina intend to enter into a Stockholder and Registration Rights Agreement. For additional information, see "Certain Relationships and Related Party Transactions—Stockholder and Registration Rights Agreement" beginning on page 218 of this Information Statement.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be Computershare.

Stock Exchange Listing

We intend to list our common stock on the Nasdaq Global Select Market under the ticker symbol "GRAL."

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

WHERE YOU CAN FIND MORE INFORMATION

We have filed a Registration Statement on Form 10 with the SEC with respect to the shares of our common stock that Illumina's stockholders will receive in the Distribution, as contemplated by this Information Statement. This Information Statement is a part of, and does not contain all the information set forth in, the Registration Statement and the other exhibits and schedules to the Registration Statement. For further information with respect to us and our common stock, please refer to the Registration Statement, including its other exhibits and schedules. Statements we make in this Information Statement relating to any contract or other document are not necessarily complete, and you should refer to the exhibits attached to the Registration Statement for copies of the actual contract or document.

As a result of the Spin-Off, we will become subject to the information and reporting requirements of the Securities Exchange Act of 1934, which we refer to as the "Exchange Act," and, in accordance with the Exchange Act, we will file periodic reports, proxy statements, and other information with the SEC. The SEC maintains a website, www.sec.gov, that contains periodic reports, proxy statements, and information statements and other information regarding issuers, like us, that file electronically with the SEC. The Registration Statement, including its exhibits and schedules, and the periodic reports, proxy statements, and information statements and other information that we file electronically with the SEC will be available for inspection and copying at the SEC's website.

You can also find a copy of the Registration Statement and our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, in each case, filed with or furnished to the SEC pursuant to the Exchange Act, on our website, https://grail.com, which we will make available free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Information contained on, or connected to, any website we refer to in this Information Statement does not and will not constitute a part of this Information Statement or the Registration Statement of which this Information Statement is a part.

We intend to furnish holders of our common stock with annual reports containing financial statements prepared in accordance with GAAP and audited and reported on, with an opinion expressed, by an independent registered public accounting firm.

You should rely only on the information contained in this Information Statement or to which this Information Statement has referred you. We have not authorized any person to provide you with different information or to make any representation not contained in this Information Statement.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

Report of Independent Registered Public Accounting Firm

To the Board of Directors of Illumina, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated financial statements of GRAIL, LLC (Successor), which comprise the consolidated balance sheets as of December 31, 2023 and January 1, 2023, and the related consolidated statements of operations and comprehensive loss, member's equity and cash flows for the period from August 19, 2021 to January 2, 2022 and for the years ended January 1, 2023 and December 31, 2023, and the related notes to the financial statements, and the consolidated financial statements of GRAIL, Inc. (Predecessor), which comprise the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' deficit and cash flows for the period from January 1, 2021 to August 18, 2021, and the related notes to the consolidated financial statements, collectively referred to as the consolidated financial statements. In our opinion the consolidated financial statements present fairly in all material respects, the financial position of the Successor at December 31, 2023 and January 1, 2023, and the results of operations and cash flows of the Successor for the period from August 19, 2021 to January 2, 2022 and for the years ended January 1, 2023 and December 31, 2023 and of the Predecessor for the period from January 1, 2021 to August 18, 2021 in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Predecessor's and Successor's management. Our responsibility is to express an opinion on the Predecessor's and Successor's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Predecessor and Successor in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ *Ernst & Young LLP*

We have served as the Company's auditor since 2023.

San Diego, California
March 8, 2024

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

GRAIL, LLC

CONSOLIDATED BALANCE SHEETS (SUCCESSOR)

(in thousands)

	December 31, 2023	January 1, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 97,287	$ 241,596
Accounts receivable, net	16,862	15,346
Accounts receivable, net—related parties	80	213
Supplies	14,788	14,771
Supplies—related parties	6,907	4,984
Prepaid expenses and other current assets	20,100	18,655
Prepaid expenses and other current assets—related parties	41	68
Total current assets	156,065	295,633
Property and equipment, net	81,355	91,501
Property and equipment, net—related parties	3,640	2,515
Operating lease right-of-use assets	84,386	104,707
Restricted cash	4,225	4,532
Intangible assets, net	2,687,223	2,935,556
Goodwill	888,936	1,497,402
Other non-current assets	7,984	6,140
Total assets	**$ 3,913,814**	**$ 4,937,986**
Liabilities and member's equity		
Current liabilities:		
Accounts payable	$ 18,845	$ 15,189
Accounts payable—related parties	828	2,292
Accrued liabilities	73,711	64,962
Accrued liabilities—related parties	95	116
Incentive plan liabilities	54,513	35,935
Operating lease liabilities, current portion	14,809	13,335
Other current liabilities	809	3,112
Total current liabilities	163,610	134,941
Operating lease liabilities, net of current portion	69,598	82,675
Deferred tax liability, net	32,921	71,075
Other non-current liabilities	1,498	3,134
Total liabilities	267,627	291,825
Commitments and contingencies (Note 6)		
Member's equity	11,421,446	10,955,907
Accumulated other comprehensive income	1,066	894
Accumulated deficit	(7,776,325)	(6,310,640)
Total member's equity	3,646,187	4,646,161
Total liabilities and member's equity	**$ 3,913,814**	**$ 4,937,896**

See accompanying notes to consolidated financial statements.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

GRAIL, LLC

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share data)

	(Successor)			(Predecessor)
	Year Ended December 31, 2023	Year Ended January 1, 2023	August 19, 2021 to January 2, 2022	January 1 to August 18, 2021
Revenue:				
Screening revenue	$ 74,347	$ 39,123	$ 7,074	$ 1,953
Screening revenue—related parties	652	694	381	46
Development services revenue	18,106	15,733	4,978	180
Total revenue	93,105	55,550	12,433	2,179
Costs and operating expenses:				
Cost of screening revenue (exclusive of amortization of intangible assets)	39,284	27,998	4,664	4,965
Cost of screening revenue—related parties	8,682	4,142	662	227
Cost of development services revenue	6,623	5,741	624	261
Cost of development services revenue—related parties	238	227	133	—
Cost of revenue—amortization of intangible assets	133,889	133,889	44,630	—
Research and development	318,088	310,431	309,781	138,366
Research and development—related parties	20,657	19,145	1,475	10,590
Sales and marketing	162,292	122,328	100,512	24,814
General and administrative	200,062	173,494	478,071	160,140
General and administrative—related parties	206	614	35	4
Goodwill and intangible impairment	718,466	4,700,431	—	—
Total costs and operating expenses	1,608,487	5,498,440	940,587	339,367
Loss from operations	(1,515,382)	(5,442,890)	(928,154)	(337,188)
Other income (expense):				
Interest income	7,954	1,740	19	313
Other income (expense), net	(208)	(238)	(884)	642
Total other income (expense), net	7,746	1,502	(865)	955
Loss before income taxes	(1,507,636)	(5,441,388)	(929,019)	(336,233)
Benefit from income taxes	41,951	42,290	17,477	—
Net loss	**$ (1,465,685)**	**$ (5,399,098)**	**$ (911,542)**	**$ (336,233)**
Net loss attributable to Class A and Class B common stockholders (Predecessor)				
Basic and Diluted				$ (2.25)
Weighted-average shares of Class A and Class B common stock used in computing net loss per share attributable to Class A and Class B common stockholders (Predecessor):				149,574,238

See accompanying notes to consolidated financial statements.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

G
RAIL, LLC

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

	(Successor)			(Predecessor)
	Year Ended December 31, 2023	Year Ended January 1, 2023	August 19, 2021 to January 2, 2022	January 1 to August 18, 2021
Net loss	$ (1,465,685)	$ (5,399,098)	$ (911,542)	$ (336,233)
Other comprehensive income (loss):				
Net unrealized loss on marketable securities, net of tax	—	—	—	(101)
Foreign currency translation income (loss) adjustment	172	579	315	(701)
Comprehensive loss	**$ (1,465,513)**	**$ (5,398,519)**	**$ (911,227)**	**$ (337,035)**

See accompanying notes to consolidated financial statements.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

GRAIL, LLC

CONSOLIDATED STATEMENTS OF MEMBER'S EQUITY (SUCCESSOR)

(in thousands)

	Member's Equity	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Member's Equity
Balance as of August 19, 2021	**$ 9,745,477**	**$ —**	**$ —**	**$ 9,745,477**
Net loss	—	—	(911,542)	(911,542)
Stock-based compensation expense	639,188	—	—	639,188
Other comprehensive income	—	315	—	315
Distribution to member, net	(42,915)	—	—	(42,915)
Balance at January 2, 2022	**10,341,750**	**315**	**(911,542)**	**9,430,523**
Net loss	—	—	(5,399,098)	(5,399,098)
Stock-based compensation expense	9,884	—	—	9,884
Other comprehensive income	—	579	—	579
Contribution from member, net	604,273	—	—	604,273
Balance as of January 1, 2023	**10,955,907**	**894**	**(6,310,640)**	**4,646,161**
Net loss	—	—	(1,465,685)	(1,465,685)
Stock-based compensation expense	1,773	—	—	1,773
Other comprehensive income	—	172	—	172
Contribution from member, net	463,766	—	—	463,766
Balance as of December 31, 2023	**$11,421,446**	**$ 1,066**	**$(7,776,325)**	**$ 3,646,187**

See accompanying notes to consolidated financial statements.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

GRAIL, LLC

CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT (PREDECESSOR)

(in thousands, except share data)

