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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

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**FORM 10-K**

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(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

For the transition period from to

Commission file number 001-42045

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**GRAIL, Inc.**

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(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**1525 O'Brien Drive  
Menlo Park, California**

(Address of Principal Executive Offices)

**86-3673636**

(I.R.S. Employer Identification No.)

**94025**

(Zip Code)

**(833) 694-2553**

Registrant's telephone number, including area code

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value	GRAL	Nasdaq Global Select Market

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes  No

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

Yes  No

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

Yes  No

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

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

Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, as of the last business day of the Registrant's most recently completed second fiscal quarter was approximately \$1.9 billion (based on the closing price of the Registrant's Common Stock on June 30, 2025 of \$51.42 per share).

As of March 6, 2026, the registrant had 41,020,255 shares of common stock, par value \$0.001 per share, outstanding.

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to its 2026 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. Such definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended December 31, 2025.

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## Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (this “Form 10-K”) contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). In some cases, you can identify these statements by forward-looking words such as “aim,” “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “should,” “would,” or “will,” the negative of these terms, and other comparable terminology. These forward-looking statements, which are subject to risks, uncertainties, and assumptions about us, may include expectations and projections of our future financial performance, future tests or products, technology, clinical studies, regulatory landscape, compliance and strategy, potential market opportunity, increased competition, anticipated growth strategies, sufficiency of cash on hand to finance our business, seasonality, cost savings, facilities plans and lease commencement, budgets and strategies, restructuring and stock-based compensation costs, legal proceedings, impact of the restructuring on our operations, expected closing and benefits from the Samsung Investment (defined below), including the related collaboration agreements, and anticipated trends in our business.

These statements are only predictions based on our current expectations and projections about future events and trends. There are important factors that could cause our actual results, level of activity, performance, or achievements to differ materially and adversely from those expressed or implied by the forward-looking statements. You should specifically consider the numerous factors and risks described under the section entitled “Risk Factors.” Moreover, we operate in a dynamic and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results, level of activity, performance, or achievements to differ materially and adversely from those contained in any forward-looking statements we may make.

Forward-looking statements relate to the future and, accordingly, are subject to inherent uncertainties, risks, and changes in circumstances that are difficult to predict and many of which are outside of our control. Although we believe the expectations and projections expressed or implied by the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance, or achievements. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Except to the extent required by law, we undertake no obligation to update any of these forward-looking statements after the date of this Form 10-K to conform our prior statements to actual results or revised expectations or to reflect new information or the occurrence of unanticipated events.

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## Summary of Material Risks Associated with Our Business

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

- We operate in a rapidly evolving field and have a limited operating history, which make it difficult to evaluate our current business and predict our future performance.
  - We have incurred significant net losses in each period since our inception and anticipate that we will continue to incur net losses for the coming years.
  - Our products or future products may not perform as expected, and the results of our clinical studies may not be replicated in the post-market or real-world setting.
  - The clinical study process is lengthy and expensive with uncertain outcomes. We have encountered delays and may encounter future delays in, or unexpected, uncertain or negative 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.
  - A substantial majority of our revenue is generated from sales of Galleri and we are highly dependent on it for our success.
  - If our products do not receive adequate coverage and reimbursement, if at all, from third-party payors, our ability to expand access to our products and our overall commercial success beyond our existing sales channels will be limited.
  - Our commercial products may fail to achieve the degree of market acceptance necessary for commercial success.
  - We have launched Galleri as a laboratory developed test in the United States. In 2024, the FDA finalized a regulation that has been successfully challenged in federal court, pursuant to which the FDA planned to subject laboratory developed tests to medical device requirements through a phase-out of its historical policy of enforcement discretion over laboratory developed tests over a period of four years. A federal court recently vacated this rule.
  - The regulatory clearance, approval, or certification processes of the FDA and comparable foreign regulatory authorities or notified bodies are lengthy, time-consuming, and unpredictable.
  - Our multi-cancer detection tests are a new approach to cancer screening, which present a number of novel and complex issues for FDA review. Because the FDA has never cleared or approved a multi-cancer detection test, we cannot provide assurances regarding information we will need to submit to obtain approval of a premarket application 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.
  - We may not be able to generate sufficient revenue to offset our ongoing operating expenses and achieve and maintain profitability, and it may be difficult for us to offset the costs of our royalties, including the high single-digit royalty that we will be required to pay to Illumina in perpetuity or our royalties payable to the Chinese University of Hong Kong.
  - We may be unable to develop and commercialize new products, including enhanced versions of current products.
  - If similar third-party products are developed and do not perform as intended or cause harm or injury to patients, the market for our products could be impaired.
  - If we fail to obtain additional financing, we may be unable to expand our commercialization efforts or to develop and commercialize additional products.
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- If our products result in direct or indirect participant or patient harm or injury, we could be subject to significant reputational and liability risks.
- We rely on Illumina, Inc. as a sole supplier for our next-generation sequencers and associated reagents, Madison Industries as a sole supplier of blood collection tubes, and Twist Bioscience Corporation as a sole supplier of 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.
- If our facilities become inoperable, our ability to provide our products will be significantly impaired, and our business will be harmed.
- Our operations and business are materially dependent on various third parties, including information technology, sample collection, processing, transfer facilities, and other patient-facing service providers, any of which could experience disruption, failure, or interruption.
- If we are unable to scale our operations successfully to support demand for our products, our business could suffer.
- 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 information technology systems, or those used by our third-party collaborators, other contractors, or consultants, may fail or suffer cybersecurity incidents or cyberattacks.
- 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.
- If we are unable to obtain and maintain intellectual property protection for our technology, or if the scope of the intellectual property protection we obtain is not sufficiently broad, third parties could in the future develop and commercialize technology and tests similar or identical to ours, and our ability to successfully commercialize our products may be impaired.
- If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.
- We could have an indemnification obligation to Illumina if the Distribution were determined not to qualify for non-recognition treatment for U.S. federal tax purposes.
- We have agreed to numerous restrictions to preserve the non-recognition treatment of the Spin-Off, which may reduce our strategic and operating flexibility.

The summary risk factors described above should be read together with the text of the full risk factors below in Item 1A. "Risk Factors" and the other information set forth in this Form 10-K, including our consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

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## PART I

### Item 1. 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 shifting the paradigm in early cancer detection at population scale. 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 multi-cancer early detection test (“Galleri”) can screen for many types of cancer, accurately predicting the specific organ or tissue type where the cancer signal originated (the “Cancer Signal of Origin”, or “CSO”), with high positive predictive values (“PPV”) and low false positive rates, all from a simple blood draw. Galleri has detected some of the most aggressive cancers in early stages including, among others, endometrial, esophageal, gastrointestinal, head and neck, liver, pancreatic, and rectal cancers. We have conducted what we believe is the largest clinical program in genomic medicine to date with data from over 385,000 participants that we believe demonstrate the clinical validation and clinical utility of Galleri in its intended use population. We have deep operational experience with over 800,000 tests processed across this clinical program and from our commercial experience, including through partnerships with leading healthcare systems, employers, digital health platforms, payors, and life insurance providers.

Recently we announced results from two of our large clinical trials, PATHFINDER 2 and NHS-Galleri Trial, and included certain results from those studies in our pre-market approval application (“PMA”) to the Food and Drug Administration (“FDA”), the last module of which we submitted in January 2026. Performance and safety data focused on the first approximately 25,000 participants of our approximately 35,000 participant PATHFINDER 2 study were presented at the European Society for Medical Oncology (“ESMO”) in October 2025 (the “PATHFINDER 2 Initial Results”) and demonstrated that adding Galleri to recommended (breast, cervical, colorectal and lung) screenings led to a cancer detection rate more than seven-fold increase in the number of cancers found within a year, and an approximately three-fold increase when prostate screening was included. Results from the full approximately 35,000 participants in the PATHFINDER 2 study were generally consistent with the results presented at ESMO. We also announced topline results from our three year, randomized control NHS-Galleri Trial which demonstrated a substantial reduction in stage 4 cancer diagnoses (including greater than 20% reduction in the second and third screening rounds), increased stage 1 and 2 detection of deadly cancers, and four-fold higher cancer detection rate when compared to recommended screenings alone. The primary endpoint of statistically significant combined stage 3 and 4 reduction was not observed. However, there was a favorable trend toward fewer combined stage 3 and 4 cancers in a pre-specified group of 12 deadly cancers in the intervention arm after the prevalent screening round. The PATHFINDER 2 Initial Results and the performance and safety metrics from the first year (prevalent screening round) of our NHS-Galleri Trial (“NHS-Galleri Prevalent Screening Round Results”) were included in our PMA submission, along with results of a bridging study.

Cancer is a major public health crisis. It is a 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 70% 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. 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 Multi-Cancer Early Detection (“MCED”) testing on mortality reduction based on test performance in our foundational case-control Circulating Cell-free Genome Atlas (“CCGA”) 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 estimated 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. We believe this model provides helpful context regarding the potential benefits of screening for multiple cancers at once with a singular screening test, like Galleri, in addition to the five standard of care single-cancer screening tests; however, there can be no assurance when or even if Galleri will be added to the USPSTF guidelines or standard of care screening. 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, when 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 CSO). In the PATHFINDER 2 Initial Results, Galleri correctly predicted the CSO in 122 of 133 participants with a cancer diagnosis following a cancer signal detected (positive) test result (i.e., participants with true positive test results), demonstrating a high CSO prediction accuracy. Galleri's screening test results can be used by healthcare providers to guide required follow-up diagnostic testing for a diagnosis of cancer.

As an early pioneer 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"), 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.

In January 2026, we submitted a PMA to the FDA to help support broad access for Galleri in the United States. Galleri is not a diagnostic test and has not been approved or cleared by the FDA. Our PMA submission package includes the NHS-Galleri Prevalent Round Results, together with data from the PATHFINDER 2 Initial Results. Our PMA submission package also includes a bridging analysis to compare performance of the version of Galleri used in the NHS-Galleri Trial and PATHFINDER 2 study to the updated version for which we are seeking approval (the "Bridging Analysis"). 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, including self-insured employers, but do not currently have broader coverage and reimbursement by government healthcare programs, such as Medicare. In February 2026 a new law created a Medicare coverage benefit category for MCED tests. The law included certain standards, including that Centers for Medicare and Medicaid Services ("CMS") would establish coverage through a national coverage determination ("NCD") process under "reasonable and necessary" evidentiary requirements. An NCD typically involves a multi-step review that can include evidence assessment by CMS staff, consultation with external technology assessment organizations, a Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) meeting, and opportunities for public comment. CMS may issue an NCD to provide coverage for MCED tests that are cleared under 510(k), classified under 513(f)(2) or approved by the FDA, with authority to initiate coverage as early as January 1, 2029, although any NCD may be delayed or be more restrictive than the full authority provided by statute. Coverage eligibility is phased in, with those aged 50-65 eligible under the law in 2029, expanding by one age-year annually. No version of Galleri has been approved or cleared by the FDA and obtaining PMA approval can take several years from the time an application is submitted. Galleri may not be approved on our expected timeline or at all. If FDA approval is obtained, we also expect to pursue inclusion of Galleri in the USPSTF's guideline recommendation, although such inclusion is not certain even with FDA approval and may take several years.

In the United Kingdom, NHS England (which is being merged with the Department of Health and Social Care) (the “NHS”) will evaluate the final results from the NHS-Galleri Trial before determining whether to implement the Galleri test in the NHS. We plan to share final results from the full three year NHS-Galleri trial in mid-2026. We believe the decision may include, in addition to an evaluation of the final results, considerations such as NHS budget, political priorities, cost-effectiveness and implementation constraints. Under our agreement with the NHS, these results have met certain success criteria and missed others. As a result, we and NHS England will convene meetings of our joint steering committee to discuss how best to proceed with deployment to the UK population, if at all, considering deployment approaches and which population groups would most benefit. We also believe our work with the NHS and the data generated from our NHS-Galleri Trial could help facilitate adoption in other single-payor systems around the world and support evidence of clinical utility worldwide. We believe the evidence of clinical utility from the trial, particularly the stage 4 reduction, increased stage 1 and 2 detection and a favorable trend over time in each screening round on combined stage 3 and 4 reduction, could be compelling to these systems even though the primary endpoint was not met. We believe the evidence package is even stronger when taken together with the positive results from our PATHFINDER 2 study.

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, including over 180,000 patients enrolled in our PATHFINDER and PATHFINDER 2 clinical studies and our NHS-Galleri Trial, the only interventional trials conducted in an intended use population to validate an MCED test. We are also enrolling up to 50,000 Medicare beneficiaries in our Real-world Evidence to Advance multi-Cancer early detection Health equity (“REACH” or “Galleri-Medicare”) interventional study designed to evaluate the clinical impact of Galleri in a population of Medicare beneficiaries, including racial and ethnic minorities, and seniors from historically underserved communities. These studies also include our foundational case-control CCGA study and interventional PATHFINDER study, which were used to develop and validate our MCED technology and launch Galleri as a commercial laboratory developed test (“LDT”) product. 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 that a number of findings in the NHS-Galleri Trial, together with the positive PATHFINDER 2 results, provide strong evidence of the clinical utility of Galleri in a population. The NHS-Galleri Trial is a rigorous, randomized control trial of over 140,000 participants that we designed in dialogue with the NHS. The main goal of the trial was to establish whether Galleri could provide a meaningful contribution towards achieving the NHS’s ambitious goal to achieve a significant shift in late stage cancer diagnosis by 2028. The endpoint of a reduction in stage 3-4 cancers combined was chosen as the primary endpoint because, at the time, it was most closely aligned with the NHS Long Term Plan, which was the basis for designing a broader implementation pilot within the NHS. We believe that the trial’s most important secondary endpoint, stage 4 reduction, also works toward this goal. Although the primary endpoint of statistically significant combined stage 3 and 4 reduction was not observed in the NHS-Galleri Trial, we believe the results of the trial provide evidence that Galleri can contribute to this goal. This goal is supported by the favorable trend shown toward fewer stage 3 and 4 cancers in the intervention arm after the prevalent screening round in the pre-specified group of 12 deadly cancers. Importantly, we also saw substantial and clinically meaningful reduction in stage 4 cancer, with more than 20% reductions in the second and third screening round. Had the stage 4 reduction endpoint been the primary endpoint, it would have been met. The trial also showed a substantial reduction in the number of cancers detected clinically through emergency presentation, which are associated with significantly higher mortality and healthcare costs, and a substantial increase in stage 1 and 2 cancers detected. In the trial, four times as many cancers were detected through Galleri combined with recommended screening compared to recommended screening alone, which adds proof to a similar seven fold increase shown in PATHFINDER 2. Taken together, we believe these strong results can provide a compelling evidence package to payers and other stakeholders, despite the trial not reaching the primary endpoint.

The clinical utility of Galleri is enabled by the strong underlying performance of the test. We believe our clinical studies, including our early discovery work, have demonstrated robust and reproducible test performance. Notably, the PATHFINDER 2 Initial Results presented at ESMO in October 2025 showed a PPV of 61.6%, substantially higher than our case-control CCGA study, and CSO accuracy of 92% and false positive rate of 0.4%, each consistent with the CCGA study. In 2025, we also announced topline NHS-Galleri Prevalent Round Results, which also showed a substantially higher PPV than our CCGA study. We believe the replication or improvement of the results from our case-control CCGA study in interventional studies in an intended use population is evidence supporting the generalizability and robustness of Galleri and the potential usefulness of returned Galleri results in clinical diagnostic and care pathways. Our previously published modeled PPV of 44% was 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 2 study was performed in an intended use population and PPV was measured directly. Data from our foundational CCGA study was presented in oral and poster presentations at multiple major medical conferences including the AACR, ASCO and ESMO and were published in *Annals of Oncology* in 2020 and 2021 and *Cancer Cell* in 2022. Results from our first PATHFINDER study presented at ASCO in 2021, analyzing data from 6,629 individuals aged 50 years or older, showed a PPV consistent with CCGA. Results from the full approximately 35,000 participants in the PATHFINDER 2 study were generally consistent with the results presented at ESMO. Galleri test performance in the NHS-Galleri Trial was consistent with the range previously reported from our North American studies. We expect to continue to report clinical data from our clinical program over many years.

We have also gained insight from studies of the use of our methylation technology in other populations and in the real world. Our SYMPLIFY study, a prospective multi-center observational study, represents the first large-scale evaluation of an MCED test in symptomatic patients who were referred from the primary care setting due to clinical suspicion of cancer. This patient population represents a distinct patient population from the asymptomatic screening population assessed in the PATHFINDER and PATHFINDER 2 studies and the NHS-Galleri Trial. Initial analysis from the study after nine month follow up showed strong PPV and consistent CSO. But in an analysis based on continued follow up through 24 months through national cancer registries, we found that 35.4% (28 of 79) of patients initially determined to be false positives were diagnosed with cancer. This reduction in false positives by approximately one third resulted in an updated PPV of 84.2%, and 27 of these 28 participants had a correct CSO prediction. Real world evidence, while not directly comparable to our clinical study evidence, is also an important part of our program, with publications and presentations by us and our partners showing Galleri performance in the clinic and building best practices for implementation and follow up that can be used in key health systems.

Based on our extensive, published and peer reviewed discovery work, we believe that a targeted methylation approach, which entails interrogating specific methylation sites within a genome to assess methylation patterns and which is an integral part of the technology used in our Galleri test, is the best approach for detecting a cancer signal and identifying a CSO. In our head-to-head analyses we compared multiple different classifiers that were trained to detect a cancer signal and predict the CSO, and which were independently validated. We found that interrogating methylation patterns yielded significantly better results for cancer detection (based on sensitivity, CSO 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 CSO 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.

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 can leverage our proprietary platform for additional applications, including our precision oncology portfolio. We 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. Applications for our technology in our precision oncology partnerships include pre-treatment prognosis, post-treatment prognosis or minimal residual disease, 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 collaborative opportunities with biopharma partners, we believe that our methylation platform could enable standalone clinical products and support patient care across the cancer care continuum in the future.

We have also published data that demonstrates the value of applying our proprietary methylation platform as a diagnostic aid for cancer to accelerate diagnostic resolution for patients with non-specific signs and symptoms, but with a clinical suspicion of cancer. 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 screening test, Galleri.** Galleri is a commercially available MCED screening test that is setting the standard for multi-cancer early detection. While Galleri has not been approved or cleared by the FDA, we believe Galleri is clinically validated as a screening test 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. Galleri has shown strong clinical utility in the NHS-Galleri Trial, showing substantial reduction in stage 4 cancer diagnoses, increased stage 1 and 2 detection of deadly cancers, and four-fold higher cancer detection rate when compared to recommended screenings alone. Although the primary endpoint of statistically significant combined stage 3 and 4 reduction was not observed, there was a favorable trend toward fewer combined stage 3 and 4 cancers in a pre-specified group of 12 deadly cancers after the prevalent screening round Galleri achieves these clinical utility results through its strong performance characteristics in MCED screening for asymptomatic individuals, and has demonstrated an ability to accurately predict CSO, with high PPVs and low false positive rates. Galleri screening test results can help guide next steps for a diagnosis of cancer by healthcare providers in required follow-up diagnostic testing. 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.

- **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, 2025, we have sold more than 475,000 commercial tests, including more than 185,000 tests in 2025, and have established commercial partnerships, including leading healthcare systems, employers, digital health platforms, payors, and life insurance providers. In late 2024, we began use of a new version of Galleri in commercial channels which incorporates significant automation and is intended to enable us to scale more efficiently with future demand. In this real-world setting, Galleri is detecting deadly cancers in early stages, and healthcare providers have self-reported to us that Galleri's signal origin capability enables them to efficiently direct the pathway following a positive test. 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 dialogue with the NHS presents an opportunity to drive further adoption of Galleri, including by payors and health systems around the world. The NHS will evaluate the final results from the NHS-Galleri Trial, alongside other factors, before determining whether to implement the Galleri test in the NHS. We have also begun entering select international markets through distributor partners, including Israel and Canada, and intend to enter South Korea through our partnership with Samsung. Our commercial leadership is further supported by our high-capacity laboratory which is equipped to process Galleri tests at population screening volumes.

- **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 have deep operational experience with over 800,000 tests processed across this clinical program and from our commercial experience, including through partnerships with leading healthcare systems, employers, digital health platforms, payors, and life insurance providers. We are collecting population-scale clinical data from more than 385,000 participants across nine clinical studies, including over 180,000 patients enrolled in our PATHFINDER and PATHFINDER 2 clinical studies and our NHS-Galleri Trial, the only interventional trials conducted in an intended use population to validate an MCEd test. Our NHS-Galleri Trial, the first and largest randomized controlled trial of an MCEd test, enrolled more than 140,000 individuals in just over 10 months. We are also enrolling up to 50,000 Medicare beneficiaries in our REACH/Galleri-Medicare study designed to evaluate the clinical impact of the Galleri MCEd 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 as evidenced in the consistency in performance - including PPV, CSO accuracy and false positive rate - between our foundational work in CCGA and large scale study results from the NHS-Galleri Trial and PATHFINDER 2. We have submitted data from the NHS-Galleri Prevalent Screening Round and the PATHFINDER 2 Initial Results to the FDA as part of our PMA package. Together with our partners at leading community and academic medical centers in the United States and the United Kingdom, we expect to continue to report ongoing and long-term follow-up clinical data from our 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. Our first version of Galleri was built from an atlas that characterized 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 CSO. We have continued to use data from our clinical studies to refine Galleri, designing for improved performance and cost efficiency over time. We have also used our proprietary methylation platform, on which Galleri is based, 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, biomarker discovery, detection of recurrence, and clinical monitoring. We have also published data supporting the use of our technology 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, 2025, we have exclusive licenses to approximately 408 granted patents globally, and own or co-own more than 221 issued patents, with more than 400 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 in major global markets 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 the United Kingdom, and extending to other markets over time through both direct market entry and distributors. 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 and Galleri's utility in clinical practice, as demonstrated in our NHS-Galleri Trial (although it did not reach its primary endpoint) and PATHFINDER 2 studies, will drive clinical outcomes and high patient and provider satisfaction that will lead to further awareness and adoption. In particular, we have conducted market research showing that a stage 4 shift like that shown in the NHS-Galleri Trial would significantly influence a provider's willingness to prescribe.
- **Expanding access to our products by pursuing FDA approval and 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, health systems and digital health platforms to accelerate utilization, and with self-insured employers and health insurers to offer and cover Galleri. In the United States, as of December 31, 2025 we have established coverage and reimbursement from a number of self-insured employers and multiple payors and health systems, including certain government payors such as TRICARE, but do not currently have broad coverage and reimbursement by government healthcare programs, such as Medicare, or large commercial payors. We are pursuing FDA approval to help support broad access for Galleri in the United States, and submitted our PMA to the FDA in January, 2026. We believe that FDA approval could unlock large commercial payors in the United States. In February 2026, a new law created a coverage benefit category to enable coverage of FDA-approved MCEd tests by Medicare, with authority for CMS to initiate coverage as early as January 1, 2029 for the aged 50-65 Medicare population and expanding one age-year at a time annually. Nonetheless, no version of Galleri has been approved or cleared by the FDA and obtaining PMA approval can take several years, if at all, from the time the premarket application was submitted. Galleri may not be approved on our expected timeline or at all. If FDA approval is obtained, 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 in dialogue with NHS England. The NHS will evaluate the final results from the NHS-Galleri Trial, alongside other factors, before determining whether to implement the Galleri test in the NHS. We believe our work with the NHS and the data generated from our NHS-Galleri Trial (although it did not reach its primary endpoint), could help 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 pioneered the field of 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, 2025, we have published more than 90 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 30 podium and 250 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. We believe this market development strategy will drive adoption of our products and further awareness of the benefits of MCED testing generally.
- **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 of up to one million tests per year while satisfying stringent certification parameters. Our high-capacity laboratory is accredited by the College of American Pathologists (“CAP”) and certified by the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”) and the New York State Department of Health (“NYSDoH”), which represents one of the most rigorous levels of validation required for laboratory developed tests. With the roll-out of our new version of Galleri in late 2024, our facility is able to process test volumes in excess of our current forecasts without requiring significant additional investment in capital expenditures. 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, 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.
- **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. Further, we plan to improve our products to enhance performance, offerings, scalability, and/or cost of goods. New products, including enhanced versions of current products, require the completion of certain clinical development and regulatory activities, such as any required non-inferiority or bridging studies, which may draw on clinical or real world data obtained through Galleri’s commercial use and which may need to be agreed upon with regulatory authorities. We will continue to improve our technologies and launch innovative products across the cancer care continuum.

- **Sustaining a patient-first corporate culture that attracts top talent.** We have built a multi-disciplinary organization of leading scientists, engineers, clinicians and other professionals with a variety of backgrounds, all driven to improve outcomes for cancer patients. In our pursuit to improve cancer care and solve one of healthcare’s most important challenges, we recognize the importance of a workforce with different experiences, and we will continue to foster an agile and inclusive environment that is a destination for world-class talent with expertise from a variety of backgrounds. 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 a leading cause of death in both the United States and worldwide, with more than 20 million new cases and 10 million deaths globally in 2022. This burden is expected to grow as the global population ages. According to the data in the American Cancer Society’s *Cancer Facts & Figures 2026*, there are expected to be 2.1 million new cancer cases and 626,000 cancer deaths in the United States in 2026. 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 the American Cancer Society, the ability to cure cancer depends on the type and stage of cancer, the type of treatment the patient receives, and other factors. While there is not one cure for cancer and not all cancers may be cured, according to the World Health Organization many cancers can be cured if detected early and treated effectively and some of the most common cancer types, such as breast cancer, cervical cancer, oral cancer, and colorectal cancer, have high cure probabilities when detected early and treated according to best practices. 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. MCED screening also has the potential to detect more cancers without emergency department involvement, which is associated with twice the mortality rate and over \$100,000 higher health care costs in the first year, even when adjusted for cancer stage.

## Product

### ***Our Multi-Cancer Early Detection Test: Galleri***

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

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 screens an individual for a cancer signal shared by over 50 types of cancer, over 45 of which do not have recommended screening guidelines. Galleri has been studied in large clinical trials, including over 180,000 participants enrolled in interventional trials in the intended use population. In these clinical studies, Galleri has demonstrated an ability to predict the location of the suspected cancer with high accuracy, high PPV and a low false positive rate. For additional information, see "Business—Our Clinical Studies." Galleri screening test results can help guide next steps for a diagnosis of cancer by healthcare providers in required follow-up diagnostic testing. We launched Galleri in the United States in mid-2021. As of December 31, 2025, we have sold more than 475,000 commercial tests. In this real-world setting, Galleri has detected deadly cancers in early stages, including, among others, endometrial, esophageal, gastrointestinal, head and neck, liver, pancreatic, and rectal cancers. Our test has been deployed across healthcare systems, employers, digital health platforms, payors, and life insurance providers, and for additional at-risk groups such as first responders, 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 across many 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%. This is supported by our PATHFINDER 2 Initial Results, where adding Galleri to recommended screenings led to a more than seven-fold increase in the number of cancers found within a year, and an approximately three-fold increase when prostate screening was included. Similarly we saw a four-fold increase in the number of cancers found in our NHS-Galleri Trial. Approximately three-quarters of the cancers detected by Galleri do not have standard of care screening options.

#### **High PPV and low false positive rate**

In the PATHFINDER 2 Initial Results, Galleri demonstrated a high PPV of 61.6% and a low false positive rate of only 0.4%. Results from the full approximately 35,000 participants in the PATHFINDER 2 study were generally consistent with the PATHFINDER 2 Initial Results and performance from our NHS-Galleri Trial was consistent with the range previously reported from our North American studies. 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. While Galleri is designed to complement the current standard of care screening tests, Galleri's high PPV 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 PPV reported in PATHFINDER 2 for Galleri is based on whether cancer could be confirmed or other diagnostic resolution reached within 12 months after the blood draw, given that the true cancer status of participants was not known at the time of blood draw. Importantly, in our SYMPLIFY study in a symptomatic population, which is a different population than the asymptomatic population studied in PATHFINDER 2, PPV improved when the follow up window was extended from nine to 24 months, with 35.4% (28 of 79) of patients initially believed to have a false positive result later diagnosed with cancer.

### **Ability to predict with high accuracy the CSO and direct diagnostic workup**

In the PATHFINDER 2 Initial Results, Galleri demonstrated a high CSO accuracy of 92% for identifying the location of cancer, which supports physician approaches to diagnostic resolution through well-established workup pathways. Results from the full approximately 35,000 participants in the PATHFINDER 2 study showed a generally consistent CSO accuracy and CSO accuracy from our NHS-Galleri Trial was consistent with the range previously reported from our North American studies. CSO prediction accuracy represents the extent to which the CSO identified were correct among true positive tests. In the PATHFINDER 2 Initial Results, we found that Galleri's CSO prediction facilitated diagnostic resolution in a median of 46 days, with only 0.6% of all participants undergoing an invasive procedure (159 of 25,114). Invasive procedures were two times more common in participants with cancer than in those without. Further, Galleri's CSO 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, expose patients to radiation, and can lead to false alarms and unnecessary ancillary workups. In the commercial setting healthcare providers have self-reported to us that Galleri's signal origin capability enables them to efficiently direct the pathway following a positive test.

### **Backed by robust analytical and clinical performance**

Galleri screening test performance is validated by extensive clinical studies. We have established a broad population-scale clinical evidence program, including approximately 35,000 participants in our PATHFINDER 2 interventional study in our intended use population and over 140,000 participants in our NHS-Galleri Trial measuring clinical utility, and more than 21,000 participants included in the studies that supported the development and initial launch of Galleri. We initially locked our assay for our commercial launch and have made periodic planned updates with additional locks, such as our implementation of our highly automated laboratory process and for our PMA submission. We believe we have established clinical validation on the locked versions of our 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, other than planned updates. Each version update to our assay and classifier involves a concordance or non-inferiority study to show similar performance to our prior version. 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, study design and product development processes were robust enough to enable translation of similar performance from our foundational case control CCGA study to our interventional PATHFINDER study without seeing a degradation of performance, and showing improved performance on some metrics in our PATHFINDER 2 and NHS-Galleri Trial. 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. For example, data published in JCO Precision Oncology in 2024 demonstrated that prostate cancers that were detected by Galleri were more aggressive and clinically significant as compared to indolent and slow growing prostate cancers. We believe these results demonstrate that the use of MCED tests in a population-based screening program is unlikely to contribute to overdiagnosis of slow-growing prostate cancers that may not need treatment.