	Redeemable Convertible Preferred Stock								Common Stock						
	Preferred Series A		Preferred Series B		Preferred Series C		Preferred Series D		Class A		Class B		Additional Paid-In Capital	Accumulated Other Compre-Hensive (loss) Income	Accumulated Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance as of January 1, 2021	**85,000,000**	**$68,263**	**309,256,591**	**$1,235,404**	**63,144,600**	**$299,557**	**76,743,836**	**$391,694**	**121,672,294**	**$ 123**	**24,989,397**	**$ 28**	**$ 180,952**	**$ 3,602**	**$(1,617,787)**
Issuance of shares upon exercise of options	—		—		—		—		6,775,603	6	—	—	5,972	—	—
Repurchases of early exercised stock options	—	—	—	—	—	—	—	—	(20,000)	—	—	—	(5)	—	(165)
Vesting of early exercised stock options	—	—	—	—	—	—	—	—	—	—	—	—	878	—	—
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(336,233)
Continuation payment received from Illumina—related party	—	—	—	—	—	—	—	—	—	—	—	—	245,000	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	31,647	—	—
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(802)	—
Balance at August 18, 2021	**85,000,000**	**$68,263**	**309,256,591**	**$1,235,404**	**63,144,600**	**$299,557**	**76,743,836**	**$391,694**	**128,427,897**	**$ 129**	**24,989,397**	**$ 28**	**$ 464,444**	**$ 2,800**	**$(1,954,185)**

See accompanying notes to consolidated financial statements.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

GRAIL, LLC

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	(Successor)			(Predecessor)
	Year Ended December 31, 2023	Year Ended January 1, 2023	August 19, 2021 to January 2, 2022	January 1 to August 18, 2021
Cash flows from operating activities				
Net loss	**$ (1,465,685)**	**$ (5,399,098)**	**$ (911,542)**	**$ (336,233)**
Adjustments to reconcile net loss to net cash used by operating activities:				
Amortization of intangibles assets	138,333	138,333	46,111	—
Depreciation	20,364	16,430	5,422	6,916
Stock-based compensation expense	97,235	75,729	650,260	31,647
Cash payment for equity awards	(76,910)	(41,009)	(184,963)	—
Deferred income taxes	(38,153)	(39,063)	(17,477)	—
Amortization of premium on marketable securities	—	—	—	498
Goodwill and intangible impairment	718,466	4,700,431	—	—
Other	2,829	1,398	281	(637)
Changes in operating assets and liabilities:				
Accounts receivable	(1,516)	(8,584)	(6,089)	(672)
Accounts receivable—related parties	133	(92)	(79)	(43)
Supplies	(17)	(11,868)	(1,334)	(1,569)
Supplies—related parties	(1,923)	(2,214)	(2,409)	(361)
Operating lease right-of-use assets and liabilities, net	6,712	4,924	1,412	19,859
Prepaid expenses and other assets	(935)	(11,287)	1,468	168
Prepaid expenses and other current assets—related parties	27	761	(706)	442
Accounts payable	5,194	9	(61,267)	62,531
Accounts payable—related parties	(2,305)	2,331	(1,947)	1,980
Accrued and other liabilities	2,372	13,956	(2,881)	13,335
Accrued and other liabilities—related parties	(21)	(2,400)	(130)	(121)
Net cash used by operating activities	**(595,800)**	**(561,313)**	**(485,870)**	**(202,260)**
Cash flows from investing activities				
Purchases of property and equipment	(10,243)	(21,104)	(7,158)	(59,857)
Purchases of property and equipment—related parties	(2,644)	(1,755)	(818)	(2,093)
Purchases of marketable securities	—	—	—	(159,411)
Proceeds from sale of marketable securities	—	—	—	400,367
Proceeds from maturities of marketable securities	—	—	—	173,782
Net cash provided by (used by) investing activities	**(12,887)**	**(22,859)**	**(7,976)**	**352,788**
Cash flows from financing activities				
Proceeds from exercise of stock options	—	—	—	5,978
Repurchase of early exercised stock options	—	—	—	(170)
Proceeds from early exercise of unvested stock options	—	—	—	3
Proceeds from continuation payment received from Illumina—related party	—	—	—	245,000
Cash funding received from Illumina	464,000	609,000	774,000	—
Cash payments for acquisition consideration on behalf of Illumina	—	—	(625,749)	—
Taxes paid related to net share settlement of equity awards	(234)	(4,183)	(4,320)	—
Net cash provided by financing activities	**463,766**	**604,817**	**143,931**	**250,811**
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	305	(511)	(135)	(64)
Net increase (decrease) in cash, cash equivalents, and restricted cash	(144,616)	20,134	(350,050)	401,275
Cash, cash equivalents and restricted cash—beginning of year	246,128	225,994	576,044	174,769
Cash, cash equivalents and restricted cash—end of year	**$ 101,512**	**$ 246,128**	**$ 225,994**	**$ 576,044**
Represented by:				
Cash and cash equivalents	$ 97,287	$ 241,596	$ 221,155	$ 571,205
Restricted cash	4,225	4,532	4,839	4,839
Total	**$ 101,512**	**$ 246,128**	**$ 225,994**	**$ 576,044**
Supplemental cashflow information:				
Vesting of early exercised stock options	$ —	$ —	$ —	$ 878
Property and equipment included in accounts payable and accrued liabilities	(1,326)	(1,940)	(6,261)	(4,768)
Operating cashflows from operating leases, net	(18,733)	(17,536)	(6,379)	(6,626)

See accompanying notes to consolidated financial statements.

Confidential Treatment Requested by GRAIL, LLC
Pursuant to 17 C.F.R. Section 200.83

GRAIL, LLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. ORGANIZATION AND DESCRIPTION OF BUSINESS

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

On September 20, 2020, GRAIL, Inc., Illumina and its subsidiaries, SDG Ops, LLC, and SDG Ops, Inc., entered into an agreement and plan of merger (the "Merger Agreement"). On August 18, 2021 (the "Closing Date"), Illumina completed its acquisition of GRAIL, Inc. (the "Predecessor Company" or "Predecessor"). According to the terms and conditions of the Merger Agreement, SDG Ops, Inc. and GRAIL, Inc. merged, with GRAIL, Inc. surviving and becoming a wholly owned subsidiary of Illumina (the "First Merger").

Immediately following the First Merger and as part of the same overall transaction, GRAIL, Inc., as the surviving corporation, merged with SDG Ops, LLC (the "Second Merger"). According to the terms and conditions of the Merger Agreement, SDG Ops, LLC became the surviving corporation and was renamed GRAIL, LLC (the "Successor Company" or "Successor"). At the effective time of the First Merger (the "Effective Time"), each issued and outstanding share of Predecessor Class A Common Stock, par value $0.001 per share, Class B Common Stock, par value $0.001 per share, Series A Preferred Stock, par value $0.001 per share, Series B Preferred Stock, par value $0.001 per share, Series C Preferred Stock, par value $0.001 per share, and Series D Preferred Stock, par value $0.001 per share, of GRAIL (collectively, the "GRAIL Stock," subject to limited exceptions, including shares with respect to which dissenters' rights were validly exercised in accordance with Delaware law) was converted into each holder's elected merger consideration.

Prior to the Closing Date, references to the "Company" or "GRAIL" within these consolidated financial statements refer to GRAIL, Inc., and its consolidated subsidiaries, while references to the "Company" or "GRAIL" on or after the Closing Date refer to GRAIL, LLC and its consolidated subsidiaries.

The accompanying consolidated financial statements of the Company as of December 31, 2023 and January 1, 2023, and for the years ended December 31, 2023 and January 1, 2023, and the period from August 19, 2021 to January 2, 2022 (the "Successor," or the "Post-Combination" period), reflect the basis applied by Illumina in connection with its accounting for the acquisition of GRAIL as a business combination ("pushdown accounting"), and for the period from January 1, 2021 to August 18, 2021 (the "Predecessor" or the "Pre-Combination" period), reflect the activity of the Predecessor Company. Due to the application of pushdown accounting, the Successor periods have been clearly distinguished from the Predecessor period as these periods are not comparable.

GRAIL, headquartered in Menlo Park, California, is an innovative commercial-stage healthcare company focused on saving lives and shifting the paradigm of early cancer detection. GRAIL's Galleri blood test screens for various types of cancers before individuals are symptomatic. Illumina is the sole member and 100% owner of GRAIL. Illumina implemented extensive and binding Hold Separate Commitments upon the Acquisition in order for Illumina and GRAIL to be held and operated as distinct and separate entities. The Hold Separate Commitments also provided for the appointment of a monitoring trustee. Notwithstanding the foregoing, the European Commission has adopted an order requiring Illumina and GRAIL to be held and operated as distinct and separate entities. Compliance with the order is monitored by an independent monitoring trustee. Refer to note "11. Legal and Regulatory Proceedings" for additional details.

Our Ability to Continue as a Going Concern

The accompanying 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 our net loss, and to become profitable and operate profitably, to manage our negative cash flows from operations and to generate positive cash flows from operations and our ability to obtain financing to support our working capital requirements. As part of Illumina, the Company is dependent upon Illumina for its working capital and financing requirements. The Company had $97.3 million of cash and cash equivalents as of December 31, 2023.

We believe that our existing cash and cash equivalents, in addition to the funding that Illumina is required to provide, will be sufficient to meet our working capital and capital expenditure needs for at least the next 12 months, as of the date these consolidated financial statements were filed.

Fiscal Year

The Company's fiscal year is the 52 or 53 weeks ending the Sunday closest to December 31. References to 2023 and 2022 refer to the fiscal years ended December 31, 2023, and January 1, 2023, respectively, which were both 52 weeks. References to 2021 refer either to the Predecessor period from January 1, 2021 to August 18, 2021, or the Successor period from August 19, 2021 to January 2, 2022.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements represent the historical operations of the standalone GRAIL legal entity and in the Successor periods include purchase accounting adjustments and certain tax adjustments as if GRAIL filed a separate income tax return and was not included in Illumina's consolidated return. All revenues and costs as well as assets and liabilities directly associated with the business activity of the Company are included in the consolidated financial statements. Assets and liabilities were reflected at fair value under the new basis of accounting established at the Closing Date.

Management considered the need to allocate any shared costs incurred by the parent, Illumina, to the accompanying consolidated financial statements. As previously discussed, the European Commission has adopted an order requiring Illumina and GRAIL to be held and operated as distinct and separate entities. As no integration has occurred, management has concluded that no material allocations are required in the Successor periods. However, amounts recognized in the Successor periods 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 "8. Related Party Transactions."

These consolidated financial statements are prepared in accordance with United States Generally Accepted Accounting Principles ("U.S. GAAP") and include the accounts of GRAIL and its wholly owned subsidiaries. All intercompany balances have been eliminated in consolidation.

Use of Estimates

The preparation of the consolidated financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the amounts of assets and liabilities, disclosure of contingent assets and liabilities, and the reported amounts of revenues and expenses in the consolidated financial statements and accompanying notes. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. On an ongoing

basis, management evaluates its estimates, including, but not limited to, those related to estimation of variable consideration, estimation of credit losses, standalone selling price included in contracts with multiple performance obligations, measure of progress toward the completion and satisfaction of performance obligations, accrued clinical studies and research and development expenses, stock-based compensation expense, measurement of liability-classified awards, valuation of goodwill and intangible assets, useful lives of intangible assets and property and equipment, determination of incremental borrowing rate for operating leases, contingencies, and the provision for income taxes, among others. These estimates generally involve complex issues and require judgments, involve the analysis of historical results and prediction of future trends, can require extended periods of time to resolve and are subject to change from period to period. Actual results could differ from those estimates, and such differences could be material to the consolidated financial statements.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash and cash equivalents to the extent recorded in the consolidated balance sheets.

As of December 31, 2023, the Company had approximately $97.3 million of cash deposits and cash equivalents deposited in accounts with three accredited financial institutions, the majority of which were invested in money market securities that serve as sweep accounts. Such deposits have and will continue to exceed federally insured limits. The Company has not experienced any losses on its cash deposits.

The Company's investment policy limits investments to certain types of securities issued by the U.S. government and its agencies and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. As of December 31, 2023, the Company had no off-balance sheet concentrations of credit risk.

The Company is subject to credit risk related to its accounts receivable. Accounts receivable primarily arise from testing services in the United States and are primarily with biopharmaceutical companies, employers, healthcare organizations, concierge medicine practices, life insurance companies, and individuals. The Company does not require collateral. Accounts receivable are recorded net of the allowance for credit losses.

The Company had sales to a single customer that accounted for approximately 14%, 21% and 38% of total sales, for the years ended December 31, 2023 and January 1, 2023, and period from August 19, 2021 to January 2, 2022, respectively. No single customer accounted for more than 10% of net sales for the period from January 1 to August 18, 2021.

Amounts due from this same single customer represented approximately 43% and 45% of total accounts receivable as of December 31, 2023 and January 1, 2023, respectively.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to emerging and commercial-stage healthcare companies, including, but not limited to, the Company's operation in a dynamic and highly regulated industry, its ability to successfully commercialize products, its ability to drive industry education and awareness of its products and multi-cancer early detection generally, difficulties or delays in clinical studies, delays in planned commercial launches, complex regulatory regimes, regulatory implications and issues, including approvals, recommendations, coverage and reimbursement determinations, its ability to establish and maintain strategic relationships and key third-party vendors and providers, developments involving the Company's infrastructure and platform, dependence on key personnel, and other factors. Any of these factors and other factors could negatively impact operating results.

The Company's first commercial product, Galleri, was commercially launched in mid-2021. As a result, the Company has a limited history as a commercial-stage company and this product has not and may not generate revenues sufficient to fund operations. The Company is subject to risks and uncertainties regarding its need for, and ability to obtain, additional financing.

Significant Accounting Policies

Cash and Cash Equivalents

Cash and cash equivalents consist of cash on deposit with banks denominated in U.S. Dollars and British Pounds. To be considered cash equivalents, all investments purchased must be highly liquid and have an original maturity date of three months or less. As of December 31, 2023, and January 1, 2023, the Company's cash equivalents were held in money market funds, totaling $92.6 million and $236.0 million, respectively. Cash equivalents held in money market funds were categorized as Level 1 investments within the fair value hierarchy.

Restricted Cash

Restricted cash is comprised of cash that is restricted as to withdrawal or use related to letters of credit for the Company's operating lease agreements.

Accounts Receivable, Net

Accounts receivable represent unconditional rights to consideration from customers. Accounts receivable are evaluated regularly for collectability and potential credit losses. Allowance for credit losses is estimated based on management's assessment of historical collection trends and the financial conditions of customers, among other factors. As of December 31, 2023, and January 1, 2023, the Company had $3.1 million and $1.3 million of allowance for credit losses, respectively.

Supplies

Supplies consists of materials and reagents consumed in the performance of testing services. The Company periodically analyzes supply levels and expiration dates, and writes down supply that has become obsolete or that has a cost basis in excess of expected sales requirements as cost of revenue. The Company records an allowance for excess or obsolete supplies using an estimate based on historical trends and evaluation of near-term expirations. 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.

Fair Value of Financial Instruments

The fair value of financial assets and liabilities is determined using the fair value hierarchy established in Accounting Standards Codification ("ASC") Topic 820, Fair Value Measurement ("ASC 820"). ASC 820 identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. The hierarchy describes three levels of inputs that may be used to measure fair value, as follows:

Level 1 —Observable inputs, such as quoted prices in active markets for identical assets and liabilities.

Level 2 —Observable inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 —Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The carrying amounts for financial instruments such as accounts receivable, net, accounts receivable, net—related parties, prepaid expenses and other current assets, prepaid expenses and other current assets—related parties, accounts payable, accounts payable—related parties, accrued liabilities and accrued liabilities—related parties' approximate fair value due to their short-term nature.

Property and Equipment, Net

Property and equipment, net is stated at cost less accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets. Leasehold improvements are amortized using the straight-line method over the shorter of the lease term or the useful life of the improvements. Repair expenses and maintenance costs are expensed as incurred. When an item is sold or disposed of, the cost and related accumulated depreciation or amortization is eliminated and the resulting gain or loss, if any, is recorded in the consolidated statements of operations.

The estimated useful lives of the major classes of property and equipment are generally as follows:

	Useful Life (in Years)
Laboratory equipment	3 to 5
Computer hardware	3
Computer software	3
Furniture and fixtures	5
Leasehold improvements	Lease Term

Leases

Leases are classified as operating or financing at lease inception and as necessary at modification. Leased assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease.

Operating leases are included in operating lease right-of-use ("ROU") assets and operating lease liabilities in the consolidated balance sheets. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. When readily determinable, the Company uses the rate implicit in the lease to discount lease payments; however, when the rate is not readily determinable, the Company uses the incremental borrowing rate based on the information available at the commencement date. The incremental borrowing rate is the rate of interest that a company would have to pay to borrow an amount equal to the lease payments on a collateralized basis over a similar term and in a similar economic environment. The Company's weighted average remaining lease term is approximately 7.6 years and 7.8 years as of December 31, 2023, and January 1, 2023, respectively. The Company's weighted average discount rate for operating leases is 2.4% and 2.1% as of December 31, 2023, and January 1, 2023, respectively, which were based on Illumina's incremental borrowing rate as GRAIL was a wholly owned subsidiary. The operating lease ROU asset also includes any initial direct costs, lease payments made prior to lease commencement, and lease incentives received. Variable lease payments are expensed as incurred and are not included within the ROU asset and lease liability calculation. Variable lease payments primarily include reimbursements of costs incurred by lessors for common area maintenance and utilities.

For each lease, the determined lease term is based on a noncancellable period, including any rent-free periods provided by the lessor, and may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease cost for lease payments is recognized on a straight-line basis over the lease term. Certain lease agreements contain lease and non-lease components. The Company accounts for non-lease components as part of the lease component to which they relate.

The Company does not recognize ROU assets and lease liabilities for short-term leases, which have a lease term of twelve months or less and do not include an option to purchase the underlying asset that the Company is reasonably certain to exercise.

Goodwill and Intangible Assets

Intangible assets identified in the Acquisition include GRAIL trade names, developed technology, and GRAIL in-process research and development ("IPR&D") and were measured at fair value as of the Closing Date. Goodwill represents the excess of purchase price paid cost over fair value of the net identifiable assets acquired.

The Company's trade names, GRAIL and Galleri, have brand recognition in the market related to the services GRAIL provides customers and the research and development activities GRAIL performs. GRAIL's developed technology includes intangible assets related to Galleri, its multi-cancer early detection test that was launched as a laboratory-developed test ("LDT") in 2021, as well as a diagnostic aid for cancer ("DAC") test. The developed technology underpins both Galleri, designed as a cancer screening test for asymptomatic individuals over 50 years of age, and DAC that is being designed to accelerate diagnostic resolution for patients for whom there is a clinical suspicion of cancer. The cost of identifiable intangible assets with finite lives, such as trade names and developed technology assets, are amortized on a straight-line basis over the assets' respective estimated useful lives of 9 years and 18 years, respectively.

The Company's IPR&D includes assets related to GRAIL's development of a minimal residual disease ("MRD") test, a post-diagnostic test, that is currently under development. IPR&D is considered indefinite-lived and therefore is not amortized until completed and placed into service, at which point it will begin to be amortized over its estimated useful life or expensed upon abandonment of the associated research and development efforts.

While goodwill and IPR&D are not amortized, they are reviewed for impairment at least annually or more frequently if events or circumstances indicate a potential for impairment. Goodwill and IPR&D are considered impaired if the carrying value of the reporting unit or IPR&D asset exceeds its respective fair value.