### **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. Additionally, we implemented multiple strategies to enroll a diverse and representative sample for our 140,000 participant NHS-Galleri study to enable trial results to be widely applicable.

We believe these validation studies in broad and diverse populations are essential for any MCED test to launch in a broad intended use population, such as adults over the age of 50.

### **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, over 70% 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. We believe this model provides helpful context regarding the potential benefits of screening for multiple cancers at once with a singular screening test, like Galleri, in addition to the five standard of care single-cancer screening tests; however, there can be no assurance when or even if Galleri will be added to the USPSTF guidelines or standard of care screening.

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. This modelling is supported by our PATHFINDER 2 study, where we found that adding Galleri to recommended screenings for breast, cervical, colorectal, and lung cancers (USPSTF A and B recommendations) led to a more than seven-fold increase in the number of cancers found within a year. In that study, Galleri detected approximately three times as many cancers when added to standard-of-care screening for breast, cervical, colorectal, lung, and prostate cancers (USPSTF A, B, and C recommendations). 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 65%.

### **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. In the commercial setting, healthcare providers have self-reported to us that Galleri's CSO capability enables them to efficiently direct the pathway following a positive test. The test is available through a wide range of in-person and telemedicine care settings in the United States. Importantly, in 2025 and early 2026 we have established partnerships with a number of digital health partners to bring Galleri to a broader audience of patients. Galleri is conveniently accessible to patients who can complete the blood draw at physician offices, reference labs, and mobile phlebotomy labs, among other locations. Key integrations, such as our integration with Quest to provide a simpler blood draw process and our planned integration with EPIC to simplify provider ordering, help make Galleri even more accessible. 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. We also provide patient navigation services in the rare cases that patients require support in navigating post-positive care pathways.

In addition, our software systems support a positive experience for providers and their patients. Our provider 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, that is delivered through our secure web portal to the ordering healthcare providers and patient to show whether or not a cancer signal is detected, and if so, to predict where in the body the cancer signal is located.

Through commercial and clinical use of Galleri, we have collected a number of positive patient testimonials from patients where Galleri detected a cancer signal, including from patients who have self-identified in media stories.

### ***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, efficiency and other test characteristics. Real-world evidence is already informing product improvements today. In late 2024, we deployed an updated commercial version of our Galleri test incorporating an automated platform and in preparation for our PMA submission we developed and locked a new version for FDA review. 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 CSO detection to reduce panel size, we could achieve deeper sequencing coverage and lower sequencing costs, as we did with our new version launched in 2024. 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 non-inferiority studies using clinical study data and real world evidence data obtained through Galleri's commercial use and 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 will need to be agreed upon with regulatory authorities.

### ***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.

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 and AstraZeneca has selected Galleri for use in important trials. Our RUO offering business is highly dependent on these partnerships and trials, and delays or terminations of trials can have a significant impact on the revenue we generate from this business, even if the reason for termination is unrelated to our RUO offering. For example, in late 2025, one of our pharmaceutical partners terminated its phase 3 trial due to low enrollment, for which our methylation technology was used as a potential companion diagnostic for enrolling participants. Even where trials are delayed or terminated, we may continue to have opportunities with the partner to continue developing companion diagnostics and other technology, or conduct other trials. 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, we conducted an analytical validation study in which 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.

### ***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 enable bringing potential new applications of our technology to market.

### **Clinical**

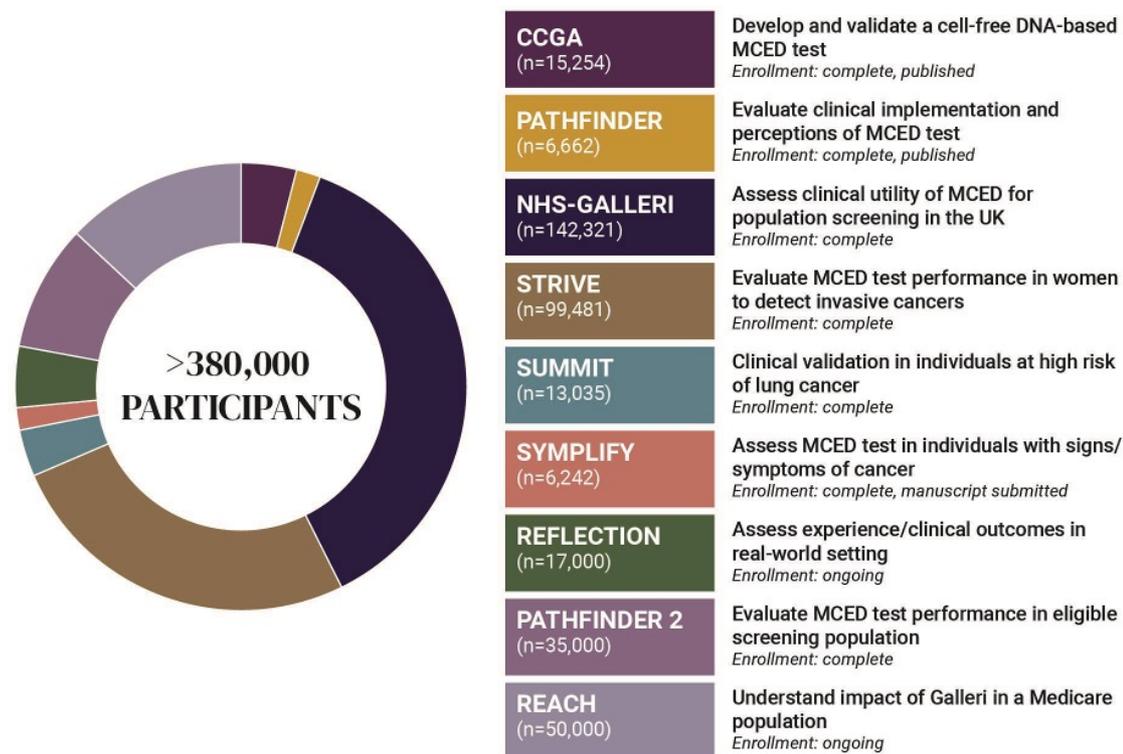
#### ***Our Clinical Studies***

We have built what we believe is one of the largest clinical programs in genomic medicine to date. Since our founding, we have undertaken a rigorous approach to identify in a blood sample the most informative markers of cancer. We are collecting population-scale clinical data from more than 385,000 participants across nine clinical studies, including over 180,000 patients enrolled in our PATHFINDER and PATHFINDER 2 clinical studies and our NHS-Galleri Trial, the only interventional trials conducted in an intended use population to validate an MCED test. We are also enrolling up to 50,000 Medicare beneficiaries in our Real-world Evidence to Advance multi-Cancer early detection Health equity (“REACH” or “Galleri-Medicare”) interventional study designed to evaluate the clinical impact of Galleri in a population of Medicare beneficiaries, including racial and ethnic minorities, and seniors from historically underserved communities. These studies also include our foundational case-control CCGA study and interventional PATHFINDER study, which were used to develop and validate our MCED technology and launch Galleri as a commercial LDT product and other products. 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.

The PATHFINDER 2 study and NHS-Galleri Trial were designed to support our PMA submission, with select inclusion criteria (matching the intended use population for Galleri), use of an appropriate locked assay, and enrollment of a sufficient number of participants to facilitate the generation of appropriate data and evidence to support safety and efficacy. These foundational population-scale studies involve partnerships with numerous leading academic and cancer institutions and large community networks, including, among others, Cancer Hope Network, the Cleveland Clinic, Dana-Farber Cancer Institute, Geisinger Health, Guardian Research Network, HCA Healthcare, Memorial Sloan Kettering, Mayo Clinic, OcshnerHealth, Oregon Health Sciences University, Sutter Health, University of California San Francisco 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, scan data and clinical data from participants. We integrate this information with the genomic data created from sequencing the samples and utilize these data to both train and validate our 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. Each of our studies has been conducted on an earlier version of Galleri than the currently available commercial version or the version we have submitted to the FDA for PMA approval.

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 the launch of Galleri and understand how clinicians implement Galleri into care pathways in clinical practice. Our PMA submission package includes the PATHFINDER 2 Initial Results, the NHS-Galleri Prevalent Round Results, and the Bridging Analysis. We have completed enrollment in these studies: NHS-Galleri, PATHFINDER 2, PATHFINDER, Circulating Cell-free Genome Atlas (“CCGA”), SUMMIT, STRIVE, and SYMPLIFY. We are actively enrolling our REACH/Galleri-Medicare Study. We are also conducting a real world evidence collection program called REFLECTION.

We have presented data and published results from many of these 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.

Importantly, our clinical program was designed to enable test development for a diverse population, and enrollment was managed to capture 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 potentially confounding indications or characteristics. Understanding and cataloging this diversity has enabled us to develop a test with a low false positive rate, cancer signal detection across many cancer types, and accurate CSO prediction. Long-term follow-up in the studies we have launched in years past will continue to yield critical data that we believe can continue to 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 was provided by us. Collaborators include Queen Mary University of London, Kings College London Cancer Prevention Trials Unit, and NHS England. The NHS-Galleri Trial was conducted pursuant to an FDA-approved investigational device exemption ("IDE") application. The primary objective of the trial was to assess whether implementation of Galleri can reduce the incidence of stage 3 and 4 cancers through early cancer detection. Secondary objectives included measuring the reduction of incidence of stage 4 cancers through early detection and collecting outcomes reported by participants with a cancer signal detected test over several timepoints. These outcomes included 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. The trial was 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 received the Galleri test, and half had their blood sample stored for future analysis. Any participant in the interventional arm with a cancer signal detected result was sent for further diagnostic workup with the NHS. The third and final round of screening was completed in July, 2024. The trial was overseen by an Independent Data Monitoring Committee.

The NHS previously evaluated results of an early analysis from the first screening test (the prevalent screening round) in the NHS-Galleri Trial to determine whether the results were compelling enough to commence an implementation pilot prior to the final trial results. The results of this early analysis represented limited information from only one year of results out of the three-year trial period. In May 2024, the NHS determined not to initiate the pilot until the final trial results are available. The NHS will evaluate the final results from the NHS-Galleri Trial before determining whether to implement the Galleri test in the NHS. We submitted data from the NHS-Galleri Trial, together with data from our PATHFINDER 2 study and the Bridging Analysis, to support our PMA submission for Galleri in the United States.

In May 2025, we announced positive top-line results from the prevalent screening round (first year) of the study. Data from the prevalent screening round of the study showed a substantially higher PPV than that observed in the PATHFINDER study. CSO accuracy and specificity were consistent with those observed in the PATHFINDER study. There were no serious safety concerns in the NHS-Galleri prevalent screening round.

In February 2026, we announced topline results from the NHS-Galleri Trial that showed:

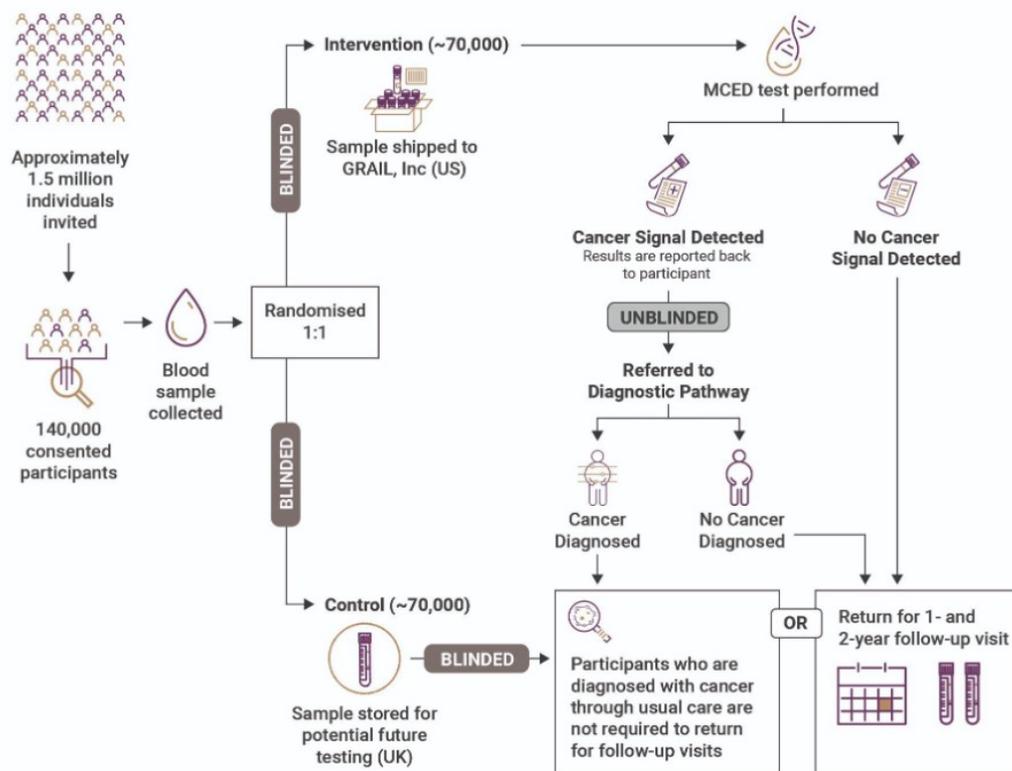
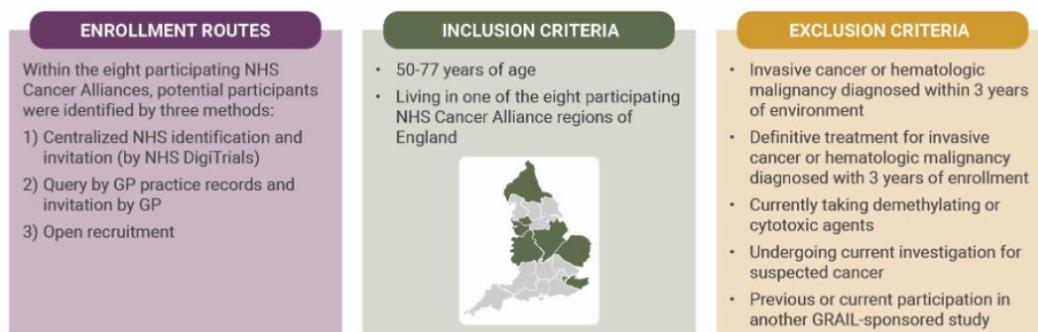
- While the trial did not meet its primary endpoint of statistically significant reduction in combined stage 3 and 4 cancers, there was a favorable trend toward fewer combined stage 3 and 4 cancers in a pre-specified group of 12 deadly cancers in the intervention arm after the prevalent screening round. The pre-specified group of cancers consisted of anus, bladder, colorectal, esophagus, head and neck, liver/bile duct, lung, lymphoma, myeloma/plasma cell neoplasm, ovary, pancreas, and stomach, which together are responsible for over 60% of all cancer deaths in the United States and the United Kingdom.
- Adding Galleri to standard of care screening resulted in a substantial and clinically meaningful reduction in stage 4 diagnoses compared with standard of care alone across the pre-specified group of 12 deadly cancers. Stage 4 diagnoses in these cancers decreased with each year of sequential screening, with a greater than 20% reduction in the second and third rounds.
- A similar stage 4 reduction overall and in each year of sequential screening was observed across all cancers.
- Annual screening with the Galleri test plus standard of care screening resulted in a four-fold improvement in the overall cancer detection rate compared to standard of care screening alone in England for (breast, colorectal, cervical and high risk lung cancer).

- A substantial increase in the number of Stage I-II cancers in the 12 pre-specified deadly cancer types that are typically found in late stages were observed in the intervention arm.
- Screening with the Galleri test resulted in a substantial reduction in the number of cancers detected clinically through emergency department presentation, which are associated with significantly higher mortality and healthcare costs.
- Test performance on PPV, CSO accuracy and false positive rate was consistent with the range reported in previous studies.

We are undertaking additional analyses to better understand these rich data, and intend to submit detailed results for presentation at the ASCO 2026 Annual Meeting. Among other initial observations about the results, we found a higher than anticipated incidence of stage 3 cancers in the trial. Time to diagnostic resolution did not appear to change significantly between screening rounds, and was not substantially different than our PATHFINDER 2 study.

In addition to the full data to be presented at ASCO, we plan to collect and readout additional data over time. Based on our observation of the trends and number and distribution of cancer stages across screening rounds, we also plan to extend the follow up period by an additional 6 to 12 months, which we believe will provide additional insights as data in both the intervention and control arms mature and more cancers appear.

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 enrolled approximately 35,000 participants at 32 clinical institutions in North America. Enrollment was completed in July, 2024. Funding for PATHFINDER 2 was provided by us. Collaborators include, among others, the Cleveland Clinic, Duke Health, Henry Ford Health System, Mayo Clinic, Oregon Health and Science University (OHSU), Memorial Care, Sutter Health, and the US Oncology Network. These collaborations are subject to terms generally consistent with industry sponsored studies.

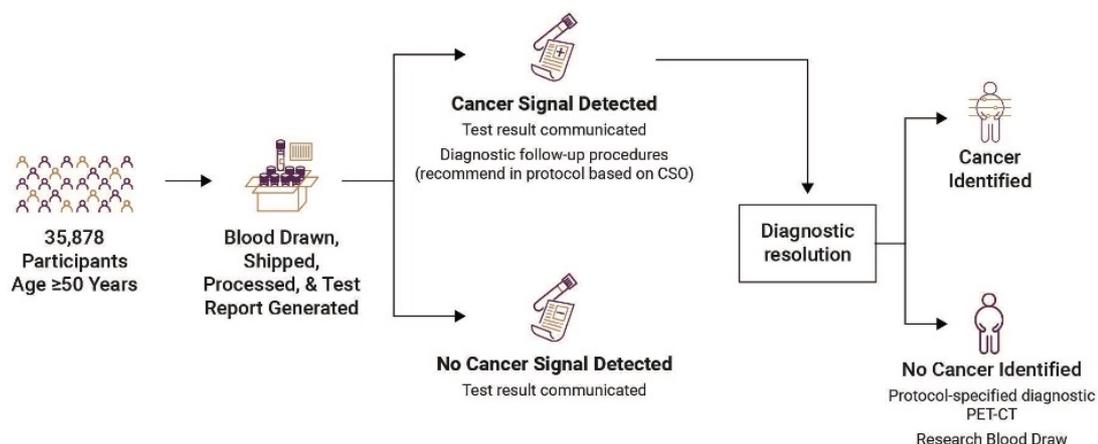
PATHFINDER 2 is being conducted pursuant to an FDA-approved IDE application. The primary objectives of the study are to evaluate the safety of Galleri based on the number and type of diagnostic procedures performed in participants who receive a cancer signal detected but do not receive a cancer diagnosis (i.e., false positive) and to evaluate the performance of Galleri across various measures, including PPV, NPV, sensitivity, specificity, and CSO prediction accuracy, among others. Participants who received a cancer signal detected result underwent additional diagnostic testing based on the predicted CSO 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. Collection was made at baseline measurement prior to testing, post-results, and post-diagnostic resolution for positive test results.

In October 2025, we presented positive PATHFINDER 2 Initial Results from the first approximately 25,000 participants in the study with 12 months of follow-up at the ESMO meeting. Data also showed a PPV of 61.6%, substantially higher than in the previous PATHFINDER study. The CSO accuracy of 92% and false positive rate of 0.4% were consistent with that observed in the PATHFINDER study. Adding Galleri to recommended screenings for breast, cervical, colorectal, and lung cancers (USPSTF A and B recommendations) led to a more than seven-fold increase in the number of cancers found within a year. Galleri detected approximately three times as many cancers when added to standard-of-care screening for breast, cervical, colorectal, lung, and prostate cancers (USPSTF A, B, and C recommendations). Approximately three-quarters of the cancers detected by Galleri do not have standard of care screening options.

Results from the full approximately 35,000 participants in the PATHFINDER 2 study were generally consistent with the results presented at ESMO.

In January 2025, we submitted the PATHFINDER 2 Initial Results, along with the NHS-Galleri Prevalent Round Results and the Bridging Analysis, to support our PMA submission for Galleri in the United States.

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



## PATHFINDER

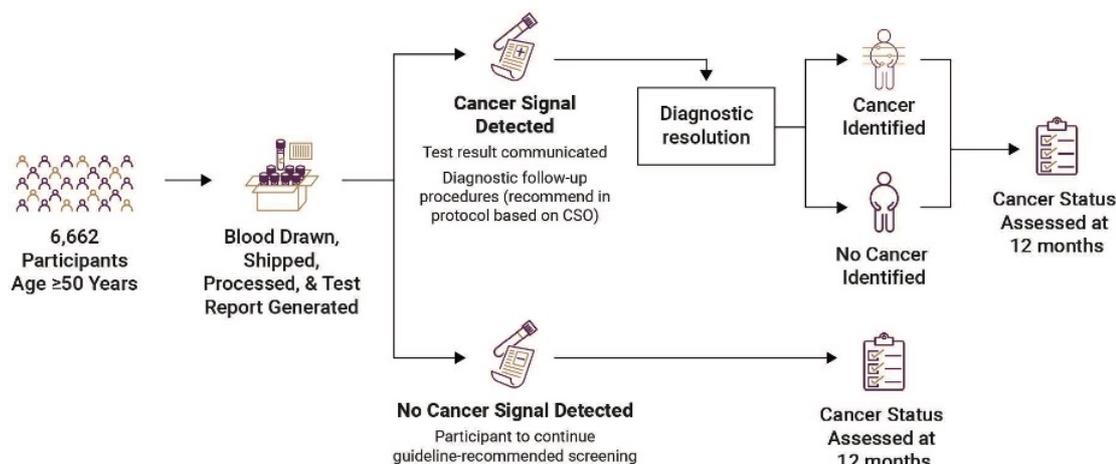
In December 2019, we initiated PATHFINDER, a prospective, multi-center, interventional study evaluating an earlier version of Galleri in clinical practice. The study enrolled 6,662 participants across several health systems in the United States. Funding for PATHFINDER was provided by us. Collaborators 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 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 CSO 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 CSO 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%) CSO 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%) CSO 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:

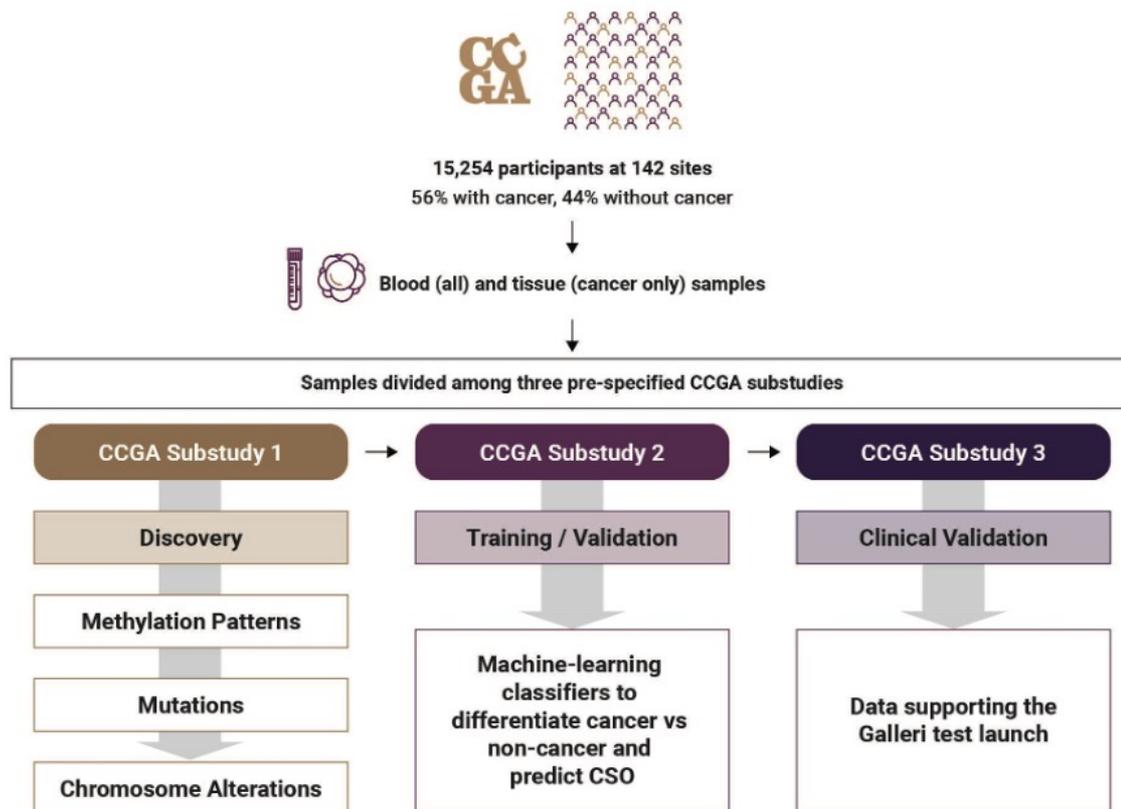


### *Circulating Cell-free Genome Atlas Study (CCGA)*

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 diagnostic aid for cancer (“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.

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 CSO. 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 CSO, 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 CSO prediction. After comprehensive analysis of these whole-genome methylation patterns, we discovered highly informative and low-noise methylation regions for cancer signal detection and CSO 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 CSO 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 CSO 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 CSO 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 CSO 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 2026 or 2027.

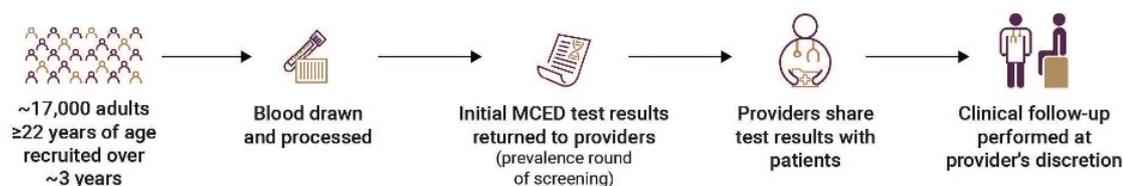
## REFLECTION

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 enrolled approximately 14,000 individuals. The purpose of the study was 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 CSO 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 in August 2021 and enrollment was completed in September, 2025. 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. These collaborations are subject to terms generally consistent with industry sponsored studies. No serious study-related adverse events have been identified.

Initial results from 2,854 participants in the study were presented in October 2024 at the Early Detection of Cancer Conference. In this initial cohort, the cancer signal detection rate was 1.30% (37/2854 participants; 95% CI: 0.94% – 1.78%), which is consistent with other populations that have received the MCED test. Among the 37 participants with a Cancer Signal Detected (CSD) at the time of analysis, 28 completed 180 days of follow-up, and of these, 12 cancer diagnoses were confirmed. More than half of the cases were identified at early stages (I-III) and the most common cancer signal of origin prediction was lung cancer (7). Positive predictive value was 42.9%, consistent with PPVs from previous Galleri testing datasets. Additional results from an expanded cohort of 3,355 participants were presented in October of 2025 at the Early Detection of Cancer Conference. In this expanded cohort, the cancer signal detection rate was 0.89% (30/3355 participants; 95% CI: 0.63 – 1.27%), in-line with other populations that have received the MCED test. Among the 30 participants with a Cancer Signal Detected result, 15 had a confirmed cancer diagnosis, resulting in a PPV of 50%, consistent with other clinical studies and real world evidence. Of the 14 confirmed new cancers, 57.1% (8/14) were detected at stages I or II. The CSO accuracy remained high at 93.3%. Additional cancers could be diagnosed during the remainder of the one-year follow-up period for the cohort.

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



## SYMPLIFY

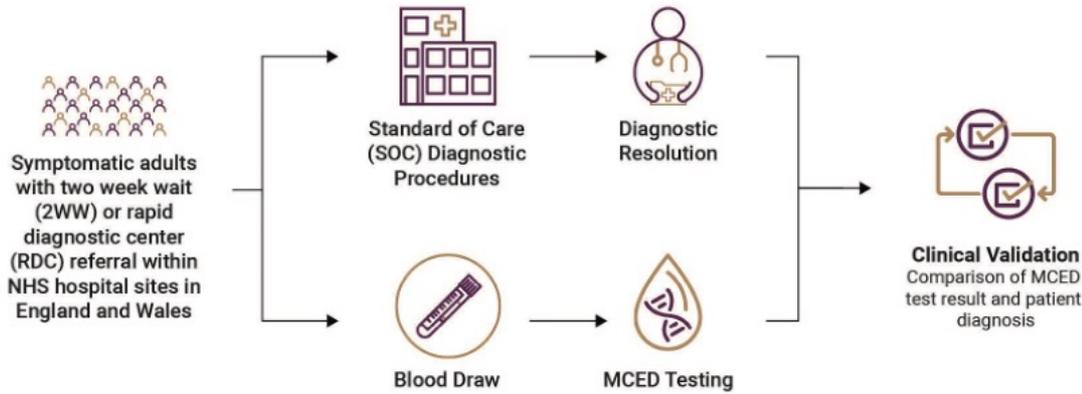
SYMPLIFY evaluated the performance of MCED in symptomatic patients in the United Kingdom that were referred from the primary care setting due to clinical suspicion of cancer. This patient population represents a distinct patient population from Galleri's targeted asymptomatic screening population. This 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 include 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 CSO 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%), esophago-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 CSO 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.

In October 2025, we presented long-term results from an extended registry follow-up of the SYMPLIFY study at the Early Detection of Cancer Conference (EDCC) in Portland, Oregon. Patients reported to have a false positive Galleri result were followed for 24 months in national cancer registries for England and Wales. The analysis showed that 35.4% (28 of 79 participants) were later diagnosed with cancer within 24 months of enrollment. This reduction in false positives from 79 to 28 resulted in an increase of PPV to 84.2%. Of those 28 participants, 27 had an accurate CSO prediction. Additional results include:

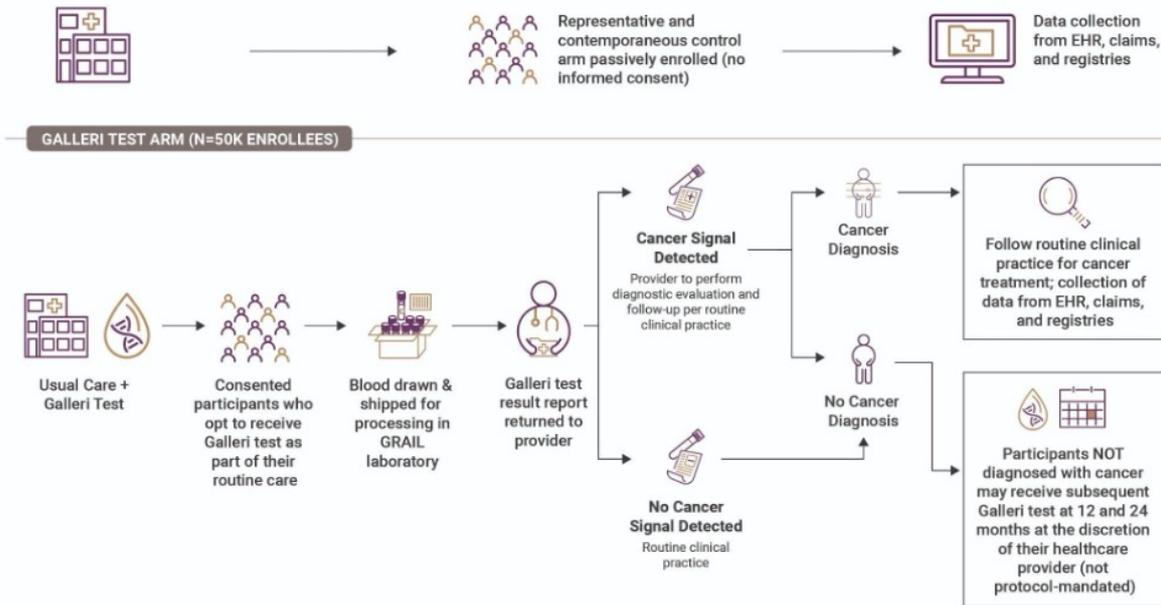
- 16 of the 28 (57.1%) were diagnosed with cancer within nine months of enrollment.
  - Eight of the 16 (50%) were diagnosed with cancers that were correctly predicted by the Galleri test's CSO finding, but were incongruent with the diagnostic pathway chosen by the general practitioner based on the participants' presenting symptoms.
- 12 of the 28 (42.9%) were diagnosed 10-24 months after enrollment.
  - Seven of the 12 (58.3%) were diagnosed outside the original referral pathway; in those cases, the CSO also was correct, matching the site that was ultimately diagnosed.

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



**REACH**

The REACH/Galleri-Medicare study is intended to evaluate the impact of Galleri in a population of Medicare beneficiaries. The study has a unique design where up to 50,000 participants will be enrolled and receive Galleri, up to three annual tests. A comparator arm of approximately 50,000 individuals matched for certain characteristics will be generated, and the rate of stage IV cancers will be compared between arms. Additional endpoints focus on performance, participant reported outcomes, and health care resource utilization. The study is being conducted under an investigational device exemption (IDE). Galleri screening tests are reimbursed by CMS. The study began enrolling in July 2024 and is ongoing.



## Commercialization

### ***Established Commercial Leadership in a Pre-Reimbursement Setting***

We launched Galleri in the United States in mid-2021. As of December 31, 2025, we have sold more than 475,000 commercial tests, including more than 185,000 tests in 2025 and established a number of commercial partnerships, including leading healthcare systems, employers, digital health platforms, payors, and life insurance providers. As of December 31, 2025, our commercial organization included approximately 250 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:

**Employers.** 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.

**Physicians and Health Systems.** 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 patient's expect innovative offerings from their primary care providers. We have evolved our sales strategy to target physicians in the most productive regions. We additionally partner with health systems, 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.

**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.

**International Strategy.** We enable access to Galleri in various countries outside of the United States through a global network of local and regional partners. Our partners assist with blood draw, sample logistics, sales and marketing, and customer support to serve patients, providers, and insurers in their markets. Market entry through our partners is subject to regulatory clearance of the Galleri test.

*Digital Health.* The Galleri test is offered by a number of digital health and telemedicine platforms that seek to provide consumer-facing healthcare products and services to cash paying patients, often anchored on a lab-based wellness and longevity offering. We believe these consumer platforms see Galleri as a complementary offering that supports their value proposition and enhances credibility with their members. These partners, with their focus and core competencies around member acquisition, engagement and retention, allow GRAIL to substantially (and cost-effectively) increase awareness and REACH of the Galleri test to a broader cohort of health seeking patients who can benefit from MCED screening.

*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.

*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.

In addition, we aim to use value-oriented partnerships, such as our integration with Quest to provide a simpler blood draw process and our planned integration with EPIC to simplify provider ordering, to help make Galleri even more accessible. We believe these partnerships can help Galleri be easily integrated into routine practice, where healthcare providers can order Galleri as part of an annual examination.

## **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. In February 2026, the Nancy Gardner Sewell Medicare MCED Coverage Act became law and created a Medicare coverage benefit category for multi-cancer early detection tests. The law included certain standards, including that Centers for Medicare and Medicaid Services (“CMS”) would establish coverage through a national coverage determination (“NCD”) process under “reasonable and necessary” evidentiary requirements. An NCD typically involves a multi-step review that can include evidence assessment by CMS staff, consultation with external technology assessment organizations, a Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) meeting, and opportunities for public comment. CMS may issue an NCD to provide coverage for MCED tests that are cleared under 510(k), classified under 513(f)(2) or approved by the FDA, with authority to initiate coverage as early as January 1, 2029, although any NCD may be delayed or be more restrictive than the full authority provided by statute. Coverage eligibility is phased in, with those aged 50-65 eligible under the law in 2029, expanding by one age-year annually. The payment rate for covered MCED tests would be in alignment with methodologies under the Protecting Access to Medicare Act (PAMA), which incorporates private market rates.

Galleri is currently offered as an LDT in our CAP-accredited and CLIA-certified laboratory. We have a Breakthrough Device designation with the FDA and, in January 2026, we submitted a PMA to the FDA. Nonetheless, no version of Galleri has been approved or cleared by the FDA and obtaining PMA approval can take several years, if at all, from the time the PMA was submitted. Galleri may not be approved on our expected timeline or at all.

The Medicare Improvements for Patients and Providers Act of 2008 also authorizes 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. In its discretion, the USPSTF generally waits for FDA authorization before it considers undertaking reviews of novel technology.

Outside of the recently enacted MCEd coverage category, another 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. Even if we were to obtain CMS coverage through the new MCEd test category, we expect to seek USPSTF recommendation because of its role in setting standard of care. Should USPSTF recommend Galleri for a more expansive population than what is covered under the MCEd benefit category, CMS would then have the authority to expand coverage following a USPSTF A/B recommendation.

If FDA approval is obtained, 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.

The NHS will evaluate the final results from the NHS-Galleri Trial, for which we announced topline results in February 2026, alongside other factors before determining whether to implement the Galleri test in the NHS. We believe the decision may include, in addition to an evaluation of the final results, considerations such as NHS budget, political priorities, cost-effectiveness and implementation constraints. Under our agreement with the NHS, these results have met certain success criteria and missed others. As a result, we and NHS are required to establish a joint steering committee that will discuss how best to proceed with deployment to the UK population, if at all, considering deployment approaches and which population groups would most benefit. In the event that we proceed with commercial implementation following such results, we expect that our partnership with the NHS would be our first national system implementation. The NHS had previously evaluated results of an early analysis from the first screening test (the prevalent screening round) in the NHS-Galleri Trial to determine whether the results were compelling enough to commence an implementation pilot in England prior to the final trial results. The results of this early analysis represented limited information from only one year of results out of the three-year trial period, and final results from the full three-year period may differ from the early analysis for a variety of reasons. In May 2024, the NHS determined not to initiate the pilot on the basis of the available data. Given that the NHS has a reputation for high evidence standards for new technologies, we anticipate that NHS approval and implementation could expand adoption in the United Kingdom and could also help facilitate adoption in other single payor systems around the world. Our initial commercial version of the Galleri test is UKCA marked.

#### *Other International*

In December 2024, we launched Galleri in Israel in partnership with a distributor, although current geopolitical conflicts have impacted recent sales. We subsequently expanded into Canada with a partner in October 2025. Also in October 2025, we announced subject to final execution of definitive agreements, that we will work with Samsung C&T as exclusive partners to commercialize the Galleri test in South Korea, with a possible extension into other Asian geographies, including Japan and Singapore. We intend to explore the launch of Galleri in select other international geographies, including through distributors.

## Operations

### ***Significant Investments for Scale***

We have made significant investments for scale in our CAP-accredited and CLIA-certified laboratory facility in Durham, North Carolina and demonstrated execution with more than 800,000 clinical and commercial individual samples processed from launch through December 31, 2025. We have an established footprint in the United States and the United Kingdom, with our headquarters in Menlo Park, California and operations in Durham, North Carolina, Washington, D.C., and London, United Kingdom.

In total we have approximately 46,000 square feet of CAP-accredited, CLIA-certified laboratory space with sufficient capacity to support multiple years of growth at our Durham facility. 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. We believe this scalable infrastructure is capable of meeting significant demand of up to one million tests per year. 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. In 2024, we also launched an updated version of Galleri increasing the amount of laboratory automation, among other improvements. In connection with implementation of this new version of Galleri, we have experienced and may continue to experience increased turnaround times, re-processing costs and sample failures. We continually monitor and evaluate laboratory operations and performance in an effort to achieve our intended sample processing metrics and costs; however from time to time, processing issues may arise that could impact our operations. In the future, it is possible that we may invest significant amounts in infrastructure to support new products or existing products in new markets. 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 sole 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 laboratory.

Our supply strategy is to maintain raw material and released reagent supplies at levels that ensure our clinical laboratory 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.

Our supply chain consists of commodity materials, multi-source, single-source or sole-source materials, services or equipment. We consider critical suppliers to be those that can impact the quality of GRAIL's product and/or our quality management system, those with consistent high volume or spend and those who are key to a specific business function.

Mitigation around our supply chain risks is critical to our business and we enable strategies that look across risk pertaining to single or sole-source; supplier financial stability, scalability, business continuity; performance and delivery consistency; quality system adherence; information security; and contract or cost maturity. GRAIL seeks to secure long-term supply agreements and quality agreements where applicable and maintains raw material and released reagent supplies at levels that ensure our clinical laboratory can maintain continuous operations 365 days a year. We employ a safety stock strategy at the part level, ensuring our materials are available, balanced against their shelf life.

GRAIL sole-source suppliers include Illumina, Inc. who is our sole supplier of sequencers and certain laboratory reagents, Madison Industries (“Madison”), who acquired our blood collection tube manufacturer Streck, Inc. in 2023 and who is our sole supplier of tubes used for sample collection, and Twist Biosciences Corporation (“Twist”) who is the sole supplier of our DNA probes. We rely on standard commercial carriers for the delivery of samples to our laboratory. 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 (“Illumina Supply Agreement”). Pursuant to the Illumina 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 Illumina Supply Agreement, regardless of whether our products incorporate any Illumina technology, we will be obligated to pay Illumina a 9% royalty, subject to certain reductions and floors, 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. The royalty is subject to anti-stacking provisions that allow royalty payments we make to other third parties to be deducted from the 9% royalty rate, to a floor of 7%. We expect that the third party royalty payments we will make in the foreseeable future will result in a 7% royalty rate. After we have cumulatively paid Illumina royalties totaling \$1 billion, the royalty rate will be reduced to 5%, without further adjustment.- Pursuant to the fourth amendment to the Illumina Supply Agreement, the perpetual royalty payment obligation to Illumina is suspended until December 24, 2026 or any earlier change of control of GRAIL, at which time royalty payments to Illumina will resume without retroactive effect. Any royalty payments that we would have made under the Illumina Supply Agreement during the suspension period are deemed to have been paid for purposes of the cumulative \$1 billion in royalty payments required to reduce the royalty rate to 5%. In addition, upon the execution of such amendment, we were permitted to elect to purchase instruments, supplies, and services from Illumina either pursuant to Illumina’s “Open Offer” universal pricing terms applicable to all of its for-profit oncology customers in the United States since March 2021, as updated, or the pricing terms we had prior to Illumina’s acquisition of us. The initial term of the Illumina Supply Agreement is scheduled to expire on February 28, 2027. The Illumina Supply Agreement will automatically renew for two year terms unless we or Illumina provide written notice of non-renewal at least 120 days prior to the end of the then-current term. Our royalty obligations under the Illumina Supply Agreement will survive any termination. For further discussion of the risks relating to these relationships, see “Risk Factors—Risks Relating to Our Business and Industry.”

### **Industry Participants**

There are market participants in the cancer detection space both in the United States and abroad, including Exact Sciences Corporation (recently announced to be acquired by Abbott Laboratories) and Guardant Health, Inc., who have each introduced MCED products into the market in 2025. A number of other companies, including Caris Life Sciences, Clearnote Health and Natera, Inc. in the United States and, Insighta, Mirxes and Seekin, Inc. outside of the United States, have announced intentions to develop or launch MCED products. In addition, companies, such as Adela, Inc., Clearnote Health, DELFI Diagnostics, Inc., Exai Bio, Inc., Freenome Inc., Guardant Health, Inc., Harbinger Health and Natera, Inc. within the United States and AnchorDx, Anpac Bio-Medical Science Co., Ltd., Burning Rock Biotech Limited, Datar Cancer Genetics, Elypta AB, Gene Solutions JSC, Insighta, Mirxes, 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, although these products are not necessarily MCED products. A number of these companies, including Natera, Inc. and Clearnote Health in the United States and, Insighta, Mirxes and Seekin, Inc. outside of the United States, have announced intentions to develop or launch multi-cancer early detection products. 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. 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 laboratory, 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 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 AI, Inc., Clearnote Health, 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 our precision oncology portfolio leverages 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, compositions, 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 December 31, 2025, we own or co-own more than 221 issued or granted patents, including 55 issued U.S. patents and 166 patents granted across Austria, Australia, Belgium, Canada, Switzerland, China, Czech Republic, Denmark, Germany, Europe, Finland, France, the United Kingdom, Greece, Hong Kong, Indonesia, Ireland, Italy, Japan, Lichtenstein, Lithuania, Luxembourg, Malaysia, Netherlands, Norway, Poland, Portugal, Sweden, Spain, Singapore, Slovenia, Slovakia, Türkiye and Taiwan. We also own or co-own more than 325 pending patent applications globally, including more than 132 pending U.S. non-provisional and provisional patent applications.

We also have exclusive licenses to approximately 408 issued or granted patents, including 55 issued U.S. patents and 353 patents granted across Australia, Brazil, Canada, China, Eurasia, Europe (including national patents and Unitary Patents covering Albania, Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, the United Kingdom, Greece, Croatia, Hungary, Ireland, Iceland, Italy, Lithuania, Luxembourg, Latvia, Monaco, North Macedonia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Switzerland, Sweden, Slovenia, Slovakia, San Marino, and Türkiye), Hong Kong, Indonesia, Israel, India, Japan, Republic of Korea, Macao, Mexico, Malaysia, New Zealand, Philippines, Singapore, Taiwan, and South Africa; and more than 79 pending patent applications globally, including more than 35 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, our precision oncology portfolio and future products or improvements to existing products that we may develop.

Of particular importance within our sizable patent portfolio are patents that relate to various aspects of Galleri and our precision oncology portfolio. For example:

- with respect to methylation analysis, which is a foundational technology underlying our current products, we own or exclusively license 156 issued or granted patents worldwide directed to systems, software, methods, compositions, mixtures, or kits for methylation analysis. These patents are expected to expire between 2033 and 2043, 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 75 issued or granted patents worldwide directed to systems, software, methods, or kits for determining cancer signal of origin. These patents are expected to expire between 2035 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 60 granted or issued patents worldwide directed to methods, assay panels, compositions, or software for assay chemistry and techniques. These patents are expected to expire between 2037 and 2040, subject to our payment of applicable maintenance fees and annuities.

Our patent portfolio also includes 337 granted or issued patents worldwide, directed to other technologies that relate to our current and future products, including, for example: systems, methods, kits, mixtures, and probes for sequencing, library preparation and enrichment; methods and nucleic acid constructs for error correction for identifying somatic variants; systems and methods for variant based assessment of cancer; systems, software, and methods for sequencing based assessment of copy number aberrations in cancer; systems, software, methods, and compositions for fragmentation based assessment of cancer; and systems, software, and methods for viral based assessment of cancer. These patents are expected to expire between 2027 and 2042, subject to our payment of applicable maintenance fees and annuities.

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. We continually assess and prioritize our patent portfolio based on its relevance to our business, while also pursuing new patent filings and grants, which may cause our total number of patents to change over time.

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. We do not expect the scheduled expiration of patents in the near term to have a material impact on our business. 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 previously faced an opposition from anonymous challengers against one of our in-licensed European patents. The patent does not relate to aspects of Galleri 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, which is currently pending. Two additional oppositions have been recently filed by anonymous opponents in connection with another two of our in-licensed European patents relating to Galleri, and these oppositions are currently pending. While we believe that these patents are valid, there is a risk that these patents could be invalidated in their entirety, or certain claims of these patents could be amended and narrowed in scope.

### ***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. We have also entered into certain additional licenses with the Chinese University of Hong Kong on substantially similar terms covering additional patents.

To the extent our products use the licensed technology, such as our current Galleri and precision oncology 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 various aspects of the operation of our assay and 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.”

### **Seasonality**

Seasonal fluctuations and underlying business trends have also affected, and are likely to continue to affect, our business. We may experience this seasonality, in particular in the third quarter due to primary care physician and patient summer vacation periods, with relatively lower volume in the first and third quarters, and relatively higher volume in the second and fourth quarters. These seasonal trends have caused, and will likely continue to cause, fluctuations in our quarterly results, including fluctuations in sequential revenue growth rates.

### **Human Capital**

Since our founding, we have built an entrepreneurial culture, driven by our mission to detect cancer early, when it can be cured. This mission statement is an expression of our commitment to improve cancer care and drive better outcomes for patients with cancer.

We recognize that our employees are key to our ability to achieve this mission and believe our employees have been and will continue to be a primary reason for our growth and success. Recognizing the importance of our human capital, our board of directors retains oversight and reviews strategies related to human capital management, including compensation, rewards and employee engagement.

#### ***Employee Base***

Our workforce consists of a highly skilled and engaged team dedicated to the company’s mission and goals. As of December 31, 2025, we had approximately 910 full-time employees. The majority of our employees are based in the United States at our sites in Menlo Park, California, Durham, North Carolina, and Washington D.C., along with our commercial team and other remote employees located throughout the US. We also have an office in London, UK. 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. Additionally, we engage with contractors, vendors, and consultants.

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 Corporate Culture: Building and Supporting our Team***

We understand the commitment our employees make to our company, and we take our commitment to them very seriously. We are committed to fostering a workplace where all employees feel valued, supported, and empowered to contribute. We believe that varying perspectives drive innovation and strengthen our ability to achieve our mission.

Our culture is built on collaboration, respect, and continuous learning, ensuring that all team members can thrive. We strongly believe our corporate culture is the operating system that powers the company and helps to achieve our mission. Our values include;

- *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.

These values are the cornerstone of our corporate culture, shaping how we interact with one another and our customers. These values are embedded in our recruiting practices, performance management and reward programs.

### **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 goal of advancing our mission. We consider both external market data and internal parity considerations when making compensation decisions, using data-informed actions to build competitive programs. To incentivize top performance, we aim to differentiate pay increases and incentive awards in recognition of colleague contributions aligned to the success of the business.

We take a holistic approach to supporting employee well-being by providing eligible colleagues and their eligible dependents with competitive health and wellness benefits, retirement savings plans, and work-life options designed to promote flexibility and support their overall well-being. We also offer paid time off and other benefits to support a healthy work-life harmony.

### **Commitment to Learning and Development**

We believe that the professional development of our employees is a critical element to the success of our company. We have invested in a learning and development program that provides employees at all levels of the company opportunities to build and grow their skills in their current roles and prepare them for future roles in the company.

We've both internally developed and thoughtfully sourced learning and development programs for all employees. Employees have access to a wide variety of online training programs, individual coaching programs for selected leaders, and mentoring programs. In addition, we offer leadership training, designed to build strong leaders who inspire our teams to achieve our corporate 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 had historically exercised enforcement discretion and not enforced certain potentially applicable provisions of the FDC Act and regulations with respect to LDTs. However, following the FDA’s September 2025 withdrawal of a final rule that intended to make explicit that in vitro diagnostic products are devices under the FDC Act, including when the manufacturer of the IVD is a laboratory, the scope of FDA’s authority to regulate LDTs remains unclear.

## **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 in 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 a CLIA Certificate of Accreditation from the CMS and an accreditation from CAP for our Durham, North Carolina laboratory, and a Clinical Laboratory Certificate of Deemed Status from the State of 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 a 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. NYSDoH 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. We have obtained NYSDoH Clinical Laboratory Evaluation Program (NYSDOH CLEP) approval for the updated commercial version of our Galleri launched in the fourth quarter of 2024. 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, 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, are a type of medical device, including tests, which can be used in the diagnosis or detection of diseases, such as cancer, or other conditions. The FDA has historically considered 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, until recently the FDA had historically exercised its enforcement discretion pursuant to which it did not seek to enforce certain otherwise potentially applicable provisions of the FDC Act and regulations with respect to LDTs, with certain exceptions. Even under that 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 prior enforcement discretion policy.

The FDA had, for a number of years, stated its intention to modify this historical enforcement discretion policy with respect to LDTs and impose applicable medical device requirements to LDTs more broadly. Recently, the FDA issued a final rule in an effort to clarify the FDA's historical view that LDTs are medical devices subject to the requirements applicable to other IVDs. However, on March 31, 2025, the United States District Court for the Eastern District of Texas vacated this final rule and remanded the matter to the FDA for further consideration. The FDA did not appeal the ruling within the required timeline, and in September 2025, the FDA officially rescinded this final rule.

Accordingly, it remains uncertain whether or when the FDA may be able to exercise medical device authority with respect to these tests, including any LDTs for which a sponsor may plan to obtain a PMA. In addition, Congress has, for over the past decade, considered a number of proposals, which if enacted, could subject LDTs to additional regulatory requirements. As a result, the FDA's oversight with respect to LDT products remains subject to significant uncertainty.

### **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 Management System Regulation ("QMSR") 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). While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification demonstrating that the device is "substantially equivalent" to either a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or another legally marketed device that was cleared through the 510(k) process. 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 QMSR 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.

**Investigational Device Exemption Process.** Clinical trials are almost always required to support a PMA and are sometimes required to support PMA supplements. 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;
- QMSR 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;
- approval of certain modifications to PMA approved devices and their manufacturing processes;
- 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;
- complying with the laws and regulations requiring Unique Device Identifiers on devices and also requiring the submission of certain information about each device to the FDA’s Global Unique Device Identification Database;
- 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 QMSR, 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 QMSR also requires, among other things, maintenance of a medical device file and complaint files. Manufacturers are subject to periodic scheduled or unscheduled inspections by the FDA. A failure to maintain compliance with the QMSR 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 approval 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 marketing authorization of new products or modified products;
- withdrawing marketing authorizations 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 are 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*

Our business operations, including any relationship we may form with physicians, healthcare providers or other potential customers or business partners, must comply with various healthcare fraud and abuse laws.

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, “progressive” roll-out of the EU IVDR was adopted and subsequently extended following the adoption of several regulations. It provides 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 December 31, 2028 subject to compliance with the transitional provisions. 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 by the end of the transitional period at the latest.

#### 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, and also generally applicable in Türkiye.

### *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 the 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.

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.

Under the powers granted by the Medicines and Medical Devices Act 2021, on December 16, 2024, the UK government passed an amendment to the UK MDR to clarify and strengthen the post-market surveillance requirements for medical devices in Great Britain. This amendment became applicable on June, 16 2025 and aims to facilitate greater traceability of incidents and trends enabling the MHRA to act swiftly when needed to address safety issues and support the entire health system in better protecting patients. In addition, the MHRA launched a consultation from November 14, 2024 to January 5, 2025 on proposed changes to the pre-market requirements for medical devices in Great Britain. On July 22, 2025, the MHRA published a response to the consultation confirming that it will incorporate feedback to this consultation in drafting new UK legislation on pre-market requirements for medical devices in Great Britain. A draft of the new legislation is expected to be published in 2026 and aims to enable greater international collaboration and practices, with more patient-centered, proportionate requirements for medical devices which are responsive to technological advances.

Under the UK MDR, in order to be lawfully placed on the Great Britain market, class A (non-sterile) IVDs need to be “UKCA” self certified, and other IVDs need to be “UKCA” certified by a UK approved body. However, certain IVDs in compliance with (a) the EU IVDD can continue to be placed on the Great Britain market until the sooner of certificate expiration or June 30, 2030; and (b) the EU IVDR can continue to be placed on the Great Britain market until June 30, 2030.

### **Coverage and Reimbursement**

We are pursuing payment for our products through a diverse and broad range of channels, including sales to integrated health systems, self-insured employers, digital health platforms, 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. In February 2026, the Nancy Gardner Sewell Medicare MCED Coverage Act became law and created a statutory Medicare coverage benefit category for multi-cancer early detection tests. The law included certain standards, including that CMS, the agency responsible for administering the Medicare program, would establish coverage through a national coverage determination (“NCD”) process under “reasonable and necessary” evidentiary requirements. An NCD typically involves a multi-step review that can include evidence assessment by CMS staff, consultation with external technology assessment organizations, a Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) meeting, and opportunities for public comment. Medicare may issue an NCD to provide coverage for MCED tests that are cleared under 510(k), classified under 513(f)(2) or approved by the FDA, with authority to initiate coverage as early as January 1, 2029, although any NCD may be delayed or be more restrictive than the full authority provided by statute. Coverage eligibility is phased in, with those aged 50-65 eligible under the law in 2029, expanding by one age-year annually. We are seeking FDA approval for Galleri, and in January 2026, we submitted a PMA to the FDA. If we receive FDA approval for Galleri, Galleri would be eligible for coverage under this new statute, subject to the NCD by CMS. Nonetheless, no version of Galleri has been approved or cleared by the FDA and obtaining PMA approval can take several years, if at all, from the time the PMA was submitted. Galleri may not be approved on our expected timeline or at all.

Beyond this new statute, CMS 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 for MCEd tests or for other screening under additional preventative services. 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, and under the new MCEd coverage benefit category, the coverage would only apply to a relatively small portion of the overall Medicare population due to the age restriction and annual phase in requirement. Accordingly, we expect to pursue inclusion in the USPSTF guidelines even if we receive initial coverage under the new statute to enable a broader CMS NCD.

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.

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 is 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% through January 30, 2026 and 15% per test per year from January 31, of 2026 through 2028.

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 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.

The One Big Beautiful Bill Act (the "OBBBA") also included significant reforms to Medicaid, including an estimated \$1 trillion in reduced federal Medicaid spending from 2025 through 2034, the imposition of work requirements for certain adult enrollees, more frequent eligibility redeterminations, and increased cost-sharing for beneficiaries. These changes are expected to reduce overall Medicaid enrollment and access to care. Although the effect on our business is currently unknown, any decrease in the number of insured patients or reimbursement levels for our tests could adversely affect our revenue and commercial prospects.

In the EU, on December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment ("HTA") amending Directive 2011/24/EU, was adopted. The Regulation entered into force in January 2022 and has been applicable since January 2025, with phased implementation based on the type of product (i.e., certain high-risk medical devices as of 2026). The Regulation intends to boost cooperation among EU member states in assessing health technologies, including certain high-risk medical devices and provides the basis for cooperation at the EU level for joint clinical assessments in these areas. It 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 highest 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 Cybersecurity Regulation**

### *Data Privacy and Cybersecurity Laws*

Numerous state, federal and international laws, regulations and standards govern the collection, use, access to, disclosure, 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 international laws govern the privacy and security of personal data, including health-related data, including but not limited to the EU General Data Protection Regulation (“EU GDPR”) and UK General Data Protection Regulation (“UK GDPR”) (EU GDPR and UK GDPR, together, “GDPR”). Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and failure to comply can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties, restrictions on data processing and reputational damage. For additional information, see Part I, Item 1A. “Risk Factors” of this Annual Report on Form 10-K.

### **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 was subject to various legal challenges, including by the U.S. Federal Trade Commission and the European Commission. These proceedings spanned more than three years and resulted in several orders, including hold-separate arrangements imposed by the European Commission. Following the European Commission’s decision on October 12, 2023 ordering Illumina to divest GRAIL, Illumina completed the divestiture via a Spin-Off on June 24, 2024 (the “Distribution Date”).

Immediately prior to the Distribution Date, GRAIL, LLC was converted into a Delaware corporation and renamed GRAIL, Inc. To effect the Spin-Off, Illumina distributed 85.5% of the shares of GRAIL’s common stock owned by Illumina to Illumina’s stockholders, and GRAIL became an independent, publicly traded company. Illumina retained 14.5% of GRAIL’s common stock. Also on the Distribution Date, we entered into a Separation and Distribution Agreement and several other agreements with Illumina related to the Spin-Off. These agreements govern the relationship between Illumina and us after completion of the Spin-Off and allocated between Illumina and us various assets, liabilities and obligations, including those related to employees and compensation and benefits plans and programs and tax-related assets and liabilities. During the fourth quarter of 2025, Illumina sold 2,000,000 shares of the Company’s common stock reducing its ownership to 2,502,126 shares, which represented approximately 6.0% of the Company’s outstanding common stock as of December 31, 2025. On February 17, 2026, Illumina filed a Schedule 13G reporting beneficial ownership of 1,302,126 shares of our common stock. See *Note 16 — Related Party Transactions* for more information.