We perform our goodwill impairment analysis at the reporting unit level. We have one reporting unit, which aligns with our reporting structure and availability of discrete financial information. During the goodwill impairment review, we assess qualitative factors to determine whether it is more likely than not that the fair value of our reporting unit is less than the carrying amount, including goodwill. If we determine that it is not more likely than not that the fair value of our reporting unit is less than the carrying amount, no additional assessment is necessary. If the carrying amount of the reporting unit exceeds its fair value, we record an impairment loss based on the excess. We may elect to bypass the qualitative assessment in a period and proceed to perform the quantitative goodwill impairment test.

Impairment of Long-Lived Assets

Long-lived assets, other than goodwill and IPR&D (as described above), are evaluated for indications of possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amounts to the future undiscounted cash flows attributable to these assets. Should impairment exist, the impairment would be measured as the amount by which the carrying amount of the assets exceeds the fair value of those assets.

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Segments

The Company operates and manages its business as one reportable operating segment which provides multi-cancer early detection testing and services. The chief operating decision maker reviews financial information on an aggregate basis for the purposes of evaluating financial performance and allocating the company resources. Substantially all of the Company's long-lived assets are located in the United States.

Revenue Recognition

Revenue is accounted for in accordance with Topic 606, which provides for a five-step model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations, and recognizing revenue when, or as, an entity satisfies a performance obligation. Revenues are derived from screening and development services. The Company's revenues were primarily generated in the United States.

Screening Revenue

The Company recognizes screening revenue from the sale of cancer screening testing services for patients. Patients obtain tests via their employers, healthcare systems, payors, concierge medicine practices, life insurance providers or directly via telemedicine. Patients receive the multi-cancer early detection kit after the order is placed and complete the blood draw. The specimen is then sent to the Company's lab, the test is processed, and the result is electronically delivered to the patients' physician. The test price is based on the negotiated contractual rate with the Company's direct customers, otherwise the Company's standard list price applies. The Company identifies each sale of its 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. Invoices are generally due within 30 days of receipt.

For self-pay patients, the Company has concluded that an implied contract exists, however the transaction price for the implied contract represents variable consideration as there are situations in which the Company is not expected to collect the full invoiced amounts from self-pay patients due to price concessions. The Company utilizes the expected value approach to estimate the transaction price and applies a constraint for such variable consideration, on a portfolio basis. The Company monitors 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. Both the estimate and any subsequent revision contain uncertainty and require the use of significant judgment in the estimation of the variable consideration and application of the constraint for such variable consideration. The Company analyzes its actual cash collections over the expected collection period and compares it with the estimated variable consideration for each portfolio and any difference is recognized as an adjustment to estimated revenue after the expected collection period, subject to assessment of the risk of future revenue reversal.

Development Services Revenue

Development services revenue includes development activities performed in partnership with biopharmaceutical companies. The Company's targeted methylation-based technology enables development of products and services to optimize treatment once a cancer has been diagnosed. Biopharmaceutical partners engage the Company to run pilots and research studies to evaluate and learn about the technology's application. The Company evaluates the terms and conditions included within its development services contracts with biopharmaceutical customers to ensure appropriate revenue recognition, including whether services are considered distinct performance obligations. The Company first identifies material promises under the contract and then evaluates whether these promises are capable of being distinct within the context of the contract. In assessing whether a promised service is capable of being distinct, the Company considers whether the customer could benefit from the service either on its own or together with other resources that are readily available to the customer, including factors such as the research, development, and commercialization capabilities of a third party as well as the availability of the associated expertise in the general marketplace. For contracts with multiple

performance obligations, the transaction price is allocated to the separate performance obligations on a relative standalone selling price basis. The Company determines the 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 the Company to run pilot and research studies by sending patient samples and comparing the Company's test result to their expected result for evaluation of performance and application. The Company recognizes revenue as performance obligations are completed.

Following favorable results from pilot and research studies, biopharmaceutical partners and the Company may enter into development service agreements related to clinical trial 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. The Company uses an input method based on costs incurred to measure its progress toward the completion and satisfaction of the performance obligations. The Company assesses 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. Invoices are generally due within 60 days.

Deferred Revenue

Deferred revenue, which is a contract liability, consists primarily of payments received in advance of revenue recognition from contracts with customers. For example, pre-payments received from patients for screening testing services and development services and other contracts with biopharmaceutical customers often contain upfront payments which results in the recording of deferred revenue to the extent cash is received prior to the Company's performance of the related development services. Contract liabilities are relieved as the Company performs its obligations under the contract and revenue is recognized. Deferred revenue was $0.8 million and $0.6 million as of December 31, 2023 and January 1, 2023, respectively, all of which is considered short-term and was recorded within other current liabilities on the accompanying consolidated balance sheets. We did not have deferred revenue prior to the year ended January 2, 2022, as we first began providing services to customers in the year ended January 2, 2022.

Cost of Screening Revenue

Cost of screening revenue generally consists of cost of materials, direct and indirect labor including salaries and wages, bonus, benefits and stock-based compensation, amortization of GRAIL intangible assets, royalty expenses primarily owed under the supply and commercialization agreement with Illumina in the Predecessor period and the Chinese University of Hong Kong in both the Predecessor and Successor periods, third-party support services, shipping and logistics costs, depreciation of equipment and allocated overhead expenses associated with processing specimens received from customers. The royalty obligation under the supply and commercialization agreement with Illumina is currently suspended in the Successor periods. Allocated overhead expenses include rent expenses, amortization of leasehold improvements and information technology costs.

Cost of Development Services Revenue

Cost of development services revenue generally consists of direct and indirect labor including salaries and wages, bonus, benefits and stock-based compensation, cost of materials and patient sample acquisition, amortization of GRAIL intangible assets, royalty expenses primarily owed under the supply and commercialization agreement with Illumina in the Predecessor period, depreciation of equipment, and allocated

overhead expenses associated with processing development samples received from biopharmaceutical customers. The royalty obligation under the supply and commercialization agreement with Illumina is currently suspended in the Successor periods. Allocated overhead expenses include rent expense, amortization of leasehold improvements, and information technology costs.

Accrued Clinical Studies and Research and Development Expenses

Estimates of unbilled costs of research and development activities for clinical studies conducted by third-party service providers are accrued. The estimated costs of research and development activities are recorded based upon the estimated amount of services provided. These costs are included in accrued liabilities and accrued liabilities—related parties in the consolidated balance sheets and within research and development and research and development—related parties expenses in the consolidated statements of operations. These costs are a significant component of research and development expenses. The costs are accrued based on factors such as estimates of the work completed and in accordance with agreements established with third-party service providers. The judgments and estimates in determining the accrued liabilities balance are assessed in each reporting period.

Research and Development and Research and Development—Related Parties

Research and development and research and development—related parties expenses include costs incurred to develop the Company's technology (prior to establishing technological feasibility), collect clinical samples, and conduct clinical studies to develop and support the Company's multi-cancer tests. These costs consist of personnel costs, including salaries, benefits, and stock-based compensation expense associated with the research and development personnel, laboratory supplies, consulting costs, costs associated with setting up and conducting clinical studies at domestic and international sites, and allocated overhead expenses including rent, information technology, and equipment depreciation. Both internal and external research and development costs are expensed in the periods in which they are incurred. Research and development—related parties expenses are further discussed in note "8. Related Party Transactions." 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.

Advertising Costs

Advertising costs are expensed as incurred. Advertising costs were $21.9 million and $24.5 million for the years ended December 31, 2023, and January 1, 2023, respectively, and $3.0 million and $4.6 million for the period from August 19, 2021 to January 2, 2022, and the period from January 1, 2021 to August 18, 2021, respectively.

Stock-Based Compensation Expense

Employee stock-based compensation expense includes expenses related to Cash-Based Equity Awards, restricted stock units, and performance stock options.

Our Cash-Based Equity Awards are classified as liability awards, as such awards may be settled in cash. For purposes of valuation and performance measurement of the awards, GRAIL's stand-alone value calculation is estimated by the Company based on its analysis and on input from independent valuation advisors. The fair value of the awards is recorded over the respective vesting periods of the awards, with recognition of a corresponding liability recorded in incentive plan liabilities in the consolidated balance sheets. The awards are remeasured at each reporting date until the awards are settled, with changes in fair value recognized in stock-based compensation expense.

In connection with the Acquisition, Illumina issued equity awards to GRAIL employees in exchange for any of their remaining outstanding and unvested GRAIL equity awards (the "Replacement Awards"). The awards

consist of restricted stock units and performance stock options that are issued as shares of Illumina common stock at vesting.

The fair value of restricted stock is determined by the closing market price of Illumina's common stock on the date of grant. Stock-based compensation expense is recognized based on the fair value on a straight-line basis over the requisite service periods of the awards.

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 Illumina's common stock. The historical volatility is generally commensurate with the estimated expected term, adjusted for the impact of unusual fluctuations and other relevant factors. The implied volatility is calculated from the implied market volatility of exchange-traded call options on Illumina's common stock. The expected term is generally based on historical forfeiture experience, exercise activity, and on the terms and conditions of the stock awards. Given that Illumina has never declared or paid cash dividends on the Illumina common stock, the expected dividend yield is determined to be 0%. Illumina does not anticipate paying cash dividends in the near 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 awards begins to be recognized when it is probable that the performance-based condition will be met.

Forfeitures are accounted for, as incurred, as a reversal of stock-based compensation expense related to awards that will not vest.

In the Predecessor period, stock-based compensation expense for awards containing both performance and market-based conditions was recorded using the accelerated attribution method. Management used the Monte Carlo simulation to determine the fair value at the grant date and recognized stock-based compensation expense over the derived service period when it became probable that the performance-based condition will be met. Under the Monte Carlo simulation, stock returns were simulated to estimate the payouts established by the vesting conditions of the awards and an estimated time that the awards will vest. The assumptions used in the Monte Carlo simulation included: the fair value of common stock, estimating the length of time employees will retain their vested stock options before exercising them (expected term), the estimated volatility of the common stock price over the expected term (expected volatility), the risk-free interest rate and expected dividends.