### **Other Information**

Our website address is <https://grail.com>. Information contained on, or connected to, our website does not and will not constitute part of this Annual Report on Form 10-K, or any other filings with, or any information furnished or submitted to, the Securities and Exchange Commission (the “SEC”).

### **Item 1A. Risk Factors**

*You should carefully consider the following risks and other information in this Annual Report on Form 10-K 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 make it difficult to evaluate our current business and predict our future performance.***

We operate in a rapidly evolving field and, having commenced operations in January 2016, have a limited operating history. We completed our first sale of our multi-cancer early detection test, Galleri, in mid-2021 and our other products and products in development have an even more limited history, with most still not in commercial distribution. We have funded our operations to date primarily with the proceeds from the sale of equity securities and capital contributions from Illumina and, to a lesser extent, revenue derived from sales of Galleri and biopharmaceutical business revenue. Our short operating history as a company, evolving business strategies, rapid growth and significant events such as our separation from Illumina and the restructuring plan (“Restructuring Plan”) approved by our Board of Directors (the “Board”) designed to reprioritize our resources to focus on our core MCED business and reduce overall spend as we pursue a PMA approval from the FDA for Galleri and broad reimbursement, 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. See Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” for more information about the Restructuring Plan.

If we fail to address the risks and difficulties that we face, including those described elsewhere in this Item 1A. “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 \$408.4 million for 2025, \$2.0 billion for 2024, and \$1.5 billion for 2023. 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 \$28.0 million, \$1.4 billion and \$0.7 billion for 2025, 2024 and 2023, respectively, related to the intangible assets and goodwill recorded by Illumina upon the Acquisition of GRAIL. As of December 31, 2025, we had an accumulated deficit of \$10.2 billion and intangible assets of \$1.9 billion.

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

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

- attract, hire, and retain qualified personnel;
- seek regulatory approvals, clearances, or certifications, or coverage and reimbursement, that may be necessary or desired for our products and future products;
- conduct our ongoing clinical studies and initiate and conduct additional clinical studies to support the development and commercialization of our products and potential future products;

- continue our research and development activities;
- maintain and potentially expand our laboratory capacity and enhance operating capabilities for greater commercial scale;
- maintain sales, marketing, and distribution infrastructure for purchases of our products;
- acquire or in-license additional intellectual property and technologies;
- make milestone, royalty, or other payments due under any license or collaboration agreements;
- obtain, maintain, protect, and enforce our intellectual property portfolio, including intellectual property obtained through license agreements;
- maintain and potentially expand our facilities and infrastructure to support our continued research and development, operations and any planned commercialization efforts in the future;
- defend against any litigation, including but not limited to any patent disputes, employment matters, product liability claims or other lawsuits related to our products, our marketing, advertising, or labeling, or our clinical research;
- support international commercial expansion of our products;
- continue to engage the medical community and others to drive awareness and adoption of MCEd testing; and
- meet the requirements and demands of being a public company.

***Our NHS-Galleri Trial did not meet its stated primary endpoint, which may adversely affect our business, stock price, and ability to obtain regulatory approvals, coverage and reimbursement, or achieve commercial adoption.***

In February 2026, we announced topline results from our NHS-Galleri Trial, which enrolled approximately 140,000 participants in England between 2021 and 2024, and which did not meet its primary endpoint of statistically significant combined Stage 3 and 4 reduction. Not meeting the stated primary endpoint may negatively impact perceptions of the clinical utility of the Galleri test among healthcare providers, payors, regulators, potential commercial partners, and the investment community. This could adversely affect our ability to obtain coverage and reimbursement from Medicare, Medicaid, and commercial third-party payors, secure implementation of Galleri screening in the NHS in England or other international single-payor healthcare systems, achieve broad commercial adoption of Galleri among healthcare providers and patients in the United States, or enter into partnerships or collaborations on favorable terms. Additionally, although the submission package submitted for our PMA includes only the NHS-Galleri Prevalent Round Results, data from the PATHFINDER 2 Initial Results and the Bridging Analysis, nevertheless it is possible that not meeting the stated primary endpoint in the NHS-Galleri Trial could impact our ability to achieve FDA approval of our pending PMA application, or result in approval with more limited indications or labeling than we seek.

We are undertaking additional analyses and plan to extend the trial's follow-up period by 6-12 months to further understand the data and other endpoints. However, there can be no assurance that such analyses will produce more favorable conclusions or that any additional data will change perceptions of the trial results among the groups identified above. Any adverse impact from the primary endpoint results could materially harm our business, results of operations, financial condition, and stock price.

***Our products or future products may not perform as expected, and the results of our clinical studies may not be replicated in the post-market or real-world setting.***

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. Our commercial product, Galleri, which we have launched as a laboratory developed test (“LDT”) in the United States and for which we are pursuing approval of a PMA from the FDA and our precision oncology portfolio, which we currently offer on a research-use-only basis, and any future products in development, may not perform as expected. Results from our ongoing or future studies, or from the post-market or real-world setting, involving current or future products or our methylation platform may be inconsistent with certain results obtained from our previous studies, or from interim results initially reported on those studies.

For example, in February 2026, we announced topline results from the NHS-Galleri Trial, which did not achieve its primary endpoint of statistically significant combined Stage 3 and 4 cancer reduction. Not meeting the stated primary endpoint may lead healthcare providers, payors, regulators, and the investment community to question the clinical utility of Galleri. Any perception that our products do not perform as expected, even if clinically meaningful benefits were demonstrated, could materially harm our ability to obtain regulatory approvals, secure reimbursement, achieve commercial adoption, and maintain the market price of our common stock.

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.

Our clinical trials to date have been conducted on an earlier version of Galleri. We have in the past improved, and intend in the future to improve, our products to enhance performance, offerings, scalability, and/or cost of sales, including through the launches of new versions. However, we may not be successful in transitioning our products to a new or enhanced version or iteration. These improvements may be made through evaluation, refinement or enhancement of our laboratory process or our algorithms and other processes. Before implementing a new version, we conduct a non-inferiority or bridging study (for example, using clinical data and/or real-world evidence data obtained through Galleri’s commercial use as an LDT) to establish performance, safety and concordance between the new version and the existing version. Even if determined to be non-inferior or concordant, these refinements and improvements may inadvertently result in unanticipated issues that may reduce our performance characteristics, such as sensitivity or specificity rates, increase our turnaround time or failure rate or otherwise adversely affect the performance of our tests and their results. For example, in late 2024, we began use of an updated commercial version of Galleri in commercial channels. This version incorporates an industrial scale platform with significant automation and is intended to enable us to scale more efficiently with future demand. In connection with implementation of this new version of Galleri, we initially experienced and may continue to experience increased turnaround times, re-processing costs and sample failures. We continually monitor and evaluate laboratory operations and performance in an effort to achieve our intended sample processing metrics and costs; however from time to time, processing issues may arise that could impact our operations.

If we are unable to adequately prevent these issues from occurring, or to adequately identify and remedy these issues, we may experience reputational harm, lose customers and revenue, need to offer discounts, require additional expenditures, delay or prevent PMA approval, or suffer other negative consequences. Our failure to successfully develop new and/or improved products (including new versions of existing products) on a timely basis could have a material adverse effect on our results of operations and business.

***The clinical study process is lengthy and expensive with uncertain outcomes. We have encountered delays and may encounter future delays in, or unexpected, uncertain or negative 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. For example, in May 2025 we disclosed positive top-line results from the NHS-Galleri Trial prevalent screening round (the first round of blood draws from a total of three blood draws with one year follow up each), which is included in our PMA submission to the FDA. The NHS will evaluate the final results from the NHS-Galleri Trial before determining whether to implement the Galleri test in the NHS. Under our agreement with the NHS, these results have met certain success criteria and missed others. As a result, we and NHS England will convene meetings of our joint steering committee to discuss how best to proceed with deployment to the UK population, if at all, considering deployment approaches and which population groups would most benefit. We believe the decision will include considerations such as NHS budget, political priorities, cost-effectiveness and implementation constraints in addition to an evaluation of the final results. Various factors are likely to cause the final results to differ from a review of the first round results only. For example, cancer screening trials designed to show clinical utility are commonly conducted over three years with an annual screening period, because data from the first screening round only can be influenced by the fact that screening detects many prevalent late-stage asymptomatic cancers that have not yet been diagnosed. It is possible that the final results will be unsuitable or unavailable, which could have a significant adverse impact on the success of our commercial efforts for Galleri, our ability to achieve FDA authorization at all or within our anticipated timelines, our brand and reputation, our business, and our growth prospects. Furthermore, other studies have been or may be conducted in populations (such as our SUMMIT study which was conducted in a population of tobacco users) or under other circumstances which make their results more complicated to interpret or result in data that is more difficult to compare. In addition, as Galleri and our research-use-only offering are currently available to customers and others, any analyses or 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.

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

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

Further, the FDA may require that we conduct additional studies or expand the enrollment or follow-up of completed or ongoing studies to support our PMA, which would delay potential approval of our PMA submission, which would negatively impact our business, financial condition, results of operations, and growth prospects.

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

- the inability to generate sufficient data to support the initiation or continuation of clinical studies;
- the inability to rely on previously-collected data on earlier versions of our products, such as Galleri, in support of the launch or submission for marketing authorization (or certification) of the later or enhanced versions of our products, including Galleri, or our other products and future products;
- the requirement to submit an Investigational Device Exemption (“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 contract research organizations (“CROs”), service providers, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays or failure in obtaining any required IRB approval or ethics committee approval for our clinical study sites;
- delays in amending, or the inability to amend, our IRB- or ethics committee-approved protocols at clinical study sites when necessary or desired;
- difficulty or delays in collaborating with sites, institutions, and investigators;
- failure by us, investigators, sites, or participants to comply with the applicable study protocol or applicable regulatory requirements and standards for data collection, reporting, records maintenance, or data integrity;
- failure by us or any CROs or other third parties to adhere to clinical study requirements, including the applicable protocol;
- failure to perform in accordance with good clinical practice (“GCP”) and good laboratory practice (“GLP”) requirements, and/or other applicable regulations and requirements of the FDA or other applicable governmental authorities; failure to comply with applicable data privacy and security laws, including laws related to processing of special categories of personal data clinical studies such as the EU GDPR or UK 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 or to regulatory authorities;

- failure of our products and future products to achieve acceptable performance metrics, such as sensitivity, specificity, positive predictive value, and/or safety endpoints;
- unacceptable safety findings, including findings related to the risk, such as higher likelihood, of false positive test results (which could lead to unnecessary confirmatory testing, such as biopsy, or anxiety) or false negative test results (which could lead to foregoing standard of care screening, a delay in diagnosis or disease progression);
- termination or suspension of a study or site by us or the data safety monitoring board (or independent data monitoring committee), suspension or termination of a study or site by an IRB, ethics committee, or institution, or clinical hold or termination of a study or site by a regulatory authority, including the FDA;
- our inability to collaborate with clinical investigators, including if they are disqualified, terminated, suspended, or change affiliated institutions;
- adverse inspections of our clinical study sites or results by any applicable regulatory authority, including the FDA, NHS, or United Kingdom Medicines and Healthcare products Regulatory Agency;
- changes in statutory or regulatory requirements or guidance, or clinical guidelines, that require amending existing or designing new clinical protocols, obtaining new IRB or ethics committee approvals, modifying our clinical studies, modifying our consent process or obtaining additional consent from study participants, or altering the pathway to clearance, approval, or certification of our products and future products;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional clinical studies;
- the cost of clinical studies of our products and future products being greater than we anticipate;
- destruction or compromise of, or other inability to access or receive, clinical study samples processed, stored, managed, or otherwise in the control of a clinical site or other third party;
- determination that data from research conducted outside the United States, including the NHS-Galleri Trial, 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. In addition, our precision oncology offering is highly dependent on collaborations with select, leading biopharmaceutical companies. For example, in late 2025, one of our pharmaceutical partners terminated its phase 3 trial due to low enrollment, for which our methylation technology was used as a potential companion diagnostic for enrolling participants. To the extent our collaborators experience any of delays, halts, unexpected data or other issues in the trials they collaborate on with us, we may be similarly delayed or halted in validating or generating revenue from our precision oncology offering, and we could experience reputational or other harms.

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

***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 MCD test. Continued adoption and use of Galleri will depend on several factors discussed in these risk factors and in the section titled Management's Discussion and Analysis, including, among others, our ability to successfully fulfill test orders, 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.

***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 and our overall commercial success beyond our existing sales channels will be limited.***

We have established coverage and reimbursement for Galleri from a number of self-insured employers and other 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.

In February 2026, the Nancy Gardner Sewell Medicare MCED Coverage Act became law and created a Medicare coverage benefit category for multi-cancer early detection tests. The law included certain standards, including that CMS would establish coverage through a national coverage determination (“NCD”) process under “reasonable and necessary” evidentiary requirements. An NCD typically involves a multi-step review that can include evidence assessment by CMS staff, consultation with external technology assessment organizations, a Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) meeting, and opportunities for public comment. CMS may issue an NCD to provide coverage for MCED tests that are cleared under 510(k), classified under 513(f)(2) or approved by the FDA, with authority to initiate coverage as early as January 1, 2029. Coverage eligibility is phased in, with those aged 50-65 eligible under the law in 2029, expanding by one age-year annually. The payment rate for covered MCED tests would be in alignment with methodologies under the Protecting Access to Medicare Act (PAMA), which incorporates private market rates. The NCD process can be lengthy and resource-intensive, and its timing, outcome, and scope are inherently uncertain, which may affect the availability, extent, and conditions of Medicare reimbursement for applicable products or services. Because of the novelty of the statutory authority and of MCED technology, it is uncertain what evidence will be required in order to achieve an NCD, or if the evidence we have collected through our completed, ongoing or planned clinical studies and commercial practice will be sufficient to support such determination.

Additionally, 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 an NCD process, which generally requires, or is significantly more likely following, FDA approval of specific screening products. 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. Historically, USPSTF has only provided grade A or B recommendations on the basis of evidence packages that include mortality data, which would require significant long-term follow up. However, even if we are successful in obtaining an NCD on the basis of the new MCED benefit category, the coverage would only apply to a relatively small portion of the overall

Medicare population due to the age restriction and annual phase in requirement. Accordingly, we would intend to seek a USPSTF grade for Galleri and, potentially, an NCD as additional preventative services. 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.

If the USPSTF does not recommend any of our products with a grade of A or B, CMS declines to initiate an NCD, CMS decides to rescind a prior NCD, or the decision regarding an NCD is negative, the impacted product would not be eligible for fee-for-service Medicare coverage in the absence of a new statutory provision providing for coverage. Even if the USPSTF were to recommend Galleri or other products we are developing, the USPSTF review process and the ensuing NCD process by CMS could take several years to complete, and coverage for our products would be delayed while review is ongoing. The Affordable Care Act (“ACA”) mandates that many private insurance plans cover, among other preventive health services, evidence-based items or services recommended by USPSTF with a grade of A or B, with certain prohibitions on cost-sharing requirements. Accordingly, if USPSTF does not recommend use of Galleri or other products we are developing or requires a substantial amount of time to review such products, our business and results of our operations would be harmed. Coverage and adequate reimbursement under Medicare are also uncertain as discussed further in “Business— Government Regulations—Coverage and Reimbursement” in this Annual Report on Form 10-K.

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 reevaluated every three years. A series of legislative amendments delayed the next PAMA reporting period to February 1, 2026 through April 30, 2026, 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, effective January 1, 2027, subject to phase-in limits. In addition, under PAMA, as amended, the payment reduction cap is 15% per test per year from January 31, 2026 through 2028. 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. Congress is currently considering additional reforms to the PAMA reporting system. The full impact of the PAMA rate-setting methodology and its applicability to our products, including interactions with potential establishment of a Medicare MCED benefit category under consideration in Congress, 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, including 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.

In determining whether to provide coverage and reimbursement for Galleri, payors may consider the results of our clinical studies, including the NHS-Galleri Trial. The NHS-Galleri Trial did not meet its primary endpoint of statistically significant combined Stage 3 and 4 reduction. Even though the trial demonstrated a substantial reduction in stage 4 cancer diagnoses, increased stage 1 and 2 detection of deadly cancers, and four-fold higher cancer detection rate when compared to recommended screenings alone, payors may view the overall trial outcome unfavorably, which could adversely impact coverage decisions or reimbursement rates for Galleri. Any inability to secure favorable coverage and reimbursement decisions as a result of the NHS-Galleri Trial results, or otherwise, could materially harm our revenue and growth prospects.

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 revenues for our products in line with our expectations, including for Galleri, any other current or future products or future versions of Galleri. 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.

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

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

- the performance, validation, and clinical utility of such products as demonstrated in clinical studies, from real-world use, and published in peer-reviewed journals;
- our ability to demonstrate the clinical validation and utility of our products and their potential advantages to the medical community;
- the ability of our products to demonstrate comparable or non-inferior performance in real-world intended use populations as in clinical studies;
- the willingness of consumers, including self-insured employers, health systems, healthcare providers, life insurance companies, patients, and others in the medical community to utilize our products;
- the willingness of commercial third-party payors and government payors to cover and reimburse our products, the scope and amount of which will affect an individual's or entity's willingness or ability to pay for our products and likely heavily influence healthcare providers' decisions to recommend our products;
- willingness of providers, patients, and others to learn about our products, and establish a sense of understanding and confidence in the use of our products;
- with respect to Galleri, which was launched as an LDT in the United States for use in an asymptomatic population, the concern that the product could lead to unnecessary medical screening procedures or a high false positive rate and the associated costs of unnecessary workups resulting from false positives;

- the belief of providers, patients, CMS 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;
- our ability to fulfill test orders in a timely manner;
- the strength of our marketing and distribution support and patient-facing service providers;
- the perception among healthcare providers, payors, regulators, and the investment community regarding the clinical significance of clinical trial results, including instances where a trial does not meet its primary endpoint, even if clinically meaningful secondary endpoints are achieved, as occurred in our NHS-Galleri Trial; and
- the willingness of healthcare providers and payors to prescribe or cover Galleri in light of the NHS-Galleri Trial not meeting its primary endpoint of statistically significant combined Stage 3 and 4 reduction, notwithstanding favorable secondary endpoint data.

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 completed our PATHFINDER study, PATHFINDER 2 study and NHS-Galleri Trial, and have additional 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 or with an adequate approved label, could limit adoption of Galleri, even if we continue to publish data on its clinical validity and utility in peer-reviewed journals. Potential rejection or material delay of our PMA submission, including a requirement by the FDA to conduct additional studies or expand the enrollment of completed or ongoing studies, may reflect negatively on Galleri and the 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 may not be able to generate sufficient revenues to offset our costs of developing and offering our products or achieve or maintain profitability on any products, and revenues from precision oncology may not be a significant source of our overall revenue in the future. Further, we cannot assure you that we will successfully be able to launch any future products as planned, if at all, and our failure to do so may prevent us from generating increased revenue. Even if we are able to launch future products in a timely manner, we may not be able to generate sufficient revenue to offset our costs and achieve profitability. Our ability to generate future revenue growth from product sales depends heavily on our success in:

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

We anticipate incurring significant costs to continue commercializing our products. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies, or notified bodies to delay the launch of any new products, narrow or change our intended use or product claims, and modify or expand our clinical studies or to perform additional clinical studies, either pre- or post-approval (or certification), in addition to those that we currently anticipate. Additionally, it may be difficult for us to offset the costs of the high-single-digit royalty that we will be required to pay under our agreement with Illumina in perpetuity. For more information, see “Business—Operations—Supply Chain and Agreement” in this Annual Report on Form 10-K.

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 from the Chinese University of Hong Kong for each product containing any licensed technology extends until the expiration or termination of such license, which shall be the later of a low double-digit number of years from our payment of the license issue fee or expiration of the last-to-expire licensed patent. Although certain provisions in our agreement with Illumina allow us to reduce our royalty to Illumina by up to a low single-digit percentage due to third party royalties actually paid, such as our royalty payment to Chinese University of Hong Kong, our obligation to pay this royalty on our net sales could reduce our gross margins and increase our expenses. See the section titled “Business—Intellectual Property—License Agreements with the Chinese University of Hong Kong” in this Annual Report on Form 10-K.

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.

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

Although we reduced investment in the development of products beyond Galleri as part of the Restructuring Plan, including in a diagnostic aid product for cancer and our precision oncology portfolio, we are continuing research and development of our proprietary methylation platform and our large clinical and genomic datasets to develop enhanced versions of Galleri. In the future, we may determine to invest further in new product development. The commercialization of any new products, including enhanced versions of current products, will require the completion of certain clinical development activities, regulatory activities, and the expenditure of additional cash resources. However, we may not be successful in transitioning our products to a new or enhanced version or iteration, or achieving the required characteristics in a new product. 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 the FDA or other regulatory authorities, in particular where we are modifying an FDA approved product or seeking FDA approval of a new product, and may be unsuccessful or insufficient to support approval of any such subsequent, enhanced version of our products.

If unsuccessful or insufficient, we would be required to revert to a prior version of the test and forgo, or be delayed in, implementing any perceived or potential updates, including enhancements, or further enhance, modify or update to a new version of the test and run additional bridging studies. Reverting to a prior version of the test or running additional bridging studies may cause delays in our efforts to obtain PMA approval for Galleri or any new product. Additionally, planned improvements to our products may cause unintentional technical, logistical or other issues. In late 2024, we began use of an updated commercial version of Galleri in commercial channels. This version incorporates an industrial scale platform with significant automation and is intended to enable us to scale more efficiently with future demand. In connection with implementation of this new version of Galleri, we initially experienced and may continue to experience increased turnaround times, re-processing costs and sample

failures. We continually monitor and evaluate laboratory operations and performance in an effort to achieve our intended sample processing metrics and costs; however from time to time, processing issues may arise that could impact our operations. If we are unable to adequately prevent these issues from occurring, or to adequately identify and remedy these issues, we may experience reputational harm, lose customers and revenue, need to offer discounts, require additional expenditures, delay or prevent PMA approval, or suffer other negative consequences.

We are pursuing a PMA with the FDA for a further updated version of Galleri, and, in January 2026, we submitted a PMA to the FDA including the full prevalent screening round analysis from the NHS-Galleri Trial, together with performance and safety data focused on the first approximately 25,000 participants in the PATHFINDER 2 study. While we have announced positive topline NHS-Galleri Prevalent Round Results and presented positive results from our PATHFINDER 2 study at ESMO in October 2025, each of these studies was conducted on an earlier version of Galleri. Our PMA submission to the FDA also includes a bridging analysis comparing and measuring concordance of the version of Galleri used in the NHS-Galleri Trial and PATHFINDER 2 study with the updated version of the Galleri test submitted to the FDA for premarket approval. The version that has been submitted to the FDA for approval may have different performance, safety, operational or other characteristics, and the FDA's approval, if at all, will depend on the results of the bridging study, which could result in different labelling than our commercially available product.

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 have recently launched or 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. In particular, to-date other MCED tests on the market have been launched based on case-controlled data only, and have not been tested in an intended use population or in an interventional trial. Case controlled studies do not always translate into an intended use population, for example because case controlled studies often have a higher number of cancer cases, a different mix of types of cancer and stronger cancer signal in the cancer samples as compared to a prospective study in an intended use population. 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 or to develop and commercialize 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, including in our recent private placement transaction and at-the-market sales, and capital contributions from Illumina and, to a lesser extent, revenue derived from Galleri sales and precision oncology portfolio revenue. Our product development, commercialization and clinical study activities are expensive, and we expect to continue to spend substantial amounts as we expand our commercialization efforts with respect to Galleri, including pursuing broader coverage and reimbursement, continue to enhance our core technology platform, broaden the applications of our technology platform, and develop new products in the future. In addition, obtaining any necessary or desirable regulatory approvals, clearances, or certifications, as well as coverage and reimbursement, for our products will require substantial additional funding.

As of December 31, 2025, we had \$249.7 million in cash and cash equivalents and short-term marketable securities of \$654.7 million. We believe that our existing cash and cash equivalents, and short-term marketable securities 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 short-term marketable securities to be available to fund our operations is based on assumptions that may prove to be inaccurate, and we could use our available capital resources sooner than we currently expect. In addition, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may need to raise additional funds sooner than we anticipate.

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

- the cost of development and commercialization activities for our products, including Galleri and our precision oncology portfolio and our future products, including marketing, sales, and distribution costs;
- the cost related to continued scaling operations to support demand for our products, including the cost of operating our laboratory in Durham, North Carolina;
- the timing of, and the costs involved in, obtaining any required or desired regulatory approvals, clearances, or certifications for our products;
- the timing, scope, progress, results, and costs of developing additional products and conducting clinical studies;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending, and enforcing patent and other intellectual property rights and claims, including litigation costs and the outcome of such litigation;
- the timing and amount of sales of our products and collection of related receivables;
- the extent to which our products are eligible for coverage and reimbursement from third-party payors;
- the emergence of new technologies, products, or services and other adverse market developments; and
- costs associated with extending the NHS-Galleri Trial follow-up period by 6-12 months, and any additional clinical studies or analyses that may be required to further demonstrate clinical utility following the trial's failure to meet its primary endpoint;
- potential increased costs of development and commercialization activities if the NHS-Galleri Trial results adversely impact our ability to obtain regulatory approval, coverage and reimbursement, or commercial partnerships on favorable terms; and
- other potential adverse developments.

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

which could materially affect our business, financial condition, results of operations, and growth prospects and cause the price of our common stock to decline.

As a result of the Spin-Off, we are subject to a number of limitations and risks that may impact our ability to obtain additional financing. For example, certain restrictions under the Tax Matters Agreement limit our ability to obtain additional financing, including offerings of common stock, or otherwise require that we undertake certain procedures with Illumina. In addition, certain terms of the Spin-Off may impact our ability to successfully obtain financing on favorable terms or at all. These restrictions under these agreements may impact our ability to obtain additional financing when needed, if at all, and, if we are required to repay any disposal funds to Illumina under the clawback provision, our cash balance will be reduced and we may have greater need for additional financing.

***The Samsung Investment is subject to closing conditions, including conditions beyond our control, and no assurance can be given that closing will take place on the timeline currently anticipated, or at all, or that we will achieve our goals under the collaboration agreements to be entered into with Samsung C&T and/or Samsung Electronics. Any failure to close the Samsung Investment or achieve such goals could adversely impact our business, financial conditions, results of operations and liquidity.***

On October 16, 2025, we entered into a stock purchase agreement (the “Samsung Stock Purchase Agreement”) with Samsung C&T Corporation (“Samsung C&T”), Samsung Electronics Singapore Pte. Ltd. (together with Samsung C&T, the “Samsung Investors”) and Samsung Electronics Co., Ltd. (“Samsung Electronics”), providing for the issuance and sale by us to the Samsung Investors in a private placement of an aggregate of 1,570,308 shares of our common stock, at a purchase price of \$70.05 per share, upon the terms and conditions set forth in the Samsung Stock Purchase Agreement (the “Samsung Investment”). The Samsung Investment is subject to the satisfaction of certain closing conditions set forth in the Samsung Stock Purchase Agreement, including, but not limited to the satisfaction of certain regulatory approvals or clearances, including with respect to the Committee on Foreign Investment in the United States (“CFIUS”). Additionally, we have entered into a Business Collaboration Agreement with Samsung C&T and a Strategic Opportunities Collaboration Agreement with Samsung Electronics in satisfaction of certain closing conditions under the Samsung Stock Purchase Agreement, which will become automatically effective upon the closing of the Samsung Stock Purchase Agreement.

We have experienced delays, and may experience further delays and difficulties in satisfying the conditions for closing of the Samsung Investment, and no assurance can be given that closing will take place on the timeline currently anticipated or at all. Some of the closing conditions are outside of our control and it is possible that not all of the closing conditions for the Samsung Investment will be satisfied or that we will not receive the expected proceeds on the timeline currently anticipated or at all. For example, the Samsung Investment is subject to, among others, certain regulatory approvals and clearances, including with respect to CFIUS. In October 2025, we and the Samsung Investors filed a declaration for CFIUS clearance of the Samsung Investment. In January 2026, CFIUS requested that we and the Samsung Investors file a joint voluntary notice, which provides CFIUS up to an additional 90 days to review the Samsung Investment. Government funding shortfalls may delay this timing. While we remain confident that we can obtain CFIUS clearance for the Samsung Investment, there can be no assurance of this, nor that we will receive clearance within the 90-day review and investigation periods.

In addition, even though we have executed the Business Collaboration Agreement with Samsung C&T and the Strategic Opportunities Collaboration Agreement with Samsung Electronics, there is no assurance that these agreements or the collaborations they govern will achieve our goals or be on terms that prove to be economically or strategically beneficial to us. For example, we may not recognize or accomplish our strategic objectives under the Business Collaboration Agreement or Strategic Opportunities Collaboration Agreement and we may ultimately find ourselves restricted by the terms that we have negotiated under such agreements.

Any such adverse developments, including any failure to close the Samsung Investment, could adversely impact our business, financial condition, results of operations and liquidity.

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

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

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

We rely on Illumina as the sole supplier of the next-generation sequencers and associated Illumina-supplied reagents we use to perform our genomic tests and as the sole provider of servicing, including maintenance and repair services for these sequencers. Additionally, as a part of the Spin-Off, Illumina distributed 85.5% of its holdings of the Company to its shareholders but remained a significant shareholder through its retention of 14.5% of our outstanding shares immediately following the Spin-Off and we are party to a number of agreements with Illumina entered into in connection with the Spin-Off. Any disruption or interruption in Illumina's operations, Illumina's breach of our supply-related agreements or disputes arising between the parties 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, including for machinery, reagents, magnetic beads, tubes and other supplies used in our laboratory workflows 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 have submitted a PMA for Galleri to the FDA, and we may similarly seek FDA authorization for future products. For RUO products or components supplied to us by any supplier, including Illumina, we would be required to validate for IVD purposes and submit to FDA as part of our marketing authorization. We are cooperating with Madison to obtain FDA authorization as part of our PMA application for their blood collection tubes to be used with our Galleri test. 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. For example, any changes to the material used in our laboratory workflow may require us to supplement or revise the information contained in any PMA or other application, which could increase our costs and delay our efforts to obtain approval for Galleri, and could delay our implementation of the material into our workflow.

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.