Defined Contribution Plan

The Company sponsors a defined contribution plan under Section 401(k) (the "401(k) Plan") of the Internal Revenue Code covering eligible employees. Employer contributions made to the 401(k) Plan are voluntary and are determined annually by the board of directors on an individual basis subject to the maximum allowable amount under federal tax regulations. The Company has not made contributions to the 401(k) Plan since inception of the plan.

Provision for (Benefit from) Income Taxes

Upon closing of the merger, as a single member limited liability company wholly owned by Illumina, GRAIL, LLC is no longer subject to U.S. income tax as a separate entity for the Successor periods ended December 31, 2023, January 1, 2023, and January 2, 2022, and is combined into Illumina's consolidated income tax return as an entity disregarded as being separate from Illumina. However, for financial statement purposes, GRAIL has elected to compute its income tax provision, including current and deferred taxes, as if GRAIL was a corporation filing a separate income tax return and was not included in Illumina's consolidated return. 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 GRAIL, LLC is not a separate taxpayer and merely a disregarded entity of Illumina, these U.S. 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 U.S. tax attributes will not be available to a standalone GRAIL entity on its income tax returns in the future.

The provision for income taxes is computed using the asset and liability method, under which deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities, and for the expected future tax benefit to be derived from tax loss and credit carryforwards. Deferred tax assets and liabilities are determined using the enacted tax rates in effect for the years in which those tax assets are expected to be realized. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in the provision for income taxes in the period that includes the enactment date.

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 the ability to recover deferred tax assets within the jurisdiction in which they arise, we consider all available positive and negative evidence. Factors reviewed include the cumulative pre-tax book income for the past three years, scheduled reversals of deferred tax liabilities, history of earnings and reliable forecasting, projections of pre-tax book income over the foreseeable future, and the impact of any feasible and prudent tax planning strategies.

The impact of a tax position is recognized in the 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. Any interest and penalties related to uncertain tax positions will be reflected in income tax expense (benefit).

Foreign Currency

The functional currencies of foreign subsidiaries are the British Pound and the Hong Kong Dollar. Adjustments resulting from translating the financial statements of the United Kingdom and Hong Kong subsidiaries into U.S. Dollars are recorded as a component of other comprehensive loss in the consolidated statements of comprehensive loss. Monetary assets and liabilities denominated in a foreign currency are translated into U.S. Dollars at the exchange rate on the balance sheet date. Revenues and expenses are translated at the weighted-average exchange rates during the period. Equity transactions are translated using historical exchange rates. Gains and losses resulting from translation of foreign currency monetary transactions are reported in other income (expense), net in the consolidated statements of operations and comprehensive loss. Gains and losses resulting from foreign currency transactions that are deemed to be of a long-term investment nature are reported as a separate component of other comprehensive loss.

NOTE 3. GRAIL ACQUISITION, GOODWILL AND INTANGIBLE ASSETS

GRAIL Acquisition

On August 18, 2021, Illumina completed its acquisition of GRAIL, Inc. The total purchase price consisted of the following:

(in thousands)	
Cash	$ 2,861,837
Fair value of common stock issued	4,975,416
Fair value of contingent consideration	757,140
Fair value of previously held investment	1,149,374
Settlement of preexisting relationships	1,710
Total purchase price	**$ 9,745,477**

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The Acquisition accelerated the vesting of certain outstanding and unvested equity awards of GRAIL. Refer to note "7. Stock Incentive Awards" for further details on the accelerated vesting of the equity awards.

The fair values of GRAIL, Inc.'s assets acquired and liabilities assumed were:

(in thousands)	
Cash and cash equivalents	$ 571,205
Property and equipment	89,486
Operating lease right-of-use assets	121,104
Goodwill (1)	6,197,833
Intangible assets	3,120,000
Other current and non-current assets	20,172
Deferred tax liability, net (1)	(127,614)
Operating lease liabilities, net of current portion	(97,333)
Other current and non-current liabilities	(149,376)
Total net assets acquired	**$ 9,745,477**

(1) Certain adjustments were made to deferred tax liability, net, as a result of re-calculating the provision on a stand-alone basis as compared to Illumina's consolidated reporting, resulting in an increase in goodwill and an increase in deferred tax liability, net, as compared to that calculated by Illumina.

The transaction costs associated with the Acquisition consisted primarily of legal, regulatory, and financial advisory fees of approximately $82.3 million, which were expensed as incurred as general and administrative expense in 2021.

Unaudited Pro Forma Financial Information

The following unaudited pro forma financial information summarizes the combined results of operations of GRAIL as if the Acquisition had been completed on January 1, 2021.

(in thousands)	Year Ended 2021
Revenue (1)	$ 14,612
Net loss	$ (1,318,098)

(1) Includes revenue—related parties.

The unaudited pro forma financial information is presented for information purposes only and is not indicative of the results of operations that would have been achieved had the Acquisition been completed on January 1, 2021. In addition, the unaudited pro forma financial information is not a projection of future results of operations of the Company. The unaudited pro forma financial information includes adjustments to reflect incremental amortization expense of the identifiable intangible assets acquired and the related tax effect.

Goodwill and Goodwill Impairment

Goodwill represents the excess of purchase price paid over fair value of the net identifiable assets acquired and is primarily attributable to assembled workforce, expanded market opportunities, and expected synergies to be achieved. Goodwill is not deductible for tax purposes.

2023 Goodwill Impairment

In Q3 2023, we concluded the sustained decrease in Illumina's stock price and overall market capitalization during the quarter was a triggering event indicating the fair value of GRAIL might be less than its carrying

amount that led us to test goodwill for impairment. The assessment was performed using a combination of both an income and a market approach to determine the fair value of goodwill. The income approach utilized the estimated discounted cash flows, while the market approach utilized comparable company information. 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 goodwill impairment assessment was 24.0%. 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 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 goodwill.

The Company recognized a goodwill impairment of $608.5 million as a result of the impairment assessment, primarily due to changes to expected timing of revenue and a higher discount rate selected for the fair value calculation of GRAIL.

2022 Goodwill Impairment

On July 13, 2022, the European General Court ruled that the European Commission had jurisdiction under the European Union Merger Regulation to review the Acquisition. Additionally, on September 6, 2022, the European Commission issued a decision prohibiting the Acquisition. These decisions constituted substantive changes in circumstances and led us to test goodwill for impairment. The assessment was performed using a combination of both an income and a market approach to determine the fair value of goodwill. The income approach utilized the estimated discounted cash flows, while the market approach utilized comparable company information. 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 goodwill impairment assessment was 22.0%. 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 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 goodwill.

The Company recognized a goodwill impairment of $4.7 billion as a result of the impairment assessment, primarily due to the negative impact of capital market conditions and a higher discount rate selected for the fair value calculation of GRAIL.

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Intangible Assets

Intangible assets recognized as part of the Acquisition include developed technologies, trade name and IPR&D that were measured at fair value as of the Closing Date. The following roll-forward indicates the fair values assigned to identifiable assets from the Acquisition and the resulting amortization and impairment:

(in thousands)	Developed Technologies	Trade Name	In-process Research and Development (IPR&D)	Total Intangible Assets
Beginning balance as of August 19, 2021				
Gross carrying amount	$2,410,000	$ 40,000	$ 670,000	$3,120,000
Amortization	(44,630)	(1,481)	—	(46,111)
Ending balance - Intangible assets, net as of January 2, 2022	**2,365,370**	**38,519**	**670,000**	**3,073,889**
Amortization	(133,889)	(4,444)	—	(138,333)
Ending balance - Intangible assets, net as of January 1, 2023	**2,231,481**	**34,075**	**670,000**	**2,935,556**
Impairment	—	—	(110,000)	(110,000)
Amortization	(133,889)	(4,444)	—	(138,333)
Ending balance - Intangible assets, net as of December 31, 2023	**$2,097,592**	**$ 29,631**	**$ 560,000**	**$2,687,223**

The fair values of the developed technologies, trade name 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 name assets are amortized on a straight-line basis over their estimated useful lives.

In conjunction with the 2023 goodwill impairment assessment, the IPR&D intangible asset was evaluated for potential impairment. 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 19.0%. 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 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.

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 impairment of $110.0 million, primarily due to a decrease in projected cash flows and a higher discount rate selected for the fair value calculation. In the 2022 impairment assessment, the carrying value of the IPR&D intangible asset did not exceed its estimated fair value. As a result, no impairment for the IPR&D intangible asset was recorded. As of December 31, 2023 the research and development project had not been completed or abandoned. The IPR&D intangible asset is not currently subject to amortization.

A recoverability test for the definite-lived intangible assets, which includes developed technology and trade name, was also performed. Based on the assessment performed, no impairment was noted for the definite-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
2024	138,333
2025	138,333
2026	138,333
2027	138,333
2028	138,333
Thereafter	1,435,558
Total	**$ 2,127,223**

NOTE 4. BALANCE SHEET COMPONENTS

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

(in thousands)	December 31, 2023	January 1, 2023
Prepaid expenses and other current assets		
Prepaid service and maintenance	$ 1,179	$ 1,676
Prepaid software	4,734	5,975
Prepaid insurance	814	747
Prepaid other	6,579	6,119
Tax receivable	5,411	3,056
Indirect taxes	1,383	1,082
Total prepaid expenses and other current assets	**$ 20,100**	**$ 18,655**

(in thousands)	December 31, 2023	January 1, 2023
Property and equipment, net		
Laboratory equipment	$ 41,768	$ 36,740
Computer hardware	4,767	5,213
Computer software	324	248
Furniture and fixtures	2,524	2,044
Leasehold improvements	58,411	55,384
Construction-in-process	7,560	10,219
Property and equipment, gross	115,354	109,848
Less accumulated depreciation and amortization	(33,999)	(18,347)
Total property and equipment, net	**$ 81,355**	**$ 91,501**

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(in thousands)	December 31, 2023	January 1, 2023
Property and equipment, net—related parties		
Laboratory equipment	$ 4,752	$ 2,714
Leasehold improvements	28	28
Construction-in-process	406	429
Property and equipment, gross	5,186	3,171
Less accumulated depreciation and amortization	(1,546)	(656)
Property and equipment, net—related parties	**$ 3,640**	**$ 2,515**

(in thousands)	December 31, 2023	January 1, 2023
Accrued liabilities		
Accrued compensation expenses	$ 41,484	$ 38,169
Accrued legal and professional expenses	7,770	4,195
Accrued clinical studies expenses	6,897	6,109
Accrued research and development expenses	6,647	6,204
Accrued marketing	1,882	1,662
Accrued other expenses	9,031	8,623
Total accrued liabilities	**$ 73,711**	**$ 64,962**

(in thousands)	December 31, 2023	January 1, 2023
Accrued liabilities—related parties		
Accrued purchases	$ —	$ 112
Accrued to Illumina	95	4
Total accrued liabilities—related parties	**$ 95**	**$ 116**

NOTE 5. LEASES

The Company has entered into operating leases for facilities and equipment used for research and development. Operating leases have remaining lease terms which range from 1 year to 10 years, and often include one or more options to renew. These renewal terms can extend the lease term from 5 to 15 years and are included in the lease term when it is reasonably certain that the option will be exercised. The exercise of lease renewal and termination options are at the sole discretion of the Company. The Company also has variable lease payments that are primarily comprised of common area maintenance and utility charges.

The components of lease costs are as follows:

	(Successor)			(Predecessor)
(in thousands)	Year Ended December 31, 2023	Year Ended January 1, 2023	August 19, 2021 to January 2, 2022	January 1 to August 18, 2021
Operating lease costs	$ 24,357	$ 23,055	$ 7,747	$ 7,287
Short-term lease costs	—	—	—	42
Variable lease costs	3,676	3,079	1,328	2,109
Total lease costs	**$ 28,033**	**$ 26,134**	**$ 9,075**	**$ 9,438**

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Future undiscounted lease payments under operating leases as of December 31, 2023 were as follows:

(in thousands)	Successor Amounts
2024	$ 17,920
2025	16,432
2026	14,043
2027	8,021
2028	8,232
Thereafter	40,580
Total undiscounted lease payments	$105,228
Less: Imputed interest	(10,113)
Less: Tenant improvement allowance*	(10,708)
Total operating lease liabilities	**$ 84,407**

* Tenant improvement allowance is estimated to be received as follows: approximately $1.0 million in 2024 and $9.7 million thereafter.

NOTE 6. COMMITMENTS AND CONTINGENCIES

The future non-lease commitments over the next five years and thereafter were as follows:

	As of December 31, 2023 (in thousands)		
	Minimum Royalties	Purchase Commitments	Total
2024	$ 1,025	$ 19,302	$20,327
2025	1,075	21,804	22,879
2026	1,075	17,375	18,450
2027	1,075	16,339	17,414
2028	1,075	—	1,075
Thereafter	2,500	—	2,500
Total	**$ 7,825**	**$ 74,820**	**$82,645**

Minimum Royalty Commitments

Minimum royalty commitments are associated with licensing agreements related to research efforts.

The table above includes minimum annual royalty payments but does not include royalties that would be payable on net sales of Galleri, and any future products, pursuant to existing agreements and licenses with Illumina, the Chinese University of Hong Kong, and other third parties in excess of minimum annual royalty payments.

Purchase Commitments

The purchase commitments primarily relate to contractual commitments for future use of web services, laboratory supplies and marketing events in the normal course of business.

Intellectual Property

The Company entered into an agreement with a third party for exclusive option rights to certain intellectual property. The Company exercised those option rights to license intellectual property in December 2022. Under

the terms of the agreement, the Company may be obligated to make future milestone payments if certain milestone events, such as new product launches or expansion into new regions, are achieved with respect to products covered by the licensed intellectual property. No such milestones were achieved or probable of achievement as of December 31, 2023.

Indemnification

The Company has agreed to indemnify its directors and officers for certain events or occurrences while the director or officer is (or was) serving in such capacity. The indemnification period covers all pertinent events and occurrences during the director's or officer's service. The maximum potential amount of future payments the Company could be required to make under the applicable indemnification agreements is not specified in the agreements.

The Company enters into standard indemnification arrangements in the ordinary course of business. Pursuant to these arrangements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to the Company's technology. The term of these indemnification agreements is generally perpetual after the execution of the agreement. The maximum potential amount of future payments that the Company could be required to make under these arrangements is not determinable. The Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the Company believes the estimated fair value of these agreements is minimal.

NOTE 7. STOCK INCENTIVE AWARDS

Stock-Based Compensation

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

	(Successor)			(Predecessor)
(in thousands)	Year Ended December 31, 2023 (1)	Year Ended January 1, 2023 (2)	August 19, 2021 to January 2, 2022 (3)	January 1 to August 18, 2021
Cost of screening revenue (exclusive of amortization of intangible assets)	$ 1,932	$ 955	$ 118	$ 83
Cost of development services revenue	38	2	32	5
Research and development	39,792	34,859	189,767	5,078
Sales and marketing	17,506	11,232	75,419	3,036
General and administrative	37,967	28,681	384,924	23,445
Stock-based compensation expense, before taxes	97,235	75,729	650,260	31,647
Related income tax benefits	(23,455)	(18,046)	(155,510)	(7,607)
Stock-based compensation expense, net of taxes	**$ 73,780**	**$ 57,683**	**$ 494,750**	**$ 24,040**

(1) Includes $95.5 million related to the Cash-Based Equity Awards and $1.7 million related to Replacement Awards.
(2) Includes $65.8 million related to the Cash-Based Equity Awards and $9.9 million related to Replacement Awards.
(3) Includes $11.1 million related to the Cash-Based Equity Awards, $24.1 million related to Replacement Awards and $615.0 million of accelerated equity awards attributable to the Post-Combination period.

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Liability-Classified Awards

Established following the Acquisition, a cash-based equity incentive award (the "Cash-Based Equity Award") was adopted to provide GRAIL, LLC employees with dollar-denominated long-term incentive awards that increase or decrease in value based on corresponding changes in GRAIL's calculated value, similar to a dollar-denominated restricted stock unit award determined in accordance with the award agreement. GRAIL's stand-alone value calculation is estimated by the Company based on its analysis and on input from independent valuation advisors. To estimate the value of GRAIL, various assumptions may be used, such as long-range financial projections, as well as the discount rate and terminal growth rate. The awards generally have terms of four years and vest in four equal installments on each anniversary of the grant date, subject to continued employment through the vesting period.

Cash-Based Equity Award activity was as follows:

(in thousands)	Year Ended December 31, 2023	Year Ended January 1, 2023	August 19, 2021 to January 2, 2022
Beginning balance	**$ 293,359**	**$ 184,532**	**$ —**
Granted	116,407	168,065	217,776
Cancelled	(32,159)	(40,937)	(41,898)
Vested and paid in cash	(76,910)	(41,009)	—
Change in fair value	(8,508)	22,708	8,654
Outstanding balance	**$292,189**	**$293,359**	**$ 184,532**

The Company's estimated incentive plan liabilities as of December 31, 2023 and January 1, 2023 were $54.5 million and $35.9 million, respectively. As of December 31, 2023, approximately $237.7 million of total unrecognized compensation cost related to awards issued to date was expected to be recognized over a weighted-average period of approximately 2.5 years.

The Company has one performance-based award outstanding 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. As of December 31, 2023, it was not probable that the performance conditions associated with the award will be achieved and, therefore, no stock-based compensation expense, or corresponding liability, has been recognized in the consolidated financial statements to date.

Accelerated Awards at Acquisition and Replacement Awards

In connection with the Acquisition, the vesting of certain outstanding and unvested equity awards was accelerated. The fair value of the accelerated awards attributable to the Post-Combination period and recognized in connection with this event was $615.0 million.

Illumina issued Replacement Awards to GRAIL employees in exchange for any of their remaining outstanding and unvested GRAIL equity awards as of the Closing Date. The Replacement Awards, granted under Illumina's 2015 Stock and Incentive Compensation Plan (the 2015 Stock Plan), consist of restricted stock units and performance stock options that are issued as shares of Illumina common stock at vesting. RSUs generally vest over a two-year period with equal vesting quarterly. The terms of the Replacement Awards are substantially similar to the former GRAIL equity awards for which they were exchanged. The fair value of the Replacement Awards was $47.5 million, all of which is attributable to Post-Combination service, and will be recognized as stock-based compensation expense over the remaining vesting period subsequent to the acquisition. The

weighted-average acquisition-date fair value of the replacement performance stock options was determined using the Black-Scholes option pricing model with the following assumptions: (i) market price of $510.61 per share, which was the closing price of Illumina's common stock on the Closing Date; (ii) weighted-average expected term ranging from 1.6 years to 2.2 years; (iii) weighted-average risk-free interest rate ranging from 0.17% to 0.28%; (iv) weighted-average annualized volatility ranging from 40% to 43%; and (v) no dividend yield. The weighted-average acquisition-date fair value per share of the replaced performance stock options was $424.39.

As of December 31, 2023, approximately $2.5 million of total unrecognized compensation cost related to performance stock options was expected to be recognized over a weighted-average period of approximately 3.7 years.