Even where we have long term supply agreements in place, these agreements are periodically up for renewal, and may not be renewed or may be terminated. For example, the initial term of the Illumina Supply Agreement is scheduled to expire on February 28, 2027. The Illumina Supply Agreement will automatically renew for two year terms unless we or Illumina provide written notice of nonrenewal at least 120 days prior to the end of the then-current term. If Illumina determined not to renew the Illumina Supply Agreement, we could lose certain preferential pricing under that agreement and other beneficial terms. Even if we were to negotiate a replacement supply agreement with Illumina, it may not provide pricing or other terms that are as beneficial to us. Our royalty obligations under the Illumina Supply Agreement will survive any termination.

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

We currently conduct commercial testing work, for our products, including Galleri, in our laboratory located in Durham, North Carolina and additionally perform certain research and development in our laboratory in Menlo Park, California. 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 commercial work could be unavailable or costly and time-consuming to repair or replace. It would be difficult, time-consuming, and expensive to rebuild our facilities, particularly in light of the licensure, permits, and accreditation requirements for clinical laboratories like ours. For example, the development and commercial test processing activities for Galleri, and future potential commercial launch of future products, are dependent on the operation of our Durham, North Carolina laboratory, which received Clinical Laboratory Improvement Amendments of 1988 (“CLIA”) certification to perform high-complexity testing, and College of American Pathologists (“CAP”) accreditation and a New York State Department of Health (“NYSDoH”) clinical laboratory permit, among other important certifications such as ISO 15189:2013. In particular, as part of the Restructuring Plan, we have consolidated the processing of commercial Galleri tests in this facility and no longer process commercial Galleri tests in our Menlo Park Facility. As a result, any disruption at our North Carolina facility could materially adversely affect our ability to process tests and return results to patients, and our revenue, operations, business and prospects could be materially harmed. Although we carry insurance for damage to our properties and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

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

We depend on third parties for information technology, telecommunication systems, the collection, processing, transport, and storage of samples, 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. As a public company, we continue to work 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 expenses. 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, and other cybersecurity incidents. 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 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. 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, or could be damaged or lost through a natural or man-made disaster, accident, or break-in, 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 the transport of our samples, which generally must be delivered to our facilities for processing within seven days of blood draw.

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

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

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

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

In Europe, on August 1, 2024, the EU Artificial Intelligence Act (the “EU AI Act”) entered into force, and establishes a comprehensive, risk-based governance framework for AI in the EU market. The majority of the substantive requirements will apply from August 2, 2026 at the earliest (although this deadline may be further extended). The EU AI Act applies to companies that develop, use and/or provide AI in the EU and, depending on the use case, includes requirements around transparency, conformity assessments and monitoring, risk assessments, human oversight, security, accuracy, general purpose AI and foundation models, and fines for breaches up to 7% of an undertaking’s worldwide annual turnover. In addition, the revised EU Product Liability Directive came into force in December 2024, to be implemented into EU member state national law by December 2026. This Directive extends the EU’s existing strict product liability regime to AI technologies and AI-enabled products, and facilitates civil claims in respect of harm caused by AI. Once fully applicable, the EU AI Act and the EU Product Liability Directive will have a material impact on the way AI is regulated in the EU. The EU AI Act and its future interpretation and application may affect our use of AI technologies and our ability to provide, improve or

commercialize our services, require additional compliance measures and changes to our operations and processes, result in increased compliance costs and potential increases in civil claims against us, and could adversely affect our business, operations and financial condition. It is also possible that further laws and regulations will be adopted in the United States and in other non-U.S. jurisdictions, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit our ability to use AI technologies for our business, or require us to change the way we use AI technologies. For example, a number of U.S. states have or are considering new legislation relating to AI, including the Colorado Artificial Intelligence Act in Colorado and the Utah Artificial Intelligence Policy Act in Utah, all of which will have implications on the ways that businesses can use AI technologies.

We currently host all of our data on, and conduct a significant portion of our data analysis through, Amazon Web Services (“AWS”) cloud-based hosting facilities. In addition, certain functions of our laboratory operations and business functions use or leverage AWS. Any technical problems or outages that may arise in connection with AWS, including its data center hosting facilities, could result in operational disruption, loss of data or delayed or ineffective data processing. A variety of factors, including infrastructure changes, human or software errors, viruses, malware, cybersecurity incidents or 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 or cybersecurity incident. If we were required to transfer to another service provider, including the transfer of data to an alternative hosting provider, the transfer and acclimation to the new provider could result in significant business delays and require additional resources.

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

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

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

We may also experience difficulties scaling in international markets in which we are required under law or contract, or decide to, construct and operate a laboratory in that market. For example, we may be required or decide to build and operate a laboratory in the United Kingdom if and when we have a commercial presence in that country. This may be challenging due to significant startup costs, difficulty recruiting, and lack of familiarity with the local jurisdiction, among other reasons. If we are unable to build and operate laboratories internationally, or ship samples in or out of international jurisdictions due to privacy, export/import controls, or other applicable laws, 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 Exact Sciences Corporation (recently announced to be acquired by Abbott Laboratories) and Guardant Health, Inc., who have each introduced MCD products into the market in 2025. In addition, Adela, Inc., Caris Life Sciences, ClearNote Health, DELFI Diagnostics, Inc., Exai Bio, Inc., Freenome Inc. and Harbinger Health and Natera, Inc. within the United States and AnchorDx, Anpac Bio-Medical Science Co., Ltd., Burning Rock Biotech Limited, Datar Cancer Genetics, Elypta AB, Gene Solutions JSC, Insighta, Singlera Genomics, Inc. and Seekin, Inc. outside of the United States, among others, 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 Exact Sciences Corporation (recently announced to be acquired by Abbott Laboratories), Roche/Foundation Medicine, Inc., Natera, Inc., Guardant, Inc., Tempus AI, Inc., Clearnote Health, 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, may have different strategies to obtain reimbursement for their products, may deploy more effective sales and marketing campaigns 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, or providers, payers, patients and other stakeholders may believe that these companies or other new market entrants may have 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 MCD and bring significant resources and disruption to the cancer detection space.

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

- 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 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 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. For example, in late 2025, AstraZeneca terminated its phase 3 TROPION-Lung12 trial due to low enrollment, for which our methylation technology was used as a potential companion diagnostic for enrolling participants. Further, our collaborators or partners may fail to properly protect our intellectual property rights, may infringe the intellectual property rights of third parties, may misappropriate our trade secrets, or may use our proprietary information or others' in such a way as to expose us to litigation and potential liability. Disagreements or disputes with our collaborators or partners, including disagreements over proprietary rights, funding, or contract interpretation, might cause delays or termination of the research, development or commercialization of our products, might lead to additional responsibilities for us with respect to these products or activities or might result in litigation or arbitration, any of which would divert management attention and resources and be time-consuming and expensive. We may not be able to renew our current agreements with collaborators or partners or negotiate additional collaboration or partnership agreements on acceptable terms, if at all, and these collaborations and partnerships may not be successful. Any transition from a current collaborator to a new collaborator could be costly and result in significant product development delays.

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

financial, regulatory, or intellectual property position. Even if we establish new collaborations, they may not result in the successful development or commercialization of our products or technology.

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

As of December 31, 2025, we had approximately 910 employees, substantially all of whom were full-time. Our headcount was reduced in 2024 following the implementation of the Restructuring Plan. As our development plans and strategies develop, and as we continue our operation as a public company, we may require a significant number of additional managerial, operational, financial, and other personnel. Moreover, despite our progress made in driving commercial implementation to date, we may not be able to market, sell, or distribute Galleri, or any future products that we may develop and commercialize, effectively enough to support our planned growth. Although we have focused our business on Galleri-related activities and our work with biopharmaceutical companies as part of the Restructuring Plan resulting in a lower number of employees as of December 31, 2025, we may nevertheless need to continue to grow our operations to achieve our goals.

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

- our inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel;
- the inability of sales personnel to generate an adequate number 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.

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

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

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

To induce valuable employees to join and remain at our company, we have generally granted incentive awards that vest over time-based continued service, in addition to salary and periodic cash incentives. Prior to the Spin-Off, these awards generally consisted of Cash-Based Equity Awards (defined below) and, since the Spin-Off, these awards have consisted of grants of restricted stock units covering GRAIL common stock ("RSUs"), in each case, vesting over set time periods based on continued service. In connection with the Spin-Off, the outstanding Cash-Based Equity Awards converted into RSUs (the "RSU Conversion") in accordance with the Employee Matters Agreement, dated June 24, 2024, by and between us and Illumina (the "Employee Matters Agreement"). As a result of the applicable RSU conversion mechanic under the Employee Matters Agreement, the fair market value of each employee's RSU award after the RSU Conversion was substantially lower than the face value of the Cash-Based Equity Awards prior to the RSU Conversion, particularly for award tranches vesting after 2024. In October 2024, we granted 2.4 million RSUs to our employees, including special retention grants made to certain members of our executive team. These RSU grants represented a smaller aggregate number of RSUs than we would ideally have issued for retention purposes in 2024, primarily due to available share constraints under our shareholder-approved incentive equity plan. As a result of the RSU Conversion mechanics and limitations our 2024 RSU grants, the perceived value to employees of these awards may be insufficient to retain certain key executives and other valuable employees, who may receive 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.

For additional information, see - "Our business is subject to economic, political, regulatory, and other risks associated with international operations."

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

- economic weakness, including inflation, or political instability, in particular non-U.S. economies and markets;

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

In addition, in recent years, U.S. administrations, including the current administration, have publicly announced or adopted trade proposals that may affect U.S. trade relations with other countries. While we have not experienced significant impact from tariffs to date and do not have significant sensitivity to tariffs, it is uncertain at this point how, if at all, such actions or other potential actions, may impact our business or operations, in particular if there are changes in our supply chain, or tariffs if rates are increased or are more targeted at countries where our suppliers are located. Policy changes or legal challenges could lead to further volatility in rates, coverage, and enforcement. Such actions could increase our expenses, reduce our margins or increase our prices, make it difficult to obtain inputs we need for our products or have a material adverse effect on the broader economy. These risks and impacts may be exacerbated by retaliatory tariffs imposed by governments in response to any initial tariff policy.

Our success depends in part on our ability to attract and retain the best available personnel with the necessary qualifications, which in a competitive global market means that our recruitment efforts should not be limited entirely to the United States. To the extent U.S. immigration-related policies, laws, rules, proclamations or orders restrict our ability to attract, or increase the cost of attracting, international talent, this could adversely impact our business and results of operations. For example, on September 19, 2025, the H-1B visa process in the

United States was changed to require a payment of \$100,000 for new petitions, which could hamper our recruitment efforts for any new personnel who require such a visa or require significant additional employment costs for those individuals. Additional changes in U.S. immigration policies, rules, laws or orders could further increase our recruitment costs or delay key projects that require specialized expertise. In addition, restrictions or delays in the issuance of other visas or in immigration processing could adversely affect our ability to collaborate effectively with our employees outside the United States and to retain the qualified personnel needed for our operations.

Moreover, future operational expansion into other geographies will subject us to additional political and regulatory regimes that will require us to invest further in compliance efforts and may result in additional risks, including, among others, exposure to various and potentially conflicting regulations, international sanctions and compliance rules, country-specific requirements for testing, approval, and processing of patient information and biological samples, as well as the risks associated with political and macroeconomic climates in any such geographies. For example, the potential commercialization of Galleri with the NHS, subject to the full results of the NHS-Galleri Trial which we expect to report in mid-2026, will be considered by the government of the United Kingdom and may be delayed or otherwise impacted depending on the circumstances and the composition of the government at the time of consideration. These and other risks associated with our planned international operations may materially and adversely affect our business, costs and growth prospects.

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

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

***Our information technology systems, or those used by our third-party collaborators or other contractors or consultants, may fail or suffer cybersecurity incidents 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 (“Confidential Information”). As we expand our direct engagement with patients, our data collection, processing, and storage activities may increase in volume and complexity, including the creation of additional copies of patient data across systems and platforms, heightening the risk of unauthorized access, disclosure, or misuse of patient information. 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, misconfigurations, “bugs” or other vulnerabilities, denial or degradation of service attacks, 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. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. As we increasingly leverage third-party digital health platforms and service providers to support our operations and patient-facing capabilities, we may become subject to cybersecurity risks outside of our direct control. As a part of these relationships, these third parties may store or process certain types of confidential or patient data. These third parties may not maintain cybersecurity practices, expertise, certifications, or controls that are equivalent to our own, which could increase the risk of security incidents, data breaches, or service disruptions that could adversely affect our business, operations, or reputation.

The risk of a cybersecurity incident 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 incident affecting our or their information technology systems or data, the costs associated with the investigation, remediation, and potential notification of the incident to counterparties 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 an incident affecting personal information has occurred and/or to provide notice and, in some circumstances, one year of credit monitoring services to individuals whose personal information has been impacted as a result of such incident. As part of our growth strategy, we have expanded into multiple jurisdictions outside of the United States, including the United Kingdom, Canada, and Israel, and intend to continue expansions in 2026 and beyond, including through our partnership with Samsung. This growth will subject us to additional regulatory regimes and increase the amount of cybersecurity requirements for compliance in multiple geographies. Complying with such numerous and complex regulations in the event of a cybersecurity 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. Data protection laws and regulations often require appropriate, reasonable or adequate technical and organizational security measures, and the interpretation and application of those laws and regulations are often uncertain and evolving. There can be no assurance that our security measures will be deemed adequate, appropriate or reasonable by a regulator or court. Moreover, even security measures that are deemed appropriate, reasonable, or otherwise in accordance with applicable legal requirements may not be able to protect the information we maintain.

Due to the technical nature of cybersecurity work, it is important for GRAIL to employ highly skilled cybersecurity professionals. If we fail to identify and retain qualified key personnel in these areas or fail to appropriately allocate responsibilities or dedicate sufficient headcount or resources to these areas, the quality of our cybersecurity efforts may be compromised. 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 confidential or proprietary information.

As a part of our cybersecurity program, we conduct a number of internal evaluations and independent, external third-party audits and reviews, including under the NIST CSF 2.0 and NIST Privacy Frameworks, along with our annual reviews under ISO 27001, SOC2 Type 2, PCI DSS, HIPAA, and other standards, in order to identify capabilities, gaps, and recommendations for improvement, and to compare our cybersecurity program to applicable requirements. These assessments generate findings and opportunities that we integrate into a formal remediation roadmap designed to mature our security posture and drive continuous improvement. However, these improvements and maturation efforts require sustained resource allocation and may span multiple reporting

cycles. Failure to execute remediations effectively or within established timelines could result in persistent control deficiencies, increasing our exposure to regulatory sanctions, cybersecurity incidents, or data breaches, which would amplify the risks otherwise described.

We, along with companies with whom we engage in data sharing, including our service providers, are from time to time subject to cyberattacks and other cybersecurity incidents. While we do not believe that we have experienced any significant system failure, or cybersecurity incident 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 a cybersecurity incident or attack, 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. Further, there can also be no assurance that our and our third-party service providers', strategic partners', contractors', consultants', CROs' and collaborators' cybersecurity risk management program and processes, including policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information. To the extent that any disruption or cybersecurity incident 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. While we may be entitled to damages if our third-party partners, vendors, or suppliers fail to satisfy their security-related obligations, any award may be insufficient to cover our damages, or we may be unable to recover such award. 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. In particular, developments in artificial intelligence tools and computing power are likely to increase the frequency and effectiveness of attacks. We may also experience cybersecurity incidents that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate cybersecurity incidents due to attackers increasingly using tools and techniques – including artificial intelligence – that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

While we maintain cybersecurity insurance, our insurance policies may not be adequate to compensate us for the potential losses arising from such disruptions, failure, or cybersecurity incidents. 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, our precision oncology portfolio and any of our future products if and when launched;
- changes in strategic focus or priorities;
- the prices at which we are able to sell our products;
- the impact of market developments or our response thereto;
- disruptions in our business due to manufacturing, supply, cybersecurity breaches, outages, or other issues;
- the cost of performing next-generation sequencing;
- the timing and amount of royalty payments, including the expected end of the suspension period of the Illumina royalty on December 24, 2026;
- 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 may experience this seasonality in particular in the third quarter due to primary care physician and patient summer vacation periods. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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

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

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

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

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

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

For example, since the Acquisition of our business by Illumina in 2021, the Acquisition has been subject to various legal challenges, including by the FTC and the European Commission. As a result, we have been a party, together with Illumina and as a separate party, to a number of regulatory and administrative proceedings regarding the Acquisition, including ongoing proceedings and proceedings in which we have filed separate appeals. In addition, we have intervened in certain procedures in support of Illumina. Following completion of the Spin-Off we and Illumina sought dismissal of the FTC's complaint on July 30, 2024, and on August 15, 2024, the FTC dismissed without prejudice the complaint on the basis that the Spin-Off effectively abandoned the transaction giving rise to the complaint. On September 3, 2024, the European Court of Justice annulled the European Commission's decision to review Illumina's acquisition of Grail on the basis the European Commission did not have the jurisdiction to do so. With the completion of the Spin-Off, the dismissal by the FTC and the annulment of the European Court of Justice, the Company believes these matters are substantially concluded. However, we may continue to be involved in litigation proceedings related to the FTC's or the European Commission's actions related to the Acquisition. We may also be a party or otherwise involved in new litigation proceedings regarding the Acquisition. For example, in July 2023, Illumina was informed that the staff of the SEC was conducting an investigation relating to Illumina and was requesting documents and communications primarily related to Illumina's acquisition of GRAIL and certain statements and disclosures concerning GRAIL, our products and the Acquisition, and related to the conduct and compensation of certain members of Illumina and GRAIL management, among other things. On May 9, 2025, the Company confirmed with the SEC that the SEC has closed its investigation into this matter.

In addition, our acquisition by Illumina and subsequent litigation resulted in the filing of three securities class actions in the United States District Court for the Southern District of California: *Kangas v. Illumina, Inc. et al.*, *Roy v. Illumina, Inc. et al.*, and *Louisiana Sheriffs' Pension & Relief Fund v. Illumina, Inc. et al.* (collectively, the "Actions"). The complaints generally allege, among other things, that defendants made materially false and misleading statements and omitted material facts relating to Illumina's acquisition of GRAIL. The complaints seek unspecified damages, interest, fees, and costs. On January 9, 2024, four movants filed motions to consolidate the Actions and to appoint a lead plaintiff ("Lead Plaintiff Motions"). On April 11, 2024, the Court issued an order consolidating the Actions into a single action (captioned in re *Illumina, Inc. Securities Litigation No. 23-cv-2082-LL-MMP*), and appointed Universal-Investment-Gesellschaft mbH, UI BVK Kapitalverwaltungsgesellschaft mbH, and ACATIS Investment Kapitalverwaltungsgesellschaft mbH as lead plaintiffs. (the "Lead Plaintiffs"). On June 21, 2024, the Lead Plaintiffs filed their consolidated amended complaint. The amended complaint alleges that GRAIL, in addition to Illumina, and certain of their respective current and former directors and others violated sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 in connection with Illumina's acquisition of GRAIL. On September 13, 2024 the plaintiffs further amended the complaint. On November 12, 2024, we moved to dismiss Lead Plaintiffs' second amended complaint for failure to state a claim under Sections 10(b) and 20(a) of the Exchange Act. Lead Plaintiffs filed their opposition to the motion to dismiss on December 20, 2024, and we filed our reply in support of its motion to dismiss on February 3, 2025. On September 26, 2025, the court granted the motion to dismiss for failure to state a claim with leave to amend, and ordered the plaintiffs to file an amended complaint. On October 27, 2025, the Lead Plaintiffs filed their third amended complaint and on December 12, 2025, we filed a motion to dismiss Lead Plaintiffs' third amended complaint. We deny the allegations in the complaints and intend to vigorously defend the litigation. See *Note 11 — Legal And Regulatory Proceedings* in Item 8. Financial Statements of this Annual Report on Form 10-K for additional details. In the event that any of the matters described above result in one or more adverse judgments or settlements, we may experience an adverse impact on our financial condition, results of operations or stock price.

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

## Risks Relating to Regulation and Legal Compliance

***We have launched Galleri as an LDT in the United States. In 2024, the FDA finalized a regulation that has been successfully challenged in federal court, pursuant to which the FDA planned to subject LDTs to medical device requirements through a phase-out of its historical policy of enforcement discretion over LDTs over a period of four years. A federal court recently vacated this rule.***

While we recently submitted our PMA seeking regulatory approval from the FDA for Galleri, we initially launched Galleri in the United States as an LDT in 2021. 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. The FDA historically exercised enforcement discretion with respect to LDTs, pursuant to which it did not seek to enforce certain potentially applicable FDA requirements, including premarket review, with certain exceptions.

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

Even for those LDTs that were subject to the historical enforcement discretion policy, the FDA for a number of years stated its intention to modify this policy and impose applicable medical device requirements to LDTs more broadly. To this end, on May 6, 2024, the FDA issued a final rule in an effort to clarify the FDA’s historical view that LDTs are medical devices subject to the requirements applicable to other IVDs (the “LDT Final Rule”), and to phase out its enforcement discretion policy over a period of four years from issuance of the LDT Final Rule.

However, on March 31, 2025, the United States District Court for the Eastern District of Texas vacated the LDT Final Rule, reasoning that LDTs are not medical devices, and remanded the matter to the FDA for further consideration. The decision was not appealed, and in September 2025, the FDA rescinded the LDT Final Rule. Accordingly, it is uncertain whether or when the FDA may be able to otherwise exercise its medical device authority with respect to LDTs. This uncertainty could adversely affect the FDA’s ability to apply and enforce its medical device requirements with respect to any LDTs for which a sponsor may plan to obtain a PMA. Such uncertainty and the FDA’s actions in response could have a material adverse effect on our business and operations.

In light of this uncertainty, we do not know if or when our offerings could become or will remain subject to FDA medical device requirements, including the need to seek and obtain marketing authorization. If we were unable to comply with any medical device requirements applicable to LDTs if and when any such requirements become applicable, we could be required to cease marketing any solutions that we market as LDTs. In addition, further efforts by the FDA or Congress to impose more regulation on LDTs could create a negative public perception about the validity, safety, effectiveness, or performance of LDTs, including our solutions, which could adversely affect patient, provider, and customer perception about, and confidence in, our solutions.

Notwithstanding the withdrawal of the LDT Final Rule, the FDA may assert that we are improperly marketing our tests, including Galleri, as LDTs and may assert we do not comply with applicable medical device requirements, and in such cases may take enforcement action against us and/or require us to seek premarket review and obtain marketing authorizations, which may require that we cease marketing any LDT products until

such marketing authorizations are obtained or the relevant applications are submitted. There can be no assurance that we will be able to obtain any required marketing authorization for our tests or that any labeling claims will be consistent with the claims we have made or intend to make for such products when launched as LDTs, or that such claims would be adequate to support continued adoption of and reimbursement for our products. In the event we are required to seek FDA marketing authorization for any current or planned products, the FDA may request that we provide additional analyses and information beyond that which we intend to produce based on the designs of our current and planned clinical studies, or that we modify or narrow our intended use or product claims. It is possible that the FDA, among other things, could disagree with our interpretation of data we have relied on to support our LDT launches for our intended uses. If we are required to provide additional analyses or additional data or perform additional clinical studies beyond those we currently contemplate to support the intended uses of our products or future products, our planned commercial launches may be delayed and we may be required to cease commercialization of any products we currently market as LDTs. A delay in the launch of our products or new versions of existing products, or significantly narrowing their intended uses, could negatively impact our financial condition and results of operations.

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

***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.***

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

Before a new medical device can be marketed in the United States, a company must first submit an application for and receive 510(k) clearance pursuant to a premarket notification submitted under Section 510(k) of the FDCA, approval of a PMA, or grant of a de novo classification request from the FDA, unless an exemption applies. 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, preclinical, 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.

The PMA approval process can be expensive, lengthy and uncertain. The process of obtaining a PMA is costly and uncertain 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 marketing authorization may require us to submit a PMA and obtain FDA approval prior to implementing the change. For example, certain modifications to a PMA-approved device may require approval of a new PMA or a PMA supplement, or alternatively a notification or other submission to the FDA. If we obtain PMA approvals from the FDA, we may make modifications or add additional features in the future that we believe do not require approval of a PMA or supplement or other regulatory submission. 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 evolved and continues to undergo legislative change. 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, and any delays in coming into compliance with these laws and regulations could prevent or delay our ability to launch Galleri in Europe. The aforementioned EU rules are generally applicable in the EEA (which consists of the 27 EU member states plus Iceland, Norway and Liechtenstein, and also generally applicable in Türkiye). 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, on December 16, 2024, the UK government passed an amendment to the UK MDR to clarify and strengthen the post-market surveillance requirements for medical devices (including IVDs) in Great Britain. This amendment became applicable on June 16, 2025. In addition, the MHRA launched a consultation from November 14, 2024 to January 5, 2025 on proposed changes to the pre-market requirements for medical devices in Great Britain. On July 22, 2025, the MHRA published a response to the consultation confirming that it will incorporate feedback to this consultation into new UK legislation on pre-market requirements for medical devices in Great Britain. A draft of the new legislation is expected to be published in 2026. Under the UK MDR, in order to be lawfully placed on the Great Britain market, Class A (non-sterile) IVDs need to be United Kingdom Conformity Assessment (“UKCA”) certified by a UK approved body. However, certain IVDs in compliance with: (a) the EU IVDD can continue to be placed on the Great Britain market until the sooner of certificate expiration or June 30, 2030; and (b) the EU IVDR can continue to be placed on the Great Britain market until June 30, 2030. IVDs also need to bear a physical UKCA mark in order to be lawfully placed on the Great Britain market. We have UKCA self-certified our Galleri test and it bears a UKCA mark. However, the MHRA has confirmed in its response to the consultation on pre-market requirements for medical devices in Great Britain that it intends to remove the requirement for a medical device or an IVD and their labelling (i.e. packaging and instructions for use) in Great Britain to bear a physical UKCA mark. Instead of requiring a medical device or an IVD and their labelling to bear a UKCA mark, manufacturers would be required to assign a unique design identification (“UDI”) to such devices and register the UDI in a publicly accessible database before they are placed on the Great Britain market. If this change is implemented, we may no longer be required to affix the physical UKCA mark to our devices, but we may need to assign and affix a UDI and register the UDI in a publicly accessible database. Understanding and ensuring compliance with any new requirements is likely to lead to further complexity and increased costs to our business.

It is currently unclear to what extent the UK government will seek to align new UK legislation on pre-market requirements for medical devices in Great Britain with the EU. The EU laws that have been transposed into UK law through secondary legislation remain applicable in Great Britain, however the full extent of the new UK legislation on pre-market requirements for medical devices in Great Britain remains uncertain and may cause additional cost to our business.

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:

- disagreement with the design, implementation, or results of, or interpretation of the data from, our clinical studies;
- determination 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;
- disagreement 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;

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

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

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

There can be no assurance that labeling claims will be consistent with our anticipated claims or current claims or marketing statements, including with respect to Galleri as an LDT and its current marketing as an MCED test in its intended use population, or adequate to support adoption of, or reimbursement for, our products. If the approved, cleared, or certified indication or other labeling claims the FDA or a comparable foreign regulatory authority or notified body allows us to make are more limited than we expect, or are more limited than current claims made with respect to Galleri, our business, prospects, and growth may be adversely affected and we may be limited in our ability to sell, or unable to sell, our products. As part of our PMA submission to the FDA for Galleri, we included a bridging analysis between the version of Galleri used in the PATHFINDER 2 study and NHS-Galleri Trial and the version we have submitted to the FDA for PMA approval. The results of this bridging analysis will likely impact any labeling claims, and may differ from previously reported performance results from those studies. If we are not able to obtain FDA approval for desired uses or indications for our current and future products, we may not market or promote them for those indications and uses, and our business, financial condition, results of operations, stock price and prospects could be materially harmed. We also must sufficiently substantiate any claims that we make for any products, including claims comparing those products to other companies' products, and must abide by the FDA's strict requirements regarding the content of promotion and advertising.

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

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

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

***Our use and disclosure of personal information, including individually identifiable health information, and biological 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 disclose 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 disclose 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 implemented thereunder (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 ("PHI"), 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 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 are and will continue to 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, as amended by the California Privacy Rights Act (collectively, the "CCPA") requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Additional compliance investment

and potential business process changes may also be required as the statute and regulations continue to evolve. Although there are limited exemptions for certain health-related data, including clinical trial data and PHI subject to HIPAA, the CCPA 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 broadly defines “consumer health data”, creates a private right of action to allow individuals to sue for violations of the law, imposes stringent consent requirements, and grants consumers certain rights with respect to their health data, including to request deletion of their information. 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, but not limited to, Connecticut, Virginia and Nevada, have also passed laws governing the privacy of consumer health data, 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 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 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. Additionally, federal and state consumer protection laws are increasingly being applied by FTC and states’ attorneys general to regulate the collection, use, storage, and disclosure of health-related and other personal information through websites or otherwise, and to regulate the presentation of website content.

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

In addition, the actual or perceived compromise of, lax oversight of, irresponsible or unauthorized use of, or unauthorized access to or release of, patient data or information by GRAIL, our partners, suppliers, contractors, consultants, or vendors, could erode provider, patient, and customer confidence, which could impact our business, financial condition, and results of operations.

In the conduct of clinical research, 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) or IRB approved waivers thereof. 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 UK GDPR and EU 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.

Among other requirements, the GDPR regulates the transfer of personal information outside of the EEA and the UK and we expect the existing legal complexity and uncertainty regarding international personal data transfers to continue, and international transfers to the United States, China, 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, we may have to implement alternative data transfer mechanisms under the GDPR and/ or take additional compliance and operational measures; 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 those regimes independently and 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. In addition to potential fines, noncompliance with applicable foreign privacy laws, such as the GDPR, may result in regulatory investigations, orders to cease/ change our data processing activities, enforcement notices, assessment notices (for a compulsory audit), civil claims (including class actions) and/or damage to the public perception of GRAIL’s data stewardship practices and policies, which could impair our business and prospects with other foreign health systems and governments.