Replacement restricted stock activity was as follows:

(Units in thousands)	Restricted Stock Units	Weighted-Average Grant-Date Fair Value Per Share
Outstanding at August 19, 2021	—	$ —
Awarded	59	$ 510.61
Vested	(7)	$ 510.61
Cancelled	(5)	$ 510.61
Outstanding at January 2, 2022	47	$ 510.61
Vested	(39)	$ 510.61
Cancelled	(6)	$ 510.61
Outstanding at January 1, 2023	2	$ 510.61
Vested	(2)	$ 510.61
Outstanding at December 31, 2023	—	**$** —

Pre-tax intrinsic value and fair value of vested restricted stock was as follows:

	December 31, 2023	January 1, 2023
Pre-tax intrinsic value of outstanding restricted stock	$ —	$ 488
Fair value of restricted stock vested	$ 519	$ 10,967

Replacement performance stock option activity was as follows:

(Units in thousands)	Performance Stock Options	Weighted-Average Exercise Price
Outstanding at August 19, 2021	—	$ —
Granted	48	$ 86.73
Exercised	(21)	$ 86.72
Cancelled	(10)	$ 89.63
Outstanding at January 2, 2022	17	$ 85.54
Outstanding at January 1, 2023	17	$ 85.54
Exercised	(1)	$ 16.69
Outstanding at December 31, 2023	**16**	**$ 87.74**

There were no outstanding performance stock options exercisable as of December 31, 2023. The aggregate intrinsic value of performance stock options outstanding as of December 31, 2023 and January 1, 2023 was $0.9 million and $3.3 million, respectively. The total intrinsic value of performance stock options exercised was $6.3

million in 2021. Outstanding performance stock options, in general, have contractual terms of ten years from the respective grant dates. The performance stock 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.

Predecessor Period Awards

During the Predecessor period, the Company granted awards under the GRAIL, Inc. 2016 Amended Equity Incentive Plan (the "2016 Plan") as well as incentive awards not under the 2016 Plan (the "Non-Plan Equity Incentive Awards"). The Company's 2016 Plan allowed for the grant of awards in the form of: (i) incentive stock options, (ii) nonqualified stock options; (iii) stock appreciation rights; (iv) RSAs; (v) RSUs; and (vi) unrestricted stock. Directors, employees, and consultants were eligible to participate in the 2016 Plan.

In connection with the Acquisition, a portion of the unvested stock options and RSUs under the 2016 Plan and Non-Plan Equity Incentive Awards were accelerated and vested. GRAIL, Inc.'s 2016 Plan and Non-Plan Equity Incentive Awards were then cancelled, with any remaining unvested equity awards replaced with equity awards issued by Illumina. Refer to the Accelerated Awards at Acquisition and Replacement Awards section of this disclosure for a further discussion of these Replacement Awards.

Stock Option Activity—A summary of all stock option activity for the 2016 Plan is as follows:

(in thousands, except years and per share data)	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Balance as of December 31, 2020	81,813	$ 1.89	8.73	$537,108
Awards Authorized				
Exercised	(3,216)	$ 1.57		
Forfeited	(1,262)	$ 1.90		
Balance as of August 18, 2021 cancelled in connection with the Acquisition	**77,335**	**$ 1.91**	**8.12**	**$506,651**

Restricted Stock Unit Activity—A summary of all restricted stock unit activity for the 2016 Plan is as follows:

(in thousands, except per share data)	Restricted Stock Units Outstanding	Weighted-Average Grant Date Fair Value Per Share
Balance as of December 31, 2020	18,768	$ 2.71
Granted	13,427	$ 8.46
Vested	(8,898)	$ 1.99
Forfeited	(485)	$ 8.35
Unvested balance as of August 18, 2021 cancelled in connection with the Acquisition	**22,812**	**$ 6.25**

NOTE 8. RELATED PARTY TRANSACTIONS

Illumina Purchases and Sales

As discussed in note "1. Organization and Description of Business," GRAIL and Illumina entered into the Merger Agreement on September 20, 2020, and on August 18, 2021, Illumina completed its acquisition of

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GRAIL, Inc. Prior to the Acquisition, Illumina held a 12% 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.

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

(in thousands)	As of December 31, 2023	As of January 1, 2023
Accounts receivable, net—related parties	$ 80	$ 213
Supplies—related parties	$ 5,855	$ 4,984
Prepaid expenses and other current assets—related parties	$ 41	$ 68
Property and equipment, net—related parties	$ 3,640	$ 2,515
Accounts payable—related parties	$ 168	$ 2,292
Accrued liabilities—related parties	$ 95	$ 4

	(Successor)			(Predecessor)
(in thousands)	Year Ended December 31, 2023	Year Ended January 1, 2023	August 19, 2021 to January 2, 2022	January 1 to August 18, 2021
Screening revenue—related parties	$ 652	$ 694	$ 381	$ 46
Cost of screening revenue—related parties	$ 8,532	$ 4,142	$ 637	$ 192
Cost of development services revenue—related parties	$ 238	$ 227	$ 133	$ —
Operating expenses—Research and development—related parties	$ 19,508	$ 18,780	$ 1,233	$ 10,076
Operating expenses—General and administrative—related parties	$ 206	$ 614	$ 35	$ 4

In accordance with the terms of the Merger Agreement, the Company received continuation payments of $35.0 million per month from the signing of the Merger Agreement until Closing, which were recorded as additional paid-in capital. During the Predecessor period from January 1, 2021 to August 18, 2021, the Company received total continuation payments from Illumina of $245.0 million.

Contributions from (Distribution to) Member, Net

The following related party transactions between the Company and Illumina have been included in these consolidated financial statements. As there is no intercompany loan agreement between Illumina and GRAIL and because these transactions have no history of being settled, the total net effect of these transactions are reflected in the consolidated statements of cash flows as cash provided by (or used by) financing activity and in the consolidated balance sheets as contribution from (distribution to) member, net, in member's equity. The following table presents the components of the net transfers to and from Illumina:

(in thousands)	December 31, 2023	January 1, 2023	January 2, 2022
Cash funding received from Illumina	$ 464,000	$609,000	$ 174,000
Cash funding received from Illumina at acquisition	—	—	600,000
Cash payments for acquisition consideration on behalf of Illumina	—	—	(625,749)
Cash payments for equity awards	—	—	(184,963)
Taxes paid related to net share settlement of equity awards	(234)	(4,183)	(4,320)
Other	—	(544)	(1,883)
Total contribution from (distribution to) member, net	**$ 463,766**	**$604,273**	**$ (42,915)**

Dr. Klausner Consulting Agreement

Effective May 2016, the Company entered into a consulting agreement for advisory consulting services with Richard Klausner, M.D., a member of the board of directors of the Company at that time. The compensation under the consulting agreement consisted of options to purchase Class A common stock and reimbursement of certain out-of-pocket expenses. The Company granted options to purchase shares of Class A common stock under the consulting agreement in 2016, 2018, and 2020. In accordance with the terms of the Merger Agreement, all awards granted to Dr. Klauser became fully vested upon the closing of the transaction, which is also when Dr. Klauser stopped providing directorship and consulting services to the Company and ceased to be a related party of the Company. Stock-based compensation expense of $0.4 million related to the consulting agreement is included in research and development—related parties for the Predecessor period from January 1, 2021 to August 18, 2021.

Agilent Relationship

From June 2019 through October 2021, Mr. Hans Bishop served as the Company's chief executive officer, during which time Mr. Bishop also served on the board of directors of Agilent Technologies, Inc. ("Agilent"), a supplier to the Company. Transactions with Agilent during the period of time Mr. Bishop held an officer role at the Company are reflected in the consolidated financial statements as related party transactions. Related party expenses of $0.1 million and $0.2 million are included in research and development—related parties in the periods of August 19, 2021 to January 2, 2022 and January 1, 2021 to August 19, 2021, respectively. Agilent was no longer a related party as of the year ended January 1, 2023.

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, a supplier to the Company. Transactions with Twist beginning when Mr. Ragusa became the Company's chief executive officer are reflected in the consolidated financial statements as related party transactions. Related party expenses of $1.1 million, $0.4 million and $0.1 million are included in research and development—related parties in the years ended December 31, 2023 and January 1,

2023 and the period from August 19, 2021 to January 2, 2022, respectively. Related party expenses of $0.2 million are included in cost of screening revenue—related parties in the year ended December 31, 2023. Related party balances with Twist of $0.7 million and $0.1 million are included in accounts payable—related parties as of December 31, 2023, and accrued liabilities—related parties as of January 1, 2023, respectively. As of December 31, 2023, a balance of $1.1 million is included in supplies—related parties.

NOTE 9. NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS

In connection with the Acquisition, each issued and outstanding share of GRAIL Stock was converted into the elected merger consideration. As the Successor Company is a single-member limited liability company wholly owned by Illumina, a separate calculation of net loss per share is not included for the years ended December 31, 2023, and January 1, 2023, and for the period ended January 2, 2022.

For the Predecessor period from January 1, 2021 to August 18, 2021, basic and diluted net loss per share attributable to common stockholders were presented in conformity with the two-class method required for participating securities. All series of its redeemable convertible preferred stock and early exercised stock options and restricted stock awards were determined to be participating securities. Under the two-class method, the net loss attributable to common stockholders was not allocated to the redeemable convertible preferred stock as the holders of the redeemable convertible preferred stock did not have a contractual obligation to share in losses. The Company had two classes of common stock, Class A and Class B, with voting rights of 1:1 and 10:1, respectively. The shares of Class B common stock were convertible into shares of Class A common stock at a ratio of 0.44 shares of Class A common stock to 0.42 shares of Class B common stock, but were otherwise obligated to share in losses equitably.

Basic net loss per share attributable to common stockholders was calculated by dividing the net loss adjusted to include deemed dividends paid to the holders of the preferred stock and accretion to the redemption value of the redeemable common stock awards, to the extent both impact accumulated deficit, by the weighted-average number of shares of common stock outstanding during the period, less shares subject to repurchase. Diluted net loss per share attributable to common stockholders was the same as basic net loss per share, since the effects of potentially dilutive securities were anti-dilutive given the net loss attributable to common stockholders for each period presented.