***Our business may be affected by the evolving regulatory framework for AI Technologies.***

The regulatory framework for artificial intelligence (“AI”), machine learning, and automated decision-making technologies (collectively, “AI Technologies”) is rapidly evolving as many federal, state, and foreign government bodies and agencies have introduced or are currently considering additional laws and regulations. Additionally, existing laws and regulations may be interpreted in ways that would affect the operation of our AI Technologies.

It is possible that new laws and regulations will be adopted in the United States and in other non-U.S. jurisdictions, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit our ability to use AI Technologies for our business, or require us to change the way we use AI Technologies in a manner that negatively affects the performance of our products, services, and business and the way in which we use AI Technologies. We may need to expend resources to adjust our products or services in certain jurisdictions if the laws, regulations, or decisions are not consistent across jurisdictions. Further, the cost to comply with such laws, regulations, or decisions and/or guidance interpreting existing laws, could be significant and would increase our operating expenses (such as by imposing additional reporting obligations regarding our use of AI Technologies). Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could adversely affect our business, financial condition and results of operations.

***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 laboratory.

We hold a CLIA certificate from CMS for our laboratory in Durham, North Carolina to conduct high complexity testing, subject to inspection to determine compliance with the CLIA regulations. We also hold a CAP accreditation for our Durham facility. Certain product additions to our test menu require notification to the regulatory and accrediting bodies that regulate our laboratory (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 laboratory at any time. Any failure to pass inspections, maintain our CLIA certificate, 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 laboratory. We have obtained a Clinical Laboratory Certificate of Deemed Status from the State of California Department of Public Health for our Durham, North Carolina 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 NYSDoH 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 NYSDoH clinical laboratory permits for our Durham facility for our initial commercial version of Galleri and approval for our new version of Galleri, 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 NYSDoH approval (or, with respect to the new version of Galleri, conditional 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 laboratory 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.

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.

For example, we recently announced the topline results of our NHS-Galleri Trial in the United. In May 2024, the NHS determined, based on data from an early analysis of Galleri test performance results in the intervention arm from the prevalent screening round of the NHS-Galleri Trial, not to initiate an implementation pilot in England prior to the final trial results. We submitted to NHS England and to the FDA information from the prevalent screening round. Various factors are likely to cause the final results to differ from the prevalent screening round results. Further, it is possible that the early preliminary, interim or final data may not be as we expect, may be inconsistent with prior NHS-Galleri Trial data, or with other studies we have conducted, or may be unsuitable to the NHS or the FDA. Importantly, preliminary or interim data may be focused on different endpoints than the overall study. The prevalent screening round results that we announced and provided to the NHS and FDA were predominantly focused on performance characteristics of the Galleri test, whereas the primary endpoint and a number of secondary endpoints of the trial were focused on clinical utility measures like cancer stage shift that can only be measured through annual testing over a number of years. Similarly, in October 2025, performance and safety results from the first approximately 25,000 participants of the PATHFINDER 2 study were presented at the ESMO Congress 2025. PATHFINDER 2 was initiated in 2021 to evaluate the safety and performance of the Galleri test when added to standard of care single cancer screening in 35,878 adults aged 50 years and older with no clinical suspicion of cancer. Results from the full approximately 35,000 participants in the PATHFINDER 2 study were generally consistent with the results presented at ESMO. While we did not include full performance and safety data from the additional 10,000 patients in our initial PMA submission, it is possible that the FDA could require these data to confirm study performance. Any unexpected, unsuitable, or inconsistent results could have a significant adverse impact on the success of our commercial efforts for Galleri, our ability to achieve FDA authorization at all or within our anticipated timelines, our ability to achieve CMS or private payor reimbursement or coverage, our brand and reputation, our business, and our growth prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, and our ability to receive regulatory clearance or approval or commercialize a particular product and our company in general. In addition, the information we choose to publicly

disclose regarding a particular study or clinical study is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding our business. If the data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to commercialize or obtain regulatory clearance or approval for our products may be harmed, which could harm our reputation, business, operating results, prospects or financial condition.

***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 2, 2026, the FDA's final rule implementing the FDA's Quality Management System Regulation ("QMSR") became effective. The QMSR, which replaced the FDA's former Quality System Regulation ("QSR"), sets forth the FDA's cGMP requirements for medical devices, and among other things, incorporates by reference certain elements of the quality management system requirements of ISO 13485:2016. Although the FDA has stated that the standards contained in ISO 13485:2016 are substantially similar to those set forth in the QSR, and although our quality management system is designed to comply with ISO:13485, the FDA has indicated that ISO:13485 certification alone will not ensure compliance under the QMSR, nor will ISO certification exempt manufacturers from FDA inspection. The QMSR also includes certain compliance obligations, such as those relating to unique device identification, product traceability, and maintenance of complaint and service records, that align more closely with the FDA's existing medical device requirements than with ISO standards. Accordingly, it remains unclear the extent to which the QMSR may impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise 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 and continues to undergo legislative changes. 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. The EU IVDR requirements are in active implementation and may change as the European Commission adopts additional implementing acts and considers targeted revisions to related IVD rules.

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

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

For products for which we obtain FDA clearance or approval or that are otherwise subject to affirmative FDA oversight, we will be subject to the FDA's medical device reporting regulations and similar foreign regulations,

which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance or approval, seizure of our products or delay in clearance or approval of future products. Similar risks exist in foreign jurisdictions.

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

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

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

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

For the FDA to approve or clear a medical device marketing application, the methods used in, and the facilities used for, the manufacture of our products must comply with the FDA's QMSR, 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 QMSR 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, on February 2, 2026, the FDA's final rule implementing the QMSR became effective. The QMSR, which replaced the FDA's former Quality System Regulation, sets forth the FDA's cGMP requirements for medical devices, and among other things, incorporates by reference certain elements of the quality management

system requirements of ISO 13485:2016. Although the FDA has stated that the standards contained in ISO 13485:2016 are substantially similar to those set forth in the QSR, and although our quality management system is designed to comply with ISO:13485 the FDA has indicated that ISO:13485 certification alone will not ensure compliance under the QMSR, nor will ISO certification exempt manufacturers from FDA inspection. The QMSR also includes certain compliance obligations, such as those relating to unique device identification, product traceability, and maintenance of complaint and service records, that align more closely with the FDA's existing medical device requirements than with ISO standards. Accordingly, it remains unclear the extent to which the QMSR may impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise negatively affect our business. If we or our third party manufacturers are unable to comply with the QMSR, once effective, or with any other applicable FDA requirements or if we or a third party manufacturer discovers previously unknown problems with our products or manufacturing processes, these could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's refusal to grant pending or future clearances or approvals for our products; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us, our suppliers, or our employees.

Any of these actions could significantly and negatively affect the 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." However, we are reliant on physicians and other providers to accurately provide information about our products to patients, including purposes, limitations, risks benefits, and interpretation of results, and we cannot, prevent a provider from using our products off-label, when in the provider'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 if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our devices are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. As described above, product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.

Misleading, untruthful, or unsubstantiated labeling, advertising, marketing, or promotional practices could cause significant harm to our business, operations, and financial conditions. The FTC has instituted enforcement actions against certain healthcare testing companies for making false or misleading advertising claims and for failing to adequately substantiate claims made in advertising. These enforcement actions may result in warning

letters, consent decrees, and the payment of civil penalties and/or restitution by the companies involved. Should the FTC determine that our claims are false or misleading or unsubstantiated, we could be subject to FTC enforcement action and may face significant penalties which may result in a material adverse effect on our reputation, business, financial condition, results of operations, and growth prospects.

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

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

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

In April 2014, Congress passed PAMA, which included substantial changes to the way in which clinical laboratory services are paid under the CLFS. Under PAMA, certain clinical laboratories are required to periodically report to CMS private payor payment rates and volumes for their tests, and laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. Medicare reimbursement for CDLTs is based on the weighted-median of the payments made by private payors for these tests, rendering private payor payment levels even more significant than in the past. As a result, future Medicare payments may fluctuate more often and become subject to the willingness of private payors to recognize the value of diagnostic tests generally and any given test individually. The impact of this payment system on rates for our tests, including any current or future tests we may develop, is uncertain. For more information, see above and the section entitled "Risks Relating to Our Business and Industry. 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 and our overall commercial success beyond our existing sales channels will be limited."

More recently, the One Big Beautiful Bill Act (the "OBBA") included significant reforms to Medicaid, including an estimated \$1 trillion in reduced federal Medicaid spending from 2025 through 2034, the imposition of work requirements for certain adult enrollees, more frequent eligibility redeterminations, and increased cost-sharing for beneficiaries. These changes are expected to reduce overall Medicaid enrollment and access to care. Although the effect on our business is currently unknown, any decrease in the number of insured patients or reimbursement levels for our tests could adversely affect our revenue and commercial prospects.

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. While the Regulation entered into force in January 2022 and has been applicable since January 2025, with phased implementation based on the type of product (i.e., certain high-risk medical devices as of 2026). This Regulation intends to boost cooperation among EU member states in assessing health technologies, including certain high-risk medical devices, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It 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 highest 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; follow our processes and procedures resulting in implementation gaps, poor organization structure or culture, lack of appropriate internal reporting and decision making or substantive weaknesses, for example, in building and maintaining cybersecurity defenses; 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. And as we continue to partner with digital health partners, we will face increased risk where Galleri is offered through third party telemedicine platforms, related to, for example, reputational considerations, promotional and marketing considerations, cybersecurity considerations, and compliance with applicable laws. 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.
- the Eliminating Kickbacks in Recovery Act of 2018 (“EKRA”), which establishes an all-payor anti-kickback prohibition for, among other things, knowingly and willfully paying or offering any remuneration directly or indirectly to induce a referral of an individual to a clinical laboratory. Violations of EKRA may result in fines, imprisonment, or both, for each occurrence. The law includes a limited number of exceptions, some of which closely align with corresponding Anti-Kickback Statute exceptions and safe harbors, and others that materially differ. Certain sales-based incentive compensation models may present risk while others may fall outside the scope of EKRA, depending on the facts and circumstances. Accordingly, we cannot guarantee that our relationships with providers, sales representatives, or customers will not be subject to scrutiny or will withstand regulatory challenge under EKRA;
- the federal physician self-referral prohibition, commonly known as the Stark Law, which, in the absence of an applicable exception, prohibits a physician from making a referral for certain designated health services covered by the Medicare or Medicaid program, including clinical laboratory services, if the physician or an immediate family member of the physician has a financial relationship with the entity

providing the designated health services. The Stark Law also prohibits the entity furnishing the designated health services from billing, presenting or causing to be presented a claim for the designated health services furnished pursuant to the prohibited referral;

- federal civil and criminal false claims laws, including the False Claims Act, which impose criminal and civil penalties, including through civil “qui tam” or “whistleblower” actions, against individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false or fraudulent. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute or Stark Law constitutes a false or fraudulent claim for purposes of the False Claims Act;
- healthcare fraud and false statements laws, which prohibit, among other things, knowingly making a false statement to improperly avoid, decrease, or conceal an obligation to pay money to the federal government. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation;
- the federal Civil Monetary Penalties Law, which, subject to certain exceptions, prohibits, among other things, the offer or transfer of remuneration, including waivers of copayments and deductible amounts (or any part thereof), to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program;
- the federal Physician Payment Sunshine Act, created under the ACA, and its implementing regulations, which require manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to the U.S. Department of Health and Human Services under the Open Payments Program, information related to payments or other transfers of value made to physicians (as defined by statute), teaching hospitals, and other healthcare practitioners, as well as ownership and investment interests held by such physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection, and unfair competition laws that may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangement, as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require healthcare companies to comply with the medical device industry’s voluntary compliance guidelines, the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers, and other potential referral sources or state-specific standards on financial interactions with healthcare providers; and 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.

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.

In addition to environmental, health, and safety laws and regulations, environmental and social governance ("ESG"), diversity, equity and inclusion ("DEI"), "anti-ESG" and "anti-DEI" sentiment has gained momentum in some parts of the United States. Increasingly, different stakeholder groups have divergent views on ESG and DEI matters, which increases the risk that any action or lack thereof with respect to ESG or DEI matters will be perceived negatively by at least some stakeholders and adversely impact our reputation and business. If we do not successfully manage ESG or DEI-related expectations and requirements across stakeholders, it could erode stakeholder trust, impact our reputation, subject us to shareholder activism or litigation, and adversely affect our business, financial condition, results of operations and cash flows. Several state and federal governmental authorities have filed suit alleging that ESG or DEI measures or initiatives violate the law. We or those in our industry could face litigation for our ESG or diversity policies and/or programs and if we were sued under any of these claims, our financial condition, reputation or business could be adversely impacted.

***Changes in funding, leadership, resources or prioritization, or other disruptions, in the U.S. or international government, including at the FDA, other government agencies, and notified bodies, could hinder our ability to develop, approve, certify, commercialize or receive reimbursement for our test.***

Our ability to develop, approve, certify, commercialize or receive reimbursement for our test depends on interactions with, decisions of and approvals and payments by the U.S. and other governments. 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. 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, notified bodies and other agencies may also slow the time necessary for new medical devices or modifications to approved, cleared, or certified medical devices to be reviewed and cleared, approved, or certified

by necessary government agencies, which would adversely affect our business. For example, the current U.S. administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

In addition, in recent 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, including during an extended shutdown between October 1, 2025 and November 12, 2025. Similar shutdowns could have a broad range of negative effects on our business. Disruptions at the FDA, other agencies, and notified bodies caused by these or other shutdowns, may also slow the time necessary for new medical devices or modifications to be cleared and approved, or certified medical devices to be reviewed and/or approved, or certified by necessary government agencies or notified bodies, or delay payment for currently reimbursed research, such as our REACH study, or reimbursed products in the future, which would adversely affect our business.

We also receive certain government reimbursement payments for tests provided to patients in our REACH clinical trial, and these payments may be delayed or not provided if the government remains shutdown, or they are not budgeted for as part of any continuing resolution. In the future, this risk could be amplified as we continue to seek, and hope to achieve, additional government reimbursement for our test.

If a prolonged government shutdown occurs, or if funding shortages, staffing limitations or similar factors hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, such events could significantly impact the ability of the FDA or other such regulatory authorities 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. Their designation process, which is significantly stricter under the new Regulation, has experienced considerable delays in the past. Despite a recent increase in designations, the current number of notified bodies designated under the new Regulation remains significantly lower than the number of notified bodies designated under the previous regime. The current designated notified bodies are therefore facing a backlog of requests as a consequence of which review times have lengthened. This has been one of the reasons for the recent extension of the transitional provisions under the EU IVDR. Despite these recent developments, 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 may still be impacted, and our ability to commercially launch Galleri in the EU and EEA could be delayed.

***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 UK 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. There is significant uncertainty whether the current U.S. administration, including as a result of the recent executive order pausing all investigations and prosecutions under the FCPA, will continue robust anti-corruption enforcement in our industry. In any case, 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.

***The biopharmaceutical and medical device industries are subject to extensive regulatory obligations and policies that may be subject to significant and abrupt change, including due to judicial challenges, election cycles, and resulting regulatory updates and changes in policy priorities.***

On June 28, 2024, the U.S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act (APA) “must exercise their independent judgment” and “may not defer to an agency interpretation of the law simply because a statute is ambiguous.” The decision will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by HHS, CMS, FDA and other agencies with significant oversight of the biopharmaceutical and medical device industries. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies will be subject to increased litigation and judicial scrutiny.

In addition, federal agency priorities, leadership, policies, rulemaking, communications, spending, and staffing may be significantly impacted by election cycles. For example, there have been recent reductions in government spending and reductions in the workforces of certain government agencies, such as HHS, FDA, and CMS. Further limitations may result in reductions to agency budgets, employees, and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates. Similarly, the current political climate could impact regulation affecting our business could lead to abrupt changes in regulation of our industry and the effectiveness of our regulatory and reimbursement strategy.

### **Risks Relating to Intellectual Property**

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

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

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

Although patents are presumed valid and enforceable upon issuance, a patent may be challenged as to its inventorship, scope, validity, or enforceability, and certain of our owned or exclusively in-licensed patents have been, and others in the future may be, challenged in the courts or patent offices in the United States or abroad. For example, certain of our in-licensed and owned European patents have been subject to oppositions in Europe, as described below. As a result of such challenges, our pending or future patent applications may not result in

issued patents, or the scope of existing or future patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, or our issued patents may be held invalid or unenforceable. It is also possible that we may fail to identify patentable technologies in a timely fashion, which could impair our ability to obtain patent protection on such technology at all. Third parties may be able to circumvent our owned or exclusively in-licensed patents by developing similar or alternative technologies or tests in a non-infringing manner. Third parties could in the future also set up laboratories outside the countries in which we have filed patent applications in order to compete without infringing upon our intellectual property, even if they process samples from countries in which we do have patent protection. In addition, to the extent we have granted, or may grant in the future, licenses or sublicenses of our intellectual property rights to third parties, we cannot provide any assurance that such intellectual property rights will not be used by those third parties in a manner that could compete with our business or otherwise negatively impact any competitive advantage provided by such intellectual property rights.

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

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

For example, while we believe our patent portfolio, including our in-licensed patents such as those from the Chinese University of Hong Kong, provide coverage of various aspects of Galleri and our precision oncology portfolio, including on methylation analysis, identification of cancer signal of origin and assay chemistry and techniques for preparing and optimizing patient samples, recently other screening companies have announced tissue-free monitoring of residual disease and intention to offer early cancer detection products using blood-based methylation analysis. Other market participants operating commercially using purportedly similar technologies will increase the likelihood of intellectual property disputes and associated risks.

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 entered into license agreements 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 and use 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, including the Patent Eligibility Restoration Act (PERA) pending in the U.S. Senate. 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. or foreign patent law could affect our susceptibility to patent infringement claims and our ability to obtain patents and, if obtained, to enforce or defend them, any of which could have a material adverse effect on our business.

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

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

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

Third parties may challenge the validity or enforceability of our owned or in-licensed patents in court or before administrative bodies in the United States or abroad. If we or one of our licensors initiated legal proceedings against a third party to enforce a patent, the defendant could counterclaim that our asserted patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of subject matter eligibility, lack of written description, and non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a material misleading statement, during prosecution. Third parties have raised, and in the future may raise, claims

challenging the validity or enforceability of our owned or in-licensed patents before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover Galleri 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 or our precision oncology portfolio. The opponents have filed an appeal, which is currently pending. An additional opposition was filed on another of our in-licensed European patents relating to Galleri by an anonymous opponent, and this opposition is currently pending. These opposition proceedings do 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 some 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, patent owners may have limited remedies in certain circumstances, which could materially diminish the value of such patents. 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 in development with intellectual property rights, such as patents, as appropriate, the process of obtaining patents is time consuming, expensive, and unpredictable.

In addition, geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement, or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's conflict in Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by

patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. If we are not able to protect our intellectual property rights throughout the world, our position may be impaired, and our business, financial condition, results of operations, and growth prospects may be adversely affected.

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

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

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

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

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

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

We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, directors, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, suppliers, service providers, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants, and remind departing employees when they leave their employment of their continuing confidentiality obligations. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite our efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. Some courts outside the United States are less willing or unwilling to protect trade secrets, and the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws within the United States. For example, in China, claims regarding

infringement or misappropriation of trade secrets are more difficult to prove, and consequently plaintiffs are rarely successful in bringing these claims. If any of our trade secrets were to be lawfully obtained or independently developed by a third party, we would have no right to prevent them from using that technology or information. If any of our trade secrets were to be misappropriated by, disclosed to, or independently developed by a third party, our market position could be materially and adversely harmed.

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

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

Our commercial success in part depends upon our ability, and the ability of our collaborators, to market, sell, and distribute our products and use our proprietary technologies without infringing, misappropriating, or otherwise violating the proprietary rights of third parties. There is considerable intellectual property litigation in the medical technology, biotechnology, diagnostic, and pharmaceutical industries. In addition, there is ongoing intellectual property litigation in the circulating nucleic acid analysis and cancer nucleic acid space, the outcome of which could also impact potential future litigation involving our intellectual property or our ability to commercialize our products. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products, including interference proceedings before the USPTO and similar bodies in other jurisdictions. Third parties may assert infringement claims against us based on existing patents or patents that may be issued in the future.

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

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

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

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

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

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

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

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

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

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

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

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

#### **Risks Relating to the Spin-Off**

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

Illumina received a private letter ruling from the IRS and a written opinion of Cravath, Swaine & Moore LLP that, subject to the limitations specified therein and the accuracy of and compliance with certain representations, warranties, and covenants, the Spin-Off will qualify for non-recognition of gain and loss under Sections 355 and 368 of the Code. Notwithstanding this ruling and opinion, if the Spin-Off were determined not to qualify for non-recognition of gain and loss under Sections 355 and 368 of the Code, we could be required, under certain circumstances, to indemnify Illumina for certain taxes and related expenses. In addition, current tax law generally creates a presumption that the Spin-Off would be taxable to Illumina, but not to holders, if we or our shareholders were to engage in transactions that result in a 50% or greater change by vote or value in the ownership of our stock during the four-year period ending on June 24, 2026, unless it were established that such transactions and the Distribution were not part of a plan or series of related transactions giving effect to such a change in ownership. If the Distribution were taxable to Illumina due to such a 50% or greater change in ownership of our stock, we could, under certain circumstances, be required under the Tax Matters Agreement to indemnify Illumina for some or all of the tax on such gain and related expenses. Any such indemnification obligation could materially adversely affect our business, financial condition, and results of operations.

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

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

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

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

- the historical financial data may not fully reflect the costs associated with the Spin-Off, including the costs related to being an independent public company;
- our historical financial data does not reflect our obligations under the various transitional and other agreements we will enter into with Illumina in connection with the Spin-Off;
- since Illumina acquired us in August 2021, our working capital requirements and capital for our general corporate purposes, including capital expenditures, have been satisfied by Illumina. Following the Spin-Off, we will need to rely on our cash on hand or obtain additional financing from banks, through public offerings or private placements of debt or equity securities, strategic relationships, or other arrangements, which may or may not be available or may be available only on less attractive terms than we may have received as a part of Illumina; and
- following the Spin-Off, we expect that the cost of capital for our business is higher than Illumina's cost of capital prior to the Spin-Off.

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

## Risks Relating to Our Common Stock

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

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

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

- the commercial success of Galleri;
- the timing of launch of any future products;
- the timing and results of clinical studies for our products and the failure or discontinuation of any of our product development and research programs;
- the success of future third-party tests, services, or technologies and the results of clinical studies, or regulatory approvals (or certifications) of tests of third parties;
- developments or disputes concerning patent applications, issued patents, or other proprietary rights;
- whether our financial results, forecasts, and development timelines meet the expectations of securities analysts or investors, and changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders, Illumina, or other stockholders;
- regulatory or legal developments in the United States, including under the new presidential administration, changes in the structure of healthcare payment systems, such as changes that would affect coverage and reimbursement by third-party payors, and other countries
- general economic, industry, and market conditions; and
- the other factors described in this Item 1A. “Risk Factors” section.

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

***If securities analysts publish negative evaluations of our stock, the price of our stock could decline.***

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

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

We expect to seek additional capital, and may pursue fundraising paths that could include public and private equity offerings, debt financings, strategic partnerships, and alliances and licensing arrangements. We, and indirectly, our stockholders, will bear the cost of issuing and servicing securities issued in any such transactions. Because our decision to issue debt or equity securities will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any future financings. To the extent that we raise additional capital through the sale of equity or convertible 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 outstanding or future equity-based awards that we expect to grant to our directors, officers, and other employees, including pursuant to our 2024 Equity Incentive Plan. We also make equity grants to certain new employees joining the Company pursuant to an inducement plan, and our compensation committee may elect to increase the number of shares available for future grant under the inducement plan without stockholder approval. We also have an Employee Stock Purchase Plan and any shares of common stock purchased pursuant to that plan will also cause dilution.

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

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

- the last day of the fiscal year in which our total annual gross revenues first meet or exceed \$1.235 billion (as adjusted for inflation);
- the date on which we have, during the prior three-year period, issued more than \$1.0 billion in non-convertible debt;
- the last day of the fiscal year in which we (i) have an aggregate worldwide market value of common stock held by non-affiliates of \$700 million or more (measured at the end of each fiscal year) as of the last business day of our most recently completed second fiscal quarter and (ii) have been a reporting company under the Exchange Act for at least one year (and filed at least one annual report under the Exchange Act and are no longer a smaller reporting company); or
- the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement under the Securities Act of 1933 (the “Securities Act”).

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

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

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

In addition, we have elected to not take advantage of the extended transition period that allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies, which means that the financial statements we file in the future, will be subject to all new or revised accounting standards generally applicable to public companies. Our election not to take advantage of the extended transition period is irrevocable. We expect to cease to be an “emerging growth company” effective December 31, 2026.

***Substantial sales of our common stock by Illumina or other significant shareholders could cause our stock price to decline.***

Immediately following the Spin-Off on June 24, 2024, Illumina retained a 14.5% ownership interest of our common stock. In connection with the Spin-Off, we have entered into a Stockholder and Registration Rights Agreement with Illumina, pursuant to which we provide Illumina registration rights with respect to the shares of our common stock it retained following the Spin-Off. In addition, Illumina has agreed to vote any shares of our common stock that it retains in proportion to the votes cast by our other stockholders and to grant us a proxy to vote its shares of our common stock in such proportion. Pursuant to the IRS private letter ruling, Illumina is required to dispose of any such shares of our common stock that it retains as soon as warranted consistent with the business reasons for the retention of such shares, but in no event later than five years after the Spin-Off. Illumina is not required to hold any retained shares for any minimum period following the Spin-Off. During the fourth quarter of 2025, Illumina sold 2,000,000 shares of the Company’s common stock, reducing its ownership to 2,502,126 shares, which represented approximately 6.0% of the Company’s outstanding common stock as of December 31, 2025. On February 17, 2026, Illumina filed a Schedule 13G reporting beneficial ownership of 1,302,126 shares of our common stock. We are unable to predict with certainty when Illumina will dispose of additional substantial numbers of shares of common stock. The sales of significant amounts of our common stock by Illumina or any other significant shareholders, or the perception in the market that this will occur, may decrease the market price of our common stock.

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

You should not rely on our common stock to provide dividend income. We do not anticipate that we will pay any dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, any future credit facility or debt securities may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock, and the terms of our Separation and Distribution Agreement with Illumina entered into in connection with the Spin-Off require us to repay portions of the disposal funding we received from Illumina in connection with the Spin-Off in the event we pay dividends.

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

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

Pursuant to SOX Section 404, we are required to furnish a report by our management on our internal control over financial reporting beginning with this filing of our Annual Report on Form 10-K. 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 are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we have and will need to continue to dedicate internal resources, 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 continuously conclude that our internal control over financial reporting is effective as required by SOX Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

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

- establish that our board of directors is divided into three classes: Class I, Class II, and Class III, with each class serving staggered three-year terms;

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

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

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

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

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

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

However, this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, our Certificate of Incorporation also provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person purchasing or otherwise acquiring or holding any interest in shares of our capital stock is deemed to have received notice of and consented to the foregoing provisions. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds more favorable for disputes with us or with our directors, officers, other employees or agents, or our other stockholders, which may discourage such lawsuits against us and such other persons. Alternatively, if a court were to find this choice of forum provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, results of operations, and financial condition.

***We could be subject to additional securities class action litigation.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us, because healthcare companies have experienced significant stock price volatility in recent years. Our stock price may be volatile and may decline significantly in response to the announcement of clinical trial results, including results that do not meet their primary endpoints or that are perceived unfavorably by the investment community. For example, in February 2026, we announced that the NHS-Galleri Trial did not meet its primary endpoint of statistically significant combined Stage 3 and 4 reduction and experienced a decline in our stock price on the following day. The announcement of these results, or any future announcements of clinical trial results that do not meet expectations, could cause significant volatility or decline in the market price of our common stock. 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.

In addition, any perceived or actual decline in our business prospects or stock price following the NHS-Galleri Trial results or other adverse developments could invite shareholder activism. Responding to shareholder activism can be costly and time-consuming, disrupt our operations, and divert the attention of our management and board of directors. Furthermore, activist shareholders may attempt to influence or change our strategic direction, capital allocation, or governance practices, which could adversely affect our business and stock price.

**Item 1B. Unresolved Staff Comments**

Not applicable.

**Item 1C. Cybersecurity**

**Risk Management and Strategy**

Given the importance of cybersecurity to our business, we maintain a cybersecurity program to help support the effectiveness of our systems, and our preparedness for cybersecurity risks, and our protection of the confidentiality, integrity, and availability of our critical systems and information. Our cybersecurity risk management program is part of our overall risk management program and shares similar governance processes and reporting channels that apply across the risk management program to financial, legal, compliance, and other operational risk areas. Our program is informed by industry frameworks, such as the National Institute of Standards and Technology ("NIST") Cybersecurity Framework 2.0 ("NIST CSF 2.0"). This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use frameworks such as NIST CSF 2.0 as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

We also require cybersecurity trainings when onboarding new employees and contractors, as well as annual cybersecurity awareness training for our employees and contractors.

We use our Enterprise Risk Management (“ERM”) process to assess and manage cybersecurity risks that may be associated with our systems, operations, and third-party service providers. We conduct internal audits and engage external assessors to help review our cybersecurity program and identify opportunities for maturing our program. For additional information, see “Item 1A. Risk Factors”.

***Identifying, assessing and managing cybersecurity risks***

Our cybersecurity team and the owners of information technology systems across the business, led by our Chief Security Officer (“CSO”) and Vice President, Security (“VP, Security”), monitor current events and trends related to cybersecurity in an effort to anticipate potential risks and threats on current systems and operations. We have implemented and continue to develop various processes to identify, review and track risks to our systems and operations, including through the use of third-party solutions and penetration testing of our systems. We have policies and procedures for performing cybersecurity risk assessments of our third-party service providers that may have access to our systems, data, facilities, or that otherwise perform services on our behalf and for conducting due diligence in connection with the onboarding of new third-party vendors.

As a core component of our enterprise risk management strategy, we maintain a rigorous cybersecurity program that is periodically evaluated through internal assessments and independent third-party audits. We perform comprehensive maturity assessments against the NIST CSF2.0 and the NIST Privacy Framework. These strategic reviews complement our sustained compliance posture, which includes recurring annual audits for ISO/IEC 27001, SOC 2 Type 2, PCI DSS, UK Cyber Essentials and HIPAA.

We leverage these assessments to identify functional gaps and benchmark our cybersecurity program against applicable regulatory requirements. The resulting findings are integrated into a formal Remediation Roadmap designed to mature our security posture and drive continuous improvement. By integrating findings from both internal evaluations and independent external audits, we foster a culture of continuous improvement and operational resilience. Recognizing that the human element is a critical line of defense, we maintain a robust cybersecurity awareness program. This initiative equips our employees and contractors to recognize and mitigate evolving threats through continuous education and regular phishing simulation exercises designed to reinforce vigilant behavior. Our process also includes initial due diligence, ongoing monitoring, and periodic reassessments of our third-party service providers.

In the event of a cybersecurity incident, we have an incident response framework that includes defined escalation procedures, cross-functional coordination protocols, regulatory notification assessment procedures, and post-incident review processes. We also periodically conduct cross-functional exercises and activities to help detect, assess and respond to cybersecurity incidents, and have relationships with external providers to assist with incident response efforts, as needed. We also seek to contractually require our third-party service providers to notify us in the event a cybersecurity incident within their systems or services impacts our data or operations. We maintain specific coverage to help mitigate losses associated with certain cybersecurity incidents that impact our or our third parties’ systems, networks and technology.

As of December 31, 2025, we have not identified any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, that have materially affected us, including our operations, business strategy, results of operations, or financial condition. We assess materiality based on quantitative and qualitative factors, including potential impact to our operations, financial condition, intellectual property, regulatory compliance obligations, and reputation. While we maintain a cybersecurity program, the techniques used to infiltrate information technology systems continue to evolve. Accordingly, we face risks from cybersecurity threats that, if realized, are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. For additional information, see Item 1A. “Risk Factors –Our information technology systems, or those used by our third-party collaborators or other contractors or consultants, may fail or suffer cybersecurity incidents or cyberattacks”.

## **Cybersecurity Governance**

Our Board of Directors administers its cybersecurity risk oversight function through its Audit Committee. The Audit Committee is charged with reviewing our cybersecurity and other information technology risks, controls, and procedures, including our processes to mitigate cybersecurity risks and respond to data or cybersecurity incidents. The Audit Committee is also charged with reviewing cybersecurity issues with management that could affect the adequacy of our internal controls. The Audit Committee meets periodically, and at least annually, with the CSO and/or VP, Security and the executive leadership team and receives a report on our cybersecurity program, posture, risks and other matters. At least annually, we conduct an organization-wide ERM process to evaluate key risks in different areas of the business including cybersecurity. During that process, cybersecurity risks are identified, and scores representing the potential likelihood and severity of each risk are determined. The executive leadership team and Audit Committee receive a direct report of the ERM program findings, including these cybersecurity risks and incidents it considers to be significant or potentially significant. Third-party assessors, consultants, counsel or other parties also participate in Audit Committee discussions as needed.

More broadly, the Audit Committee reviews our policies and practices with respect to risk assessment and risk management, including results from our overall ERM review, and discusses with management our major risk exposures and the steps that have been taken to monitor and control such exposures. Cybersecurity is a key piece of our overall ERM program. The Audit Committee oversees the activities of, and meets regularly with, our Chief Compliance Officer, and receives direct reports from the Chief Compliance Officer regarding the ERM structure and activities of our compliance program, including updates on training, policies, auditing and monitoring, investigations and any corrective and preventive actions. As part of the ERM program, our Chief Compliance Officer gathers information about cybersecurity risk, and that information is included in the Chief Compliance Officer's report to the Audit Committee.

Our cybersecurity team and information technology system owners across the business are led by our CSO and VP, Security. Our CSO has over five years of tenure with the Company and more than 29 years of experience in technology, including 15 years in cybersecurity. He previously served as Chief Technology Officer at NextBio and as Vice President of Software Engineering, Enterprise Informatics at Illumina, Inc. He is supported by a cybersecurity organization comprising experts in strategy, governance, risk management, compliance, engineering, security operations, and incident response, including our VP, Security who has over two decades of specialized experience in cybersecurity and privacy. The CSO is responsible for implementing and overseeing the controls and processes employed to identify, assess and manage the Company's risks from cybersecurity threats. We also maintain a Privacy and Security Steering Committee that regularly meets to review and discuss cybersecurity issues and review our cybersecurity-related metrics. The Privacy and Security Steering Committee is composed of the VP, Security, Chief Privacy Officer, Chief Compliance Officer, and other representatives from our cybersecurity, IT, legal, and privacy teams. The VP, Security, cybersecurity team, and members of the Privacy and Security Steering Committee combined have decades of experience in managing relevant information technology and cybersecurity matters. The VP, Security also provides regular briefings to our executive leadership team, including the CEO and CFO, and our Audit Committee on cybersecurity matters, such as threats, events, and the state of the program, and at least annually as part of our ERM process.

Our management team takes steps to stay informed about and monitor efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from IT personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in our IT environment.

## **Item 2. Properties**

Our principal office and research laboratory is approximately 74,300 square feet and located at 1525 O'Brien Drive, Menlo Park, California. We also lease office space of approximately 57,400 square feet at 1605 Adams Drive, Menlo Park, California. These leases expire on September 30, 2026. The Company plans to relocate its headquarters to Sunnyvale, California upon expiration of these leases.

In June 2020, we entered into an agreement to lease approximately 200,000 square feet of a building in Durham, North Carolina which is primarily a commercial laboratory capable of meeting demand of up to one million tests per year. We have approximately 46,000 square feet of CAP-accredited, CLIA-certified laboratory space with sufficient capacity to support multiple years of growth. This lease expires in 2033 and we have three separate options to extend the lease, each for an additional five years. We hold a CLIA Certificate of Accreditation Registration from the CMS, an accreditation from CAP, and certifications from the State of California Department of Public Health and New York State Department of Health, among others, for our North Carolina laboratory.

In September 2025, we entered into an agreement to lease an aggregate of approximately 75,556 square feet for our new corporate headquarters located at 250 S. Matilda Avenue, Suite 100 in Sunnyvale, California. This lease is expected to commence on or about October 1, 2026 and expire on or about September 30, 2037. We have the option to expand into additional space and renew the lease for an additional five-year term under specified conditions.

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

For financial information regarding leases, refer to *Note 9 — Leases* in Item 8 in this Annual Report on Form 10-K.

## **Item 3. Legal Proceedings**

For information regarding Legal Proceedings, refer to *Note 11 — Legal And Regulatory Proceedings* in Item 8 in this Annual Report on Form 10-K.

## **Item 4. Mine Safety Disclosures**

Not applicable.

## **PART II**

## **Item 5 Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

### **Market information for common stock**

GRAIL's common stock is traded under the symbol "GRAL" and is listed on the Nasdaq Stock Exchange since June 24, 2024.

### **Holders of record**

As of March 6, 2026, there were 440 holders of record of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

**Dividend policy**

We have never declared or paid any dividends on our common stock. 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.

**Unregistered sales of equity securities**

Disclosure about unregistered sales of equity securities during the quarter ended December 31, 2025 was previously reported in a Current Report on Form 8-K filed on October 20, 2025.

**Issuer purchases of equity securities**

None.

**Item 6. [Reserved]**

## Item 7. 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 and the notes thereto included under Item 8. "Financial Statements". This discussion contains forward-looking statements that involve risks and uncertainties. The forward-looking statements are not historical facts, but rather are based on current expectations, estimates, assumptions and projections about our industry and our business and financial results. Our actual results could differ materially from the results contemplated by these forward-looking statements due to a number of factors, including those discussed in the section entitled "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K and the section titled "Cautionary Statement Concerning Forward-Looking Statements" of this Annual Report on Form 10-K. Our fiscal year end is December 31. References to 2025, 2024, and 2023 refer to the fiscal years ended December 31, 2025, December 31, 2024, and December 31, 2023. This section of this report generally discusses 2025 and 2024 items and year-to-year comparisons between 2025 and 2024. A detailed discussion comparing our results of operations for 2024 and 2023 can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of our Annual Report on Form 10-K, for the year ended December 31, 2024.*

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

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

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

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

### Overview

#### **Our Business**

We are an innovative commercial-stage healthcare company focused on shifting the paradigm in early cancer detection at population scale. 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 multi-cancer early detection test ("Galleri") can screen for many types of cancer, accurately predicting the specific organ or tissue type where the cancer signal originated (the "Cancer Signal of Origin", or "CSO"), with high positive predictive values ("PPV") and low false positive rates, all from a simple blood draw. Galleri has detected some of the most aggressive cancers in early stages including, among others, endometrial, esophageal, gastrointestinal, head and neck, liver, pancreatic, and rectal cancers. We have conducted what we believe is the largest clinical program in genomic medicine to date with data from over 385,000 participants that we believe demonstrate the clinical validation and clinical utility of Galleri in its intended use population. We have deep operational experience with over 800,000 tests processed

across this clinical program and from our commercial experience, including through partnerships with leading healthcare systems, employers, digital health platforms, payors, and life insurance providers.

Recently we announced results from two of our large clinical trials, PATHFINDER 2 and NHS-Galleri Trial, and included certain results from those studies in our pre-market approval application (“PMA”) to the Food and Drug Administration (“FDA”), the last module of which we submitted in January 2026. Performance and safety data focused on the first approximately 25,000 participants of our approximately 35,000 participant PATHFINDER 2 study were presented at the European Society for Medical Oncology (“ESMO”) in October 2025 (the “PATHFINDER 2 Initial Results”) and demonstrated that adding Galleri to recommended (breast, cervical, colorectal and lung) screenings led to a cancer detection rate more than seven-fold increase in the number of cancers found within a year, and an approximately three-fold increase when prostate screening was included. Results from the full approximately 35,000 participants in the PATHFINDER 2 study were generally consistent with the results presented at ESMO. We also announced topline results from our three year, randomized control NHS-Galleri Trial which demonstrated a substantial reduction in stage 4 cancer diagnoses, increased stage 1 and 2 detection of deadly cancers, and four-fold higher cancer detection rate when compared to recommended screenings alone, although the primary endpoint of statistically significant combined stage 3 and 4 reduction was not observed. However, there was a favorable trend toward fewer combined stage 3 and 4 cancers in a pre-specified group of 12 deadly cancers in the intervention arm after the prevalent screening round. The PATHFINDER 2 Initial Results and the performance and safety metrics from the first year (prevalent screening round) of our NHS-Galleri Trial (“NHS-Galleri Prevalent Screening Round Results”) were included in our PMA submission, along with results of a bridging study.

We designed Galleri to detect cancer early, when it is more amenable to curative treatment, and we launched Galleri in the United States in mid-2021. Galleri works by detecting DNA fragments shed into the bloodstream by tumor cells and analyzing 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. We have sold approximately 475,000 commercial Galleri tests through December 31, 2025, including more than 185,000 in 2025, which have detected some of the most aggressive cancers in early stages including, among others, endometrial, esophageal, gastrointestinal, head and neck, liver, pancreatic, and rectal cancers.

As an early pioneer 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”), 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.

Since our inception, we have incurred net losses each year. Our net losses were \$408.4 million, \$2.0 billion and \$1.5 billion for 2025, 2024 and 2023. Adjusted EBITDA was \$(320.6) million, \$(483.5) million and \$(523.9) million for 2025, 2024 and 2023. Adjusted EBITDA is a non-GAAP financial measure. For a reconciliation of Adjusted EBITDA to the most directly comparable U.S. generally accepted accounting principle (“GAAP”) financial measure, information about why we consider Adjusted EBITDA useful and a discussion of the material risks and limitations of these measures, please see “Non-GAAP Financial Measures” below. Substantially all of our net losses resulted from the application of pushdown accounting, including goodwill and intangible assets impairments, amortization of intangible assets, as well as our research and development programs, general and administrative (“G&A”) costs associated with our operations, and sales and marketing costs associated with commercializing our products. Additionally, due to the application of pushdown accounting, our balance sheet includes intangible assets recognized by Illumina in connection with their acquisition of us that may be subject to additional impairment over time. We expect to continue to incur operating losses over at least the next several years as we continue to invest in research and development and commercialization of existing products.

### ***\$325 million Private Investment of Public Equity (the "PIPE")***

On October 18, 2025, we entered into a securities purchase agreement (the "Purchase Agreement") with certain investors for the private placement of (i) 2,640,970 shares of GRAIL's common stock at a price of \$70.05 per share and (ii) pre-funded warrants to purchase an aggregate of 1,998,573 shares of GRAIL's common stock (the "Pre-Funded Warrants") at a purchase price of \$70.049 per Pre-Funded Warrant, which represents the per share price for the common stock less the \$0.001 exercise price. The PIPE closed on October 21, 2025, at which time we received aggregate net proceeds of \$311.3 million, after deducting issuance costs of \$13.7 million.

In addition, in connection with the Purchase Agreement, we entered into a Registration Rights Agreement with all of the investors (the "Registration Rights Agreement"). Pursuant to the Registration Rights Agreement, we filed a registration statement on Form S-3 with the SEC on November 13, 2025 for purposes of registering the resale of the shares and the shares of common stock issuable upon exercise of the Pre-Funded Warrants purchased in the private placement.

### ***ATM Program***

On November 14, 2025, we entered into an equity distribution agreement ("Equity Distribution Agreement"), with certain sales agents, establishing an At the Market Equity Distribution Program, under which we may offer and sell shares of our common stock, having an aggregate offering price of \$300.0 million or up to 6,900,000 of common stock shares (the "ATM Program").

During the year ended December 31, 2025, we issued 1,169,218 shares of our common stock pursuant to the ATM Program and we received aggregate net proceeds of \$107.5 million, after deducting issuance costs of \$3.2 million. As of December 31, 2025, \$189.3 million worth of shares of common stock remained available for sale pursuant to the ATM Program.

### ***Strategic Collaboration with Samsung and \$110 million Equity Investment***

In October 2025, we announced a strategic collaboration with Samsung C&T Corporation ("Samsung C&T"), Samsung Electronics Singapore Pte. Ltd. (together with Samsung C&T, the "Samsung Investors") and Samsung Electronics Co., Ltd. ("Samsung Electronics"). As part of this strategic collaboration, we and Samsung C&T intend to work as exclusive partners to commercialize Galleri in Korea and, potentially, other key Asian markets, including Japan and Singapore. In addition, we and Samsung Electronics intend to explore potential additional strategic and operational collaborations, such as supporting longitudinal genomic-lifestyle clinical research and the integration of Samsung Electronics' health data platform with our technologies and data.

In connection with this strategic collaboration, we entered into a stock purchase agreement (the "Samsung Stock Purchase Agreement"), with the Samsung Investors and Samsung Electronics, providing for the issuance and sale by us to the Samsung Investors in a private placement of 1,570,308 shares of our common stock, at a purchase price of \$70.05 per share, upon the terms and conditions set forth in the Samsung Stock Purchase Agreement, for aggregate gross proceeds of approximately \$110.0 million (the "Samsung Investment"). The Samsung Investment is subject to the satisfaction of certain closing conditions set forth in the Samsung Stock Purchase Agreement, including, but not limited to the satisfaction of certain regulatory approvals or clearances, including with respect to the Committee on Foreign Investment in the United States.

We intend to use the net proceeds from all our equity offerings to fund our commercial activities and reimbursement efforts, as well as for working capital and other general corporate purposes.

### ***Separation from Illumina***

On June 21, 2024, Illumina completed the previously announced spin-off of GRAIL (the "Spin-Off"). The Spin-Off was completed through a distribution of approximately 85.5% of our outstanding common stock to the holders of record of Illumina's common stock as of the close of business on June 13, 2024 (the "Distribution"), which resulted in the issuance of 31,049,148 shares of common stock. As a result of this Distribution, GRAIL became an independent public entity. GRAIL's common stock is listed under the ticker symbol "GRAL" on the Nasdaq Stock Exchange.

We entered into or adopted agreements that provide a framework for the relationship between us and Illumina in connection with the Spin-Off. Refer to *Note 1 — Organization And Description Of Business* in Item 8 in this Annual Report on Form 10K.

On June 21, 2024, in connection with the Spin-Off, we received a cash contribution of \$932.3 million from Illumina. In connection with the Spin-Off, we incurred \$22.2 million of legal and professional fees in the year ended December 31, 2024 related to the 2021 acquisition of GRAIL by Illumina, and corresponding antitrust litigation, including compliance with the hold separate arrangements imposed by the European Commission, and divestiture of GRAIL from Illumina through the Spin-Off. See “Non-GAAP Financial Measures — Adjusted EBITDA” for further details. In addition, from 2021 to 2024, we spent \$143.8 million on legal and professional service fees related to the antitrust litigation and compliance with the hold separate order and transaction costs related to Illumina’s acquisition of GRAIL and the Spin-Off.

As of December 31, 2025, Illumina held 2,502,126 shares of common stock representing a less than 10% stake in the Company. On February 17, 2026, Illumina filed a Schedule 13G reporting beneficial ownership of 1,302,126 shares of our common stock.

### **Restructuring Plan**

On August 9, 2024, following a portfolio review, our Board of Directors (the “Board”) approved a restructuring plan (“Restructuring Plan”) designed to reprioritize our resources to focus on our core MCED business and reduce overall spend as we progressed towards completion of registrational studies and PMA submission to the FDA for Galleri.

As a result, we streamlined our commercial sales forces to focus on productive customers and high priority opportunities, while maintaining sales force coverage for the majority of our current Galleri volume and active prescribers. We also streamlined the investment in enterprise business, including our employer and life insurance businesses. These changes involved simplifying management layers and commercial roles without sales responsibilities, along with reductions in medical affairs teams involved with U.S. Galleri provider engagement.

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

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

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

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

### ***Basis of Presentation***

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

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

We have incurred and expect to incur additional costs as a separate public company, and particularly as we transition to a large accelerated filer as of December 31, 2026 and are subject to enhanced reporting and internal control requirements under the Sarbanes-Oxley Act of 2002. These additional costs are primarily related to certain supporting functions that may differ from and be higher than the costs historically incurred or allocated to us.

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

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

In addition, we have entered into a supply and commercialization agreement with Illumina (the "Illumina Supply Agreement"). Under the terms of the Illumina Supply Agreement, regardless of whether our products incorporate any Illumina technology, we will be obligated to pay Illumina a 9% royalty, subject to certain reductions and floors, 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. The royalty is subject to anti-stacking provisions that allow royalty payments we make to other third parties to be deducted from the 9% royalty rate, to a floor of 7%. We expect that the third party royalty payments we will make in the foreseeable future will result in a 7% royalty rate. After we have cumulatively paid Illumina royalties totaling \$1 billion, the royalty rate will be reduced to 5%, without further adjustment. Pursuant to the fourth amendment to the Illumina Supply Agreement, the perpetual royalty payment obligation to Illumina is suspended until December 24, 2026 or any earlier change of control of GRAIL, at which time royalty payments to Illumina will resume, without retroactive effect. Any royalty payments that we would have made under the Illumina Supply Agreement during the suspension period are deemed to have been paid for purposes of the cumulative \$1 billion in royalty payments required to reduce the royalty rate to 5%.

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

### **Key Factors Affecting Performance**

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

- **FDA and other regulatory approval and reimbursement.** Our performance will be impacted by the extent to which we can secure reimbursement and coverage for Galleri. Prior to broader coverage and reimbursement in the United States, we will continue our work with clinics and health systems to accelerate utilization, and with self-insured employers and health insurers to offer and cover Galleri. Galleri is currently available as a laboratory developed test (“LDT”) in the United States and we have established coverage and reimbursement from a number of self-insured employers and health plans, including coverage from TRICARE, but we do not currently have broader coverage and reimbursement by Medicare or large commercial insurers. While Galleri has not been approved or cleared by the FDA, FDA approval is currently not required to market our test in the United States. We are pursuing FDA approval to help support broad access for Galleri in the United States and we submitted a PMA for Galleri to the FDA in January 2026. Obtaining PMA approval can take several months or years from the time an application is submitted, if at all. Moreover, the regulatory requirements surrounding the pathway to PMA for laboratory tests has in the recent past, and may in the future, be subject to change. We believe that FDA approval, if obtained, could unlock coverage from large commercial payors in the United States. In February 2026, a new law created a coverage benefit category to enable coverage of FDA-approved MCED tests by Medicare, with authority for CMS to initiate coverage as early as January 1, 2029 for the aged 50-65 Medicare population and expanding one age-year at a time annually. If we obtain FDA approval, we expect to pursue coverage through this new law and, subsequently, inclusion of Galleri in the USPSTF’s guideline recommendation, although such inclusion may take years and is not certain even with FDA approval. Should USPSTF recommend Galleri with an A or B recommendation, CMS would then have the authority to expand coverage beyond what is covered under the MCED benefit category. We believe FDA approval and, to a greater extent, inclusion in USPSTF guideline recommendations would further increase adoption and market acceptance of our tests. Over time, we have and may continue to opt to provide rebates or discounts to certain customers, or reduce pricing in order to access a broader population base and accelerate adoption. In the United Kingdom, NHS England (which is being merged with the Department of Health and Social Care) (the “NHS”) will evaluate the final results from the NHS-Galleri Trial before determining whether to implement the Galleri test in the NHS. Under our agreement with the NHS, these results have met certain success criteria and missed others. As a result, we and NHS England will convene meetings of our joint steering committee to discuss how best to proceed with deployment to the UK population, if at all, considering deployment approaches and which population groups would most benefit. We believe the decision will include considerations such as NHS budget, political priorities, cost-effectiveness and implementation constraints in addition to an evaluation of the final results. We also believe our work with the NHS and the data generated from our NHS-Galleri Trial could help facilitate adoption in other single-payor systems around the world and support evidence of clinical utility worldwide. Although the primary endpoint of statistically significant combined stage 3 and 4 reduction was not observed in the NHS-Galleri Trial, we believe other results from the trial could be compelling to these systems.
- **International expansion.** A component of our long-term growth strategy is to expand our commercial reach internationally. We have expanded our research internationally into the United Kingdom through our partnership with NHS England in the NHS-Galleri Trial, and we expect to launch Galleri in the United Kingdom, following any positive NHS evaluation of the final results from the NHS-Galleri Trial. We continue to evaluate international expansion opportunities and we have begun expansion in select additional geographies through distributors, including Israel and Canada, and proposed expansion in South Korea through our partnership with Samsung. We expect to continue selectively engaging with international opportunities over time. Our ability to expand into new regions and jurisdictions, drive commercial sales and growth within those regions and jurisdictions and navigate economic, political, regulatory, and other risks, including geopolitical conflict, associated with international operations will be an important driver of our performance.

- **Continued development of, and competition within, the market for MCED testing.** Multi-cancer early detection is a novel technology and the market for MCED tests is evolving. We continue to drive MCED as a solution to one of healthcare's most important challenges. Our performance depends on the extent to which key stakeholders, including current and potential commercial partners, payors and health systems, regulators, policy makers, academic and community medical centers, and key opinion leaders and advocates, understand and support MCED testing as an effective solution for cancer screening. We make significant efforts to educate these key stakeholders regarding the benefits of MCED and the clinical and economic value of our products, which we believe will continue to drive awareness of MCED and expand the commercial opportunity for our products. Additionally, new MCED products from new market entrants launched commercially in the second half of 2025. We believe that the addition of new market entrants will help develop the market for MCED testing. However, these competitors will also be targeting similar markets as us and may compete with us for customers on characteristics of their tests, such as test performance, ease of use and cost. These companies may also present clinical or other information, such as test performance information, that differs from our own presentation of similar information. Our ability to differentiate Galleri from other MCED products and any such presented data will be a key factor in our success. We believe we are differentiated by our extensive and robust datasets generated from our clinical studies, our rigorous and objective approach to test development and research, our multidisciplinary capabilities leveraging the power of next-generation sequencing and advanced and trained machine learning algorithms and data science, our robust intellectual property portfolio, and our investment in our facilities and operational workflows. However, certain new market entrants may have greater financial resources, quicker reimbursement timelines, larger sales forces, more successful marketing campaigns, more experience in screening or international commercialization, lower prices or other advantages. Our ability to succeed will depend on our market success. See Item 1A. "Risk Factors".
- **Demand for our products and customer mix.** A key factor to our future success is and will be our ability to increase demand for, and sales of, Galleri from new and existing customers. Our commercial strategy is focused on innovative value-oriented partnerships and targets primary care physicians, health systems, employers, digital health platforms, payors, and life insurance providers. As Galleri is not currently broadly reimbursed, our ability to drive demand from these customers is directly linked to our ability to demonstrate the clinical and economic value of our test through clinical validation and real-world experience. As of December 31, 2025, we have entered into commercial partnerships, including with leading healthcare systems, digital health platforms, employers, payors, and life insurance providers, and have established a network of over 17,000 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, with discounts in certain channels, or, for certain customers, such as larger, higher-volume customers or international distributors, negotiated contractual rates. For certain customers, we also offer rebates. Revenue generated from customers with negotiated contractual rates, or with rebates or discounts, is generally lower margin as compared to revenue generated based on list pricing. We expect the number or magnitude of these rates, discounts and rebates to reduce our average selling price ("ASP") over time. In addition, we have entered into a number of biopharmaceutical research partnerships for our research-use-only ("RUO") offering under our precision oncology portfolio. Large customers, such as healthcare systems, employers, and biopharmaceutical partners, generally begin using our products by initiating pilots involving a limited number of tests. We believe that our ability to convert these initial pilots into long-term customer relationships has the potential to drive substantial long-term revenue. Termination of these pilots or clinical trials can have a significant impact on our revenue and results of operations. For example, in late 2025, one of our pharmaceutical partners terminated its phase 3 trial due to low enrollment, for which our methylation technology was used as a potential companion diagnostic for enrolling participants. We also expect to increase demand from new customers through our efforts to further develop the market for MCED testing.

- **Investment in clinical studies and innovation to support our strategy and growth.** A significant aspect of our business is our investment in research and development and the ongoing evidence generation supporting the clinical performance and utility of Galleri. In particular, we have invested heavily in clinical studies and designed and executed what we believe is the largest clinical program in genomic medicine to date. These studies include: NHS-Galleri, PATHFINDER, PATHFINDER 2, CCGA, REACH/Galleri-Medicare, REFLECTION, STRIVE, SUMMIT, and SYMPLIFY. We have established and maintained a leading voice in conversations regarding the early detection of multiple cancer types in the peer-reviewed literature. We have published data from these studies in high-profile journals and have presented such data at renowned medical conferences. We believe these studies are critical to driving adoption of our tests, as well as favorable coverage decisions, and expect to continue investment in data generation. In addition, we have invested heavily in the development of our methylation platform and extensive technological infrastructure. We expect our research and development expenses to decrease over the next three years as, in conjunction with our portfolio review, we determined to decrease investment in product programs beyond Galleri. Additionally, we expect to see a relative decrease in research and development expenses as we complete key milestones, such as the progress of most of our large clinical trials into the data follow-up phase and substantial completion of development of enhanced versions of our Galleri test, including the version that we use in commercial channels and the updated version that was submitted with our PMA. We will continue to prioritize key objectives for Galleri, including generating and reporting clinical utility evidence to support broad adoption of Galleri and progressing our PMA towards potential approval.
- **Leverage our operational infrastructure.** We have made significant investments to build a scalable infrastructure capable of meeting significant demand of up to one million tests per year while satisfying applicable certification and licensing requirements and accreditation standards. Our Durham, North Carolina facility is CAP-accredited and CLIA-certified. In addition, we engineered custom technology infrastructure and cloud-based tools to enable scalable data collection and analysis capabilities. With this foundational infrastructure in place, we have been able to generate scale efficiencies as the volume of tests sold has increased. As demand for our products increases, we expect to further leverage the scale efficiencies of our infrastructure and platform technology, which we believe will positively impact margins over time. In late 2024, we began using an updated version of Galleri in commercial channels. This version incorporates a highly-automated industrial scale platform and is intended to enable us to scale more efficiently with future demand. In connection with implementation of this new version of Galleri, we have experienced and may continue to experience increased turnaround times, re-processing costs and sample failures. We continually monitor and evaluate laboratory operations and performance in an effort to achieve our intended sample processing metrics and costs; however from time to time, processing issues may arise that could impact our operations. In the future, it is possible that we may invest significant amounts in infrastructure to support new products or existing products in new markets.

Seasonal fluctuations and underlying business trends have also affected, and are likely to continue to affect, our business. We may experience this seasonality, in particular in the third quarter due to primary care physician and patient summer vacation periods, with relatively lower volume in the first and third quarters, and relatively higher volume in the second and fourth quarters. These seasonal trends have caused, and will likely continue to cause, fluctuations in our quarterly results, including fluctuations in sequential revenue growth rates.

While each of these areas presents significant opportunities for us, they also pose significant risks and challenges that we must address. See Item 1A. "Risk Factors" for more information.

## **Components of Results of Operations**

### *Screening Revenue*

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

### *Development Services Revenue*

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

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

Cost of revenue represents expenses that are incurred to produce and sell our products and services. For screening revenue, these costs consist of materials, labor including salaries and wages, bonus, benefits and stock-based compensation, blood collection kits and shipping, phlebotomy, royalties, electronic medical records, equipment depreciation, and allocations of overhead expenses such as facilities and information technology costs. For development services, these costs consist of materials and patient sample acquisition, labor including salaries and wages, bonus, benefits and stock-based compensation, royalties, equipment depreciation, and allocations of overhead expenses such as facilities and information technology costs. 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. These margin improvements from scale efficiencies will at least be partially offset when we commence recognition of royalties owing under the terms of the Illumina Supply Agreement on December 24, 2026.

### *Cost of Revenue—Amortization of Intangible Assets*

As a result of the application of pushdown accounting, intangible assets recognized in our standalone financial statements relate to our own technology, and consist of developed technologies and in-process research and development that were measured at fair value upon the Acquisition. Our developed technology includes intangible assets related to Galleri, designed as a cancer screening test for asymptomatic individuals over 50 years of age, as well as our DAC product that is being designed to accelerate diagnostic resolution for patients for whom there is a clinical suspicion of cancer. As part of our Restructuring Plan, we have reduced investment in the development of products beyond Galleri, including DAC. The cost of identifiable intangible assets with finite lives, such as developed technology assets, are amortized on a straight-line basis over the assets' respective estimated useful lives of 18 years.