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

(in thousands, except share and per share data)	(Predecessor) January 1 to August 18, 2021 Class A	Class B
Numerator		
Net loss	$ (280,058)	$ (56,175)
Net loss attributable to common stockholders	$ (280,058)	$ (56,175)
Denominator		
Basic common shares outstanding:		
Weighted average shares of common stock—basic	124,584,841	24,989,397
Weighted average shares used in earnings per common share—basic	124,584,841	24,989,397
Net loss per share attributable to common stockholders		
Basic	$ (2.25)	$ (2.25)
Diluted	$ (2.25)	$ (2.25)

The Company is in a net loss position, whereby the basic net loss per share is the same as diluted net loss per share because the inclusion of potential shares of common stock would have been anti-dilutive. The following common stock equivalents were therefore excluded from the computation of diluted net loss per share for the period presented:

	August 18, 2021
Redeemable convertible preferred stock (on an if-converted basis)	534,145,027
Options to purchase common stock and restricted stock units	129,971,156
Shares subject to repurchase	479,888
Total	**664,596,071**

NOTE 10. TAXES

Income (loss) before income taxes summarized by region was as follows:

(in thousands)	(Successor) December 31, 2023	January 1, 2023	August 19, 2021 to January 2, 2022	(Predecessor) January 1 to August 18, 2021
United States	$(1,509,885)	$(5,443,759)	$ (892,906)	$ (343,465)
Foreign	2,249	2,371	(36,113)	7,232
Loss before provision for (benefit from) income taxes	**$(1,507,636)**	**$(5,441,388)**	**$ (929,019)**	**$ (336,233)**

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The provision for (benefit from) income taxes consisted of the following:

(in thousands)	(Successor) December 31, 2023	(Successor) January 1, 2023	(Successor) August 19, 2021 to January 2, 2022	(Predecessor) January 1 to August 18, 2021
Current taxes:				
Foreign	$ (3,798)	$ (3,227)	$ —	$ —
Total current income tax expense/(benefit)	(3,798)	(3,227)	—	—
Deferred taxes:				
Federal	(22,019)	(24,496)	(14,862)	—
State	(16,134)	(14,567)	(2,615)	—
Total deferred income tax expense/(benefit)	(38,153)	(39,063)	(17,477)	—
Provision for (Benefit from) income taxes	**$ (41,951)**	**$(42,290)**	**$ (17,477)**	**$ —**

The provision for (benefit from) income taxes reconciles to the amount computed by applying the federal statutory rate to income (loss) before income taxes as follows:

(in thousands)	(Successor) December 31, 2023	(Successor) January 1, 2023	(Successor) August 19, 2021 to January 2, 2022	(Predecessor) January 1 to August 18, 2021
Tax at federal statutory rate	$ (316,603)	$(1,142,691)	$ (195,094)	$ (70,609)
State, net of federal benefit	(28,833)	(22,553)	(7,718)	(67,720)
Research tax credits	(10,913)	(12,104)	(2,792)	(21,757)
Change in valuation allowance	178,867	146,621	55,907	465,038
Impact of foreign operations	(1,299)	(4,352)	6,072	(11,384)
Stock compensation	134	1,767	859	(310,191)
Impact of acquisition related items	3,520	2,548	125,179	8,959
Goodwill impairment	127,778	987,090	—	—
Change in tax rates	—	—	—	7,639
Other	5,398	1,384	110	25
Total tax provision (benefit from) income taxes	**$ (41,951)**	**$ (42,290)**	**$ (17,477)**	**$ —**

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Significant components of deferred tax assets and liabilities were as follows:

(in thousands)	December 31, 2023	January 1, 2023
Deferred tax assets:		
Net operating losses	$ 899,323	$ 807,914
Tax credits	88,571	76,579
Other accruals and reserves	19,223	15,612
Stock compensation	373	234
Capitalized U.S. research and development expenses	124,997	68,745
Other amortization	61,036	64,119
Operating lease liabilities	19,825	22,353
Other	662	579
Total gross deferred tax assets	1,214,010	1,056,135
Valuation allowance on deferred tax assets	(570,897)	(392,019)
Total deferred tax assets	**$ 643,113**	**$ 664,116**
Deferred tax liabilities:		
Purchased intangible amortization	$ (653,478)	$ (709,231)
Property and equipment	(2,964)	(2,241)
Operating lease right-of-use assets	(19,592)	(23,719)
Total deferred tax liabilities	**(676,034)**	**(735,191)**
Deferred tax liability, net	**$ (32,921)**	**$ (71,075)**

Upon closing of the merger, as a single-member limited liability company wholly owned by Illumina, GRAIL, LLC is no longer subject to U.S. income tax as a separate entity for the Successor periods ended December 31, 2023, January 1, 2023, and January 2, 2022, and is combined into Illumina's consolidated income tax return as an entity disregarded as being separate from Illumina. However, for financial statement purposes, GRAIL has elected to compute its income tax provision, including current and deferred taxes, as if GRAIL was a corporation filing a separate income tax return and was not included in Illumina's consolidated return. Under this method, the deferred tax assets and liabilities presented above are as if GRAIL, LLC filed a separate return for the Successor periods. For income tax purposes, since GRAIL, LLC is not a separate taxpayer and merely a disregarded entity of Illumina, several of the U.S. tax attributes shown above, 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 U.S. tax attributes will not be available to a standalone GRAIL entity on its income tax returns in the future.

A valuation allowance is established when it is more likely than not that the future realization of all or some of the deferred tax assets will not be achieved. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis and includes a review of all available positive and negative evidence, including operating results and future reversals of existing taxable temporary differences such as the deferred tax liabilities related to purchased intangibles. Based on the available evidence as of December 31, 2023, we were not able to conclude it is more likely than not certain deferred tax assets will be realized. Therefore, a valuation allowance of $570.9 million was recorded against certain U.S. and foreign deferred tax assets.

As of December 31, 2023, the net operating loss carryforwards for federal and state tax purposes were $3.5 billion and $2.3 billion, respectively, a portion of which will begin to expire in 2036 unless utilized prior. The federal and state tax credit carryforwards were $90.5 million and $64.2 million. The federal credits will begin to expire in 2036 unless utilized prior. The state credits do not expire and can be carried forward

indefinitely. GRAIL's U.K. subsidiary had $28.8 million of U.K. net operating losses that can generally be carried forward provided that the U.K. entity maintains its existing trade or business.

Pursuant to Section 382 and 383 of the Internal Revenue Code, utilization of net operating losses and credits may be subject to annual limitations in the event of any significant future changes in its ownership structure. These annual limitations may result in the expiration of net operating losses and credits prior to utilization.

The following table summarizes the gross amount of uncertain tax positions:

	(Successor)			(Predecessor)
(in thousands)	Year Ended December 31, 2023	Year Ended January 1, 2023	August 19, 2021 to January 2, 2022	January 1 to August 18,2021
Balance at beginning of year	$ 51,843	$ 43,595	$ 41,683	$ 11,682
Increases related to prior year tax positions	—	—	—	9,842
Decreases related to prior year tax positions	—	—	—	(843)
Increases related to current year tax positions	7,452	8,248	1,912	21,002
Balance at end of year	**$ 59,295**	**$ 51,843**	**$ 43,595**	**$ 41,683**

Included in the balance of uncertain tax positions as of December 31, 2023 and January 1, 2023 were $54.4 million and $47.6 million, respectively, of net unrecognized tax benefits that, if recognized, would reduce the effective income tax rate in future periods. The Company has not recognized any interest or penalties related to uncertain tax positions. If interest and penalties are recognized in the future, such amounts will be included in the provision for income taxes.

Tax years 2016 to 2023 remain subject to future examination by the major tax jurisdictions in which we are subject to tax. It is reasonably possible that the balance of unrecognized tax benefits could change significantly over the next 12 months. However, due to the number of years remaining that are subject to examination, we are unable to estimate a full range of possible adjustments to the balance of unrecognized tax benefits.

NOTE 11. 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.

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 the Spin-Off to facilitate a prompt resolution of the FTC proceedings and, based on the fact that Illumina had a 14.5% ownership interest in GRAIL at the time of the Acquisition, do not expect that Illumina's potential retention of up to a 14.5% ownership interest in GRAIL will affect the resolution of these proceedings.

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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 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 request is currently pending before the Court of Justice of the European Union. An oral hearing before the Court of Justice of the European Union was held on December 12, 2023.

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 Europe. 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). This procedure is currently pending and moving forward.

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"). Consistent with the previous interim measures orders, Illumina is required to continue funding the Company until any divestiture. In the instance of a capital markets transaction, Illumina must capitalize the Company at the time of the transaction with two-and-a-half years of funding based on the Company's long-range plan. The order also permits 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. The divestiture would be executed through a third-party sale or capital markets transaction, consistent with the European Commission's divestiture order, with the goal of finalizing the terms by the end of the second quarter of 2024, as publicly announced by Illumina. On December 22, 2023, Illumina submitted a draft divestment plan to the European Commission outlining proposed terms of the divestiture. The draft divestment plan is undergoing review by the European Commission, subject to comments by GRAIL and the Monitoring Trustee. GRAIL submitted its Observations to the draft divestment plan on January 12, 2024. On February 19, 2024, Illumina submitted a modified draft divestment plan to the European Commission. The Monitoring Trustee submitted its opinion on the divestment plan on January 31, 2024. The divestment plan, outlining the terms of the Company's divestiture, requires approval from the European Commission.

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.

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.

We are 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, we assess, on a regular basis, the probability and range of possible loss based on the developments in these matters. A liability is recorded in the 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. We regularly review outstanding legal matters to determine the adequacy of the liabilities accrued and related disclosures. We may change our estimates if our assessment of the various factors changes and the amount of ultimate loss may differ from our estimates, resulting in a material effect on our business, financial condition, results of operations, and/or cash flows. As of December 31, 2023, there were no pending litigations with any probable losses that can be reasonably estimated.

NOTE 12. SUBSEQUENT EVENTS

The Company has reviewed and evaluated subsequent events through March 8, 2024, the date these consolidated financial statements were filed.