### *Research and Development*

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

### *Sales and Marketing*

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

### *General and Administrative*

G&A expenses consist of personnel expenses, including salaries, benefits and stock-based compensation expenses, for executive, finance and accounting, legal, human resources, business development, corporate communications, portfolio management, medical affairs, and management information systems personnel. Also included are professional fees, legal costs, including patent and trademark-related expenses and educational activities. The related party amount in the prior year periods represents allocated stock administration expenses from Illumina. We have incurred and will incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, director and officer insurance premiums, investor relations activities, and other expenses related to administrative and professional services. We expect our G&A expenses to increase as we continue to invest in corporate infrastructure to support public company operations and the commercialization of Galleri and to continue to decrease as a percentage of revenue over the next three years and long term.

### *Goodwill and Intangible Assets Impairments*

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

We evaluate goodwill and 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. Refer to *Note 2 — Summary Of Significant Accounting Policies—Goodwill and Intangible Assets* in Item 8 in this Annual Report on Form 10K for more information.

*Interest Income*

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

*Other Income (Expense), Net*

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

*Benefit from Income Taxes*

Income taxes are accounted for under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the future tax consequences of events that have been included in the consolidated financial statements. Deferred tax assets are recognized for deductible temporary differences and tax credit carryforwards, and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portions or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment.

## Results of Operations

### Comparisons of 2025 to 2024

The following table summarizes our results of operations for 2025 and 2024:

(in thousands)	Year Ended		Change	
	December 31, 2025	December 31, 2024	\$	%
<b>Revenue:</b>				
Screening revenue	\$ 138,601	\$ 108,627	\$ 29,974	28%
Development services revenue	8,571	16,968	(8,397)	(49%)
<b>Total revenue</b>	<b>147,172</b>	<b>125,595</b>	<b>21,577</b>	<b>17%</b>
<b>Costs and operating expenses:</b>				
Cost of screening revenue (exclusive of amortization of intangible assets)	73,251	63,284	9,967	16%
Cost of development services revenue	2,605	6,444	(3,839)	(60%)
Cost of revenue — amortization of intangible assets	133,889	133,889	—	—%
Research and development	195,794	322,380	(126,586)	(39%)
Sales and marketing	116,693	153,958	(37,265)	(24%)
General and administrative	159,103	213,862	(54,759)	(26%)
Goodwill and intangible assets impairment	28,000	1,420,936	(1,392,936)	(98%)
<b>Total costs and operating expenses</b>	<b>709,335</b>	<b>2,314,753</b>	<b>(1,605,418)</b>	<b>(69%)</b>
<b>Loss from operations</b>	<b>(562,163)</b>	<b>(2,189,158)</b>	<b>1,626,995</b>	<b>74%</b>
Other income:				
Interest income	28,652	26,733	1,919	7%
Other income (expense), net	(993)	64	(1,057)	(1652%)
<b>Total other income, net</b>	<b>27,659</b>	<b>26,797</b>	<b>862</b>	<b>3%</b>
Loss before income taxes	(534,504)	(2,162,361)	1,627,857	75%
Benefit from income taxes	126,153	135,356	(9,203)	(7%)
<b>Net loss</b>	<b>\$ (408,351)</b>	<b>\$ (2,027,005)</b>	<b>\$ 1,618,654</b>	<b>80%</b>

*Cost of screening revenue (exclusive of amortization of intangible assets) as a percentage of screening revenue*

Year Ended	Change		
December 31, 2025	December 31, 2024	\$	%
53 %	58 %	(5)%	

### Revenue

(in thousands)	Year Ended		Change	
	December 31, 2025	December 31, 2024	\$	%
Screening revenue	\$ 138,601	\$ 108,627	\$ 29,974	28%
Development services revenue	8,571	16,968	(8,397)	(49%)
<b>Total revenue</b>	<b>\$ 147,172</b>	<b>\$ 125,595</b>	<b>\$ 21,577</b>	<b>17%</b>

### Screening Revenue

The increase in screening revenue of \$30.0 million or 28% was primarily driven by a 36% increase in Galleri sales volume, partially offset by a 6% decrease in ASP. Galleri sales volume increased in 2025 as a result of the continued ramp in our commercial activity following the release of positive study results, implementation of new pricing strategies, enhanced ordering pathways via new integrations, expansion of our partnerships with digital health platforms, and increased enrollment in our REACH/Galleri-Medicare clinical study.

### Development Services Revenue

The decrease in development services revenue of \$8.4 million or 49% was primarily driven by a \$7.0 million decrease in revenue from pilots with biopharmaceutical partners and a \$1.4 million decrease in revenue from research services and other services revenue.

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

(in thousands)	Year Ended		Change	
	December 31, 2025	December 31, 2024	\$	%
Cost of screening revenue (exclusive of amortization of intangible assets)	\$ 73,251	\$ 63,284	\$ 9,967	16%

The increase in cost of screening revenue (exclusive of amortization of intangible assets) of \$10.0 million or 16% was primarily driven by a 36% increase in Galleri sales volume, partially offset by a reduction in variable costs of Galleri testing performed on our automated platform.

Cost of screening revenue (exclusive of amortization of intangible assets) as a percent of revenue decreased in 2025 mainly due to the reduction in variable costs of Galleri testing performed on our automated platform, partially offset by a 6% decrease in ASP and higher sample reprocessing costs.

### Cost of Development Services Revenue

(in thousands)	Year Ended		Change	
	December 31, 2025	December 31, 2024	\$	%
Cost of development services revenue	\$ 2,605	\$ 6,444	\$ (3,839)	(60%)

The decrease in cost of development services revenue of \$3.8 million or 60% was primarily due to a decrease in pilots with biopharmaceutical partners and a decrease in the number of research samples processed.

### Research and Development

Research and development expenses for 2025 and 2024 were as follows:

(in thousands)	Year Ended		Change	
	December 31, 2025	December 31, 2024	\$	%
Compensation expenses	\$ 102,580	\$ 162,914	\$ (60,334)	(37%)
Laboratory supplies and research collaborations	12,802	41,341	(28,539)	(69%)
Clinical studies	28,012	43,890	(15,878)	(36%)
Allocated Expenses	24,206	35,436	(11,230)	(32%)
Depreciation expenses	10,347	12,237	(1,890)	(15%)
Other expenses	17,847	26,562	(8,715)	(33%)
<b>Total research and development</b>	<b>\$ 195,794</b>	<b>\$ 322,380</b>	<b>\$ (126,586)</b>	<b>(39%)</b>

The decrease in the research and development expenses of \$126.6 million or 39% was primarily attributable to:

A decrease in compensation expenses of \$60.3 million primarily due to a \$37.4 million decrease in salaries and wages, a \$14.7 million decrease in stock-based compensation expense and a \$7.7 million decrease in severance and benefits, primarily due to the workforce reductions related to the Restructuring Plan implemented in 2024.

A decrease in laboratory supplies and research collaborations of \$28.5 million primarily driven by the substantial completion of the development and validation of our automated platform, the completion of enrollment in the PATHFINDER 2 study and the completion of final study visits in the NHS-Galleri Trial in 2024.

A decrease in clinical studies of \$15.9 million primarily due to a \$20.3 million decrease in PATHFINDER 2 study and NHS-Galleri trial expenses, partially offset by a \$6.2 million increase due to increased enrollment in the REACH/Galleri-Medicare study.

A decrease in allocated expenses of \$11.2 million primarily related to ongoing cost reduction efforts, which resulted in lower software, IT, and facilities expenses being allocated to the research and development function, as well as reduced headcount.

A decrease in other expenses of \$8.7 million primarily due to a \$3.9 million decrease in contractors and temporary labor, a \$1.8 million decrease in professional services, and a \$1.8 million decrease in cloud computing expenses due to cost optimization efforts.

#### Sales and Marketing

(in thousands)	Year Ended		Change	
	December 31, 2025	December 31, 2024	\$	%
Sales and marketing	\$ 116,693	\$ 153,958	\$ (37,265)	(24%)

The decrease in sales and marketing expenses of \$37.3 million or 24% was primarily attributable to a decrease in compensation expenses of \$26.1 million, primarily due to a \$17.4 million decrease in salaries and wages, a \$4.8 million decrease in severance and benefits, and a \$4.4 million decrease in stock-based compensation expense, primarily due to workforce reductions related to the Restructuring Plan implemented in 2024. Professional services and marketing expenses decreased by \$9.6 million due to cost optimization efforts. Other expenses decreased by \$1.6 million mainly driven by decreases in the use of contractors and temporary labor as well as reductions in allocated expenses due to cost optimization efforts.

#### General and Administrative

(in thousands)	Year Ended		Change	
	December 31, 2025	December 31, 2024	\$	%
General and administrative	\$ 159,103	\$ 213,862	\$ (54,759)	(26%)

The decrease in general and administrative expenses of \$54.8 million or 26% was primarily attributable to decreases in legal and professional services expenses and compensation related expenses. Legal and professional services expenses decreased \$28.6 million primarily due to no longer incurring legal and professional service fees related to compliance with the European Commission hold separate order and transaction costs related to our Spin-Off, completed on June 24, 2024. Compensation expenses decreased by \$21.6 million primarily due to a \$9.0 million decrease in stock-based compensation expense, an \$8.4 million decrease in salaries and wages, and a \$5.9 million decrease in severance and benefits primarily due to the reduction in workforce related to the Restructuring Plan implemented in 2024, partially offset by a \$1.6 million increase in variable compensation. Costs associated with the use of contractors and temporary labor decreased by \$7.3 million due to cost optimization efforts. Other general and administrative costs increased by \$2.7 million primarily due to higher allocated expenses due to changes in headcount.

### Goodwill and Intangible Assets Impairment

(in thousands)	Year Ended		Change	
	December 31, 2025	December 31, 2024	\$	%
Goodwill and intangible assets impairment	\$ 28,000	\$ 1,420,936	\$ (1,392,936)	(98%)

Goodwill and intangible impairment decreased \$1.4 billion or 98% due to a goodwill impairment charge of \$888.9 million and an IPR&D impairment charge of \$532.0 million recognized during 2024, partially offset by an IPR&D impairment charge of \$28.0 million recognized in 2025.

### Interest Income

(in thousands)	Year Ended		Change	
	December 31, 2025	December 31, 2024	\$	%
Interest income	\$ 28,652	\$ 26,733	\$ 1,919	7%

The increase in interest income of \$1.9 million or 7% was primarily driven by an increase in interest earned on our money market funds and short-term marketable securities primarily due to an increase in the average balance on hand.

### Other Expense, net

(in thousands)	Year Ended		Change	
	December 31, 2025	December 31, 2024	\$	%
Other income (expense), net	\$ (993)	\$ 64	\$ (1,057)	(1652%)

The decrease in other income (expense), net of \$1.1 million was primarily a result of the fluctuation of foreign currency exchange rates.

### Benefit from Income Taxes

(in thousands)	Year Ended		Change	
	December 31, 2025	December 31, 2024	\$	%
Benefit from income taxes	\$ 126,153	\$ 135,356	\$ (9,203)	(7%)

The decrease in benefit from income taxes of \$9.2 million or 7% was primarily due to an increase in effective tax rate for the year ended December 31, 2025 when compared to the effective tax rate for the year ended December 31, 2024.

### Non-GAAP Financial Measures

In addition to our results provided throughout this Annual Report on Form 10-K that are determined in accordance with GAAP, this Annual Report on Form 10-K also includes the following non-GAAP financial measures for 2025, 2024, and 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 Annual Report on Form 10-K:

### Adjusted Gross Profit

Adjusted Gross Profit is a key performance measure that our management uses to assess our operational performance, as it represents the results of revenues and direct costs, which are key components of our operations. We believe that this non-GAAP financial measure is useful to investors and other interested parties in analyzing our financial performance because it reflects the gross profitability of our operations, and excludes the costs associated with our sales and marketing, product development, general and administrative activities, depreciation and amortization, and the impact of our financing methods and income taxes.

We calculate Adjusted Gross Profit as gross loss (as defined below) adjusted to exclude amortization of intangible assets and stock-based compensation allocated to cost of revenue. Adjusted Gross Profit should be viewed as a measure of operating performance that is a supplement to, and not a substitute for, operating income or loss from operations, net earnings or loss and other GAAP measures of income (loss) or profitability. The following table presents a reconciliation of gross loss, the most directly comparable financial measure calculated in accordance with GAAP, to Adjusted Gross Profit.

(in thousands)	Year Ended		
	December 31, 2025	December 31, 2024	December 31, 2023
<b>Gross loss</b> <sup>(1)</sup>	\$ (62,573)	\$ (78,022)	\$ (95,611)
Amortization of intangible assets	133,889	133,889	133,889
Stock-based compensation	2,262	1,954	1,970
<b>Adjusted Gross Profit</b>	<b>\$ 73,578</b>	<b>\$ 57,821</b>	<b>\$ 40,248</b>

<sup>(1)</sup> Gross loss is calculated as total revenue less cost of revenue (exclusive of amortization of intangible assets), cost of development services revenue, and cost of revenue — amortization of intangible assets.

### Adjusted EBITDA

Adjusted EBITDA is a key performance measure that our management uses to assess our financial performance and is also used for internal planning and forecasting purposes. We believe that this non-GAAP financial measure is useful to investors and other interested parties in analyzing our financial performance because it provides a comparable overview of our operations across historical periods. In addition, we believe that providing Adjusted EBITDA, together with a reconciliation of net 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 (loss) or income (loss) 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 loss adjusted to exclude amortization of intangible assets, stock-based compensation, depreciation, goodwill and intangible assets impairment, restructuring, interest income, benefit from income tax expense, and legal and professional services costs related to the Acquisition and corresponding antitrust litigation, including compliance with the hold separate arrangements imposed by the European Commission, and our divestment from Illumina. We believe that the items subject to these further adjustments are not indicative of our ongoing operations due to their nature, especially considering the impact of certain items as a result of the Acquisition.

Adjusted EBITDA should be viewed as a measure of operating performance that is a supplement to, and not a substitute for, operating income or loss from operations, net earnings or loss and other U.S. GAAP measures of income (loss). Additionally, it is not intended to be a measure of free cash flow for management's discretionary use, as it does not consider certain cash requirements such as interest and tax payments. Further, our definition of Adjusted EBITDA may differ from similarly titled measures used by other companies and therefore may not be comparable among companies. The following table presents a reconciliation of net loss, the most directly comparable financial measure calculated in accordance with U.S. GAAP, to Adjusted EBITDA on a consolidated basis.

(in thousands)	Year Ended		
	December 31, 2025	December 31, 2024	December 31, 2023
<b>Net loss</b>	\$ (408,351)	\$ (2,027,005)	\$ (1,465,685)
Adjusted to exclude the following:			
Amortization of intangible assets <sup>(1)</sup>	138,334	138,333	138,333
Stock-based compensation <sup>(2)</sup>	58,283	86,084	97,235
Depreciation	18,010	19,723	20,364
Goodwill and intangible assets impairment <sup>(3)</sup>	28,000	1,420,936	718,466
Restructuring <sup>(4)</sup>	(34)	18,313	—
Interest income	(28,652)	(26,733)	(7,954)
Benefit from income tax expense	(126,153)	(135,356)	(41,951)
Illumina/GRAIL merger & divestiture legal and professional services costs <sup>(5)</sup>	—	22,158	17,320
<b>Adjusted EBITDA</b>	<b>\$ (320,563)</b>	<b>\$ (483,547)</b>	<b>\$ (523,872)</b>

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

<sup>(2)</sup> Represents all stock-based compensation recognized on our standalone financial statements for the periods presented.

<sup>(3)</sup> Reflects impairment of goodwill and intangible assets recognized as a result of the Acquisition.

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

<sup>(5)</sup> Represents legal and professional services costs associated with the Acquisition and corresponding antitrust litigation, including compliance with the hold separate arrangements imposed by the European Commission, and legal and professional services costs associated with the divestiture.

Pursuant to the fourth amendment to the Illumina Supply Agreement, our perpetual royalty payment obligation to Illumina is suspended until December 24, 2026 or any earlier change of control, at which time royalty payments to Illumina will resume without retroactive effect. In future periods, when we are obliged to make royalty payments under the Illumina Supply Agreement, our gross loss, adjusted gross profit, net loss and Adjusted EBITDA will be impacted.

## Liquidity and Capital Resources

### *Sources of Liquidity*

From inception through the closing date of Illumina's acquisition of GRAIL, we had funded our operations primarily through the sale and issuance of redeemable convertible preferred stock and receipt of continuation payments from Illumina. Post- Acquisition until completion of the Spin-Off, we received funding on a quarterly basis directly from Illumina. While we generate revenue from screening and development services, these revenues have not been sufficient to fund all operations. On June 21, 2024, in connection with the Spin-Off, we received a cash contribution of \$932.3 million from Illumina.

In October 2025, we completed the PIPE and received aggregate net proceeds of \$311.3 million, after deducting issuance costs of \$13.7 million.

During 2025, we issued 1,169,218 shares of our common stock under the ATM program at the prevailing market prices for aggregate net proceeds of \$107.5 million, after deducting issuance costs of \$3.2 million. As of December 31, 2025, \$189.3 million worth of shares of common stock remained available for sale pursuant to the ATM program.

As of December 31, 2025, our cash and cash equivalents totaled \$249.7 million and our short-term marketable securities totaled \$654.7 million.

In October 2025, we signed the Samsung Stock Purchase Agreement providing for the purchase by the Samsung Investors of 1,570,308 shares for aggregated net proceeds of \$110.0 million, excluding any issuance costs. The Samsung Investment has not closed, and remains subject to the satisfaction of certain closing conditions set forth in the Samsung Stock Purchase Agreement, including, but not limited to the satisfaction of certain regulatory approvals or clearances, including with respect to the Committee on Foreign Investment in the United States.

We intend to use the net proceeds from these transactions to fund our commercial activities and reimbursement efforts, as well as for working capital and other general corporate purposes.

### *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 \$10.2 billion which includes cumulative charges of \$7.0 billion for impairment of goodwill and intangible assets. We expect to continue to incur operating losses over at least the next several years as we continue to invest in research and development and seek to achieve broad reimbursement of our current commercialized products. We believe that our existing cash, cash equivalents and short-term marketable securities will be sufficient to meet our working capital and capital expenditure needs into 2030, as of the date of this Annual Report on Form 10-K. 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 and pipeline product development, market acceptance of our products prior to broad reimbursement, and the timing of broad reimbursement. We are subject to typical risks associated with an early-stage commercial company and are developing the market for multi-cancer early detection. We may encounter complications with executing our business plans that may cause unforeseen expenses and adversely affect our business.

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

Illumina on June 24, 2024 in connection with the Spin-Off. We may also choose to raise funds through collaborations and licensing arrangements, in which case we may relinquish significant rights or grant licenses on terms that are not favorable to us. If we are unable to raise additional capital when desired, our business, results of operations, and financial condition would be adversely affected.

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

(in thousands)	Year Ended		Change	
	December 31, 2025	December 31, 2024	\$	%
Net cash used by operating activities	\$ (299,007)	\$ (577,156)	\$ 278,149	(48)%
Net cash used by investing activities	(85,049)	(551,011)	465,962	(85)%
Net cash provided by financing activities	423,321	1,244,300	(820,979)	(66)%
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(147)	(62)	(85)	137 %
<b>Net increase in cash, cash equivalents, and restricted cash</b>	<b>\$ 39,118</b>	<b>\$ 116,071</b>	<b>\$ (76,953)</b>	<b>(66)%</b>

Generally, our net cash provided by financing activities is used to fund our day to day operating activities. First quarter operating cash requirements are generally higher due to payment in the first quarter of our annual bonuses accrued during the prior year. During 2025 and 2024, cash paid for annual bonuses accrued during the prior year was \$24.2 million and \$25.9 million. As of December 31, 2025, \$22.8 million is accrued related to annual bonuses that will be paid in the first quarter of 2026.

#### ***Net Cash Used by Operating Activities***

The decrease in net cash used by operating activities was primarily driven by an improvement in the net loss, adjusted for non-cash changes of \$241.5 million and positive working capital changes of \$36.7 million, primarily due to an increase in revenue collections, a decrease in operating expenses primarily driven by a reduction in workforce related to the Restructuring Plan, a decrease in clinical studies driven by completion of enrollment in our PATHFINDER 2 study and completion of final study visits in our NHS-Galleri Trial and a decrease in purchases of laboratory supplies driven by the completion of the development and validation of our automated platform at the end of 2024 and lower clinical studies sample processing. In addition, prior to the Spin-Off, our stock based compensation was settled in cash and subsequent to the Spin-Off settled in shares.

#### ***Net Cash Used by Investing Activities***

The decrease in net cash used by investing activities was primarily related to proceeds from maturities of marketable securities, net of purchases of marketable securities.

#### ***Net Cash Provided by Financing Activities***

The decrease in net cash provided by financing activities was primarily related to the funding received from Illumina in 2024 prior to the Spin-off of \$1.2 billion, partially offset by net proceeds from equity offerings of \$418.8 million.

#### **Off-Balance Sheet Arrangements**

In accordance with our lease agreements, we provided standby letters of credit totaling \$7.0 million in lieu of a security deposit. These letters of credit remain effective through March 1, 2028 and January 28, 2038.

Except for the letters of credit mentioned above, 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, 2025:

### ***Leases***

We act as lessee in our lease agreements, which include operating leases for our corporate office, laboratory space and laboratory and office equipment. As of December 31, 2025, we had minimum operating lease payments of \$70.8 million, of which \$13.6 million is payable in 2026. These minimum lease payments exclude future lease payments associated with our Sunnyvale, California lease of \$61.7 million. The Sunnyvale, California lease will commence on October 1, 2026 and we expect the lease commencement date for accounting purposes to be in the first half of 2026. Refer to *Note 9 — Leases* in item 8 in this Annual Report on Form 10K for more details on the Sunnyvale, California lease.

### ***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 and laboratory supplies in the normal course of business. As of December 31, 2025, we had non-cancelable purchase obligations of \$52.8 million, with \$25.0 million payable within twelve months of December 31, 2025.

### ***Minimum Royalties***

Minimum royalty payments 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, 2025, we had minimum royalty commitments of \$5.7 million, with \$1.0 million payable within twelve months of December 31, 2025.

## **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 Annual Report on Form 10-K, 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.

### **Screening Revenue**

Screening revenue includes cancer screening testing services provided to patients. Patients obtain tests via their healthcare systems, employers, digital health providers, payors, concierge medicine practices, or life insurance providers, or they can order the test via telemedicine (collectively referred to as our direct customers). The test price is generally based on our list price, with discounts in certain channels, or, for certain customers, such as larger, higher-volume customers or international distributors, negotiated contractual rates. 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.

### **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 in our consolidated balance sheets and within research and development 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.

### **Goodwill and Indefinite-Lived Intangible Assets Impairment**

Goodwill represented the costs in excess of the fair value of net assets of GRAIL acquired by Illumina in August 2021. Indefinite-lived intangible assets consisted 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 whenever events or changes in circumstances indicate that goodwill and indefinite-lived intangible assets may be impaired. Goodwill and indefinite-lived intangible assets are considered to be impaired when the carrying value of a reporting unit or asset exceeds its fair value. GRAIL currently has only one reporting unit; and therefore, we measure the carrying value against the fair value of the Company.

We use qualitative factors to determine whether goodwill and indefinite-lived intangible assets are more likely than not impaired and whether a quantitative test for impairment is considered necessary. If we conclude from the qualitative assessment that goodwill and indefinite-lived intangible assets are more likely than not impaired, we are required to perform a quantitative assessment to determine the amount of impairment.

We are required to use judgment when applying the goodwill and indefinite-lived intangible assets impairment test. Changes in these estimates could materially affect our assessment of the fair value and goodwill and indefinite-lived intangible assets impairment. Significant estimates used in our impairment test include the determination of the weighted average cost of capital, revenue growth rates, long-term growth rates, and forecasted profitability of our business.

The estimates and assumptions used in our assessment of indefinite-lived intangible assets represent a Level 3 measurement because they are supported by little or no market activity and reflect our own assumptions in measuring fair value.

We fully impaired goodwill as of December 31, 2024, resulting in no remaining carrying value. In addition, we fully impaired our IPR&D assets during 2025, resulting in no remaining carrying value.

### **Income Taxes**

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

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

We recognize the impact of a tax position in our consolidated financial statements only if that position is more likely than not of being sustained upon examination by taxing authorities, based on the technical merits of the position. Due to the complexity of some of the uncertainties, the ultimate resolution may result in payments that are materially different from our current estimate of the tax liability. These differences, as well as any interest and penalties, will be reflected in the provision for income taxes in the period in which they are determined.

### **JOBS Act**

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

We will remain an emerging growth company ("EGC") 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 and are not smaller reporting company), 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. We expect to cease to be an EGC effective December 31, 2026.

### **Recent Accounting Pronouncements**

See *Note 2 — Summary Of Significant Accounting Policies* in Item 8. Financial Statements of this Annual Report on Form 10-K for details of recent accounting pronouncements.

## **Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

### ***Interest Rate Sensitivity***

We are exposed to market risk related to changes in interest rates related primarily to our cash, cash equivalents and marketable securities. We had cash and cash equivalents of \$249.7 million as of December 31, 2025, which consisted primarily of bank deposits, money market funds and U.S. government treasury bills with an original maturity of three months or less. As of December 31, 2025, we had short-term marketable securities of \$654.7 million. Our marketable securities are held in U.S. government treasury bills. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of the interest rates in the United States. The primary objective of our investment activities is to preserve capital to fund our operations. We do not enter into investments for trading or speculative purposes.

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

**Item 8. Financial Statements and Supplementary Data**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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## Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of GRAIL, Inc.

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of GRAIL, Inc. (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations, comprehensive loss, stockholders'/member's equity and cash flows for each of the three years in the period ended December 31, 2025, and the related notes (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 Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

### Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company'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 Company 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. 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 Mateo, California

March 12, 2026

**GRAIL, Inc.**  
**CONSOLIDATED BALANCE SHEETS**  
(Amounts in thousands, except share and per share data)

	As of December 31,	
	2025	2024
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 249,727	\$ 214,234
Short-term marketable securities	654,703	549,236
Accounts receivable, net <sup>(1)</sup>	18,295	20,312
Supplies <sup>(2)</sup>	16,017	18,632
Prepaid expenses and other current assets <sup>(3)</sup>	15,107	17,447
Total current assets	953,849	819,861
Property and equipment, net <sup>(4)</sup>	51,813	69,061
Operating lease right-of-use assets	52,070	66,373
Restricted cash	6,974	3,349
Intangible assets, net	1,850,556	2,016,890
Other non-current assets	6,753	7,773
<b>Total assets</b>	<b>\$ 2,922,015</b>	<b>\$ 2,983,307</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,083	\$ 4,844
Accrued liabilities <sup>(5)</sup>	63,945	57,241
Operating lease liabilities, current portion	11,715	13,260
Other current liabilities	1,927	1,580
Total current liabilities	79,670	76,925
Operating lease liabilities, net of current portion	43,148	54,881
Deferred tax liability, net	218,583	345,860
Other non-current liabilities	2,752	2,236
<b>Total liabilities</b>	<b>344,153</b>	<b>479,902</b>
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, par value of \$0.001 per share; 50,000,000 shares authorized, no shares issued and outstanding as of December 31, 2025 and December 31, 2024	—	—
Common stock \$0.001 par value per share, 1,500,000,000 shares authorized, 40,331,360 and 33,893,409 shares issued and outstanding as of December 31, 2025 and December 31, 2024.	40	34
Additional paid-in capital	12,786,848	12,305,250
Accumulated other comprehensive income	2,655	1,451
Accumulated deficit	(10,211,681)	(9,803,330)
Total stockholders' equity	2,577,862	2,503,405
<b>Total liabilities and stockholders' equity</b>	<b>\$ 2,922,015</b>	<b>\$ 2,983,307</b>

<sup>(1)</sup> Includes related party accounts receivable, net of nil and \$65, respectively.

<sup>(2)</sup> Includes related party supplies of nil and \$3,130, respectively.

<sup>(3)</sup> Includes related party prepaid expenses and other current assets of nil and \$77, respectively.

<sup>(4)</sup> Includes related party property and equipment, net of nil and \$2,227, respectively.

<sup>(5)</sup> Includes related party accrued liabilities of nil and \$104, respectively.

See accompanying notes to consolidated financial statements.

**GRAIL, Inc.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(Amounts in thousands, except per share data)

	Year Ended		
	December 31, 2025	December 31, 2024	December 31, 2023
<b>Revenue</b>			
Screening revenue <sup>(1)</sup>	\$ 138,601	\$ 108,627	\$ 74,999
Development services revenue	8,571	16,968	18,106
Total revenue	147,172	125,595	93,105
<b>Costs and operating expenses</b>			
Cost of screening revenue (exclusive of amortization of intangible assets) <sup>(2)</sup>	73,251	63,284	47,966
Cost of development services revenue <sup>(3)</sup>	2,605	6,444	6,861
Cost of revenue — amortization of intangible assets	133,889	133,889	133,889
Research and development <sup>(4)</sup>	195,794	322,380	338,745
Sales and marketing	116,693	153,958	162,292
General and administrative <sup>(5)</sup>	159,103	213,862	200,268
Goodwill and intangible assets impairment	28,000	1,420,936	718,466
Total costs and operating expenses	709,335	2,314,753	1,608,487
<b>Loss from operations</b>	(562,163)	(2,189,158)	(1,515,382)
<b>Other income</b>			
Interest income	28,652	26,733	7,954
Other income (expense), net	(993)	64	(208)
Total other income, net	27,659	26,797	7,746
Loss before income taxes	(534,504)	(2,162,361)	(1,507,636)
Benefit from income taxes	126,153	135,356	41,951
<b>Net loss</b>	<b>\$ (408,351)</b>	<b>\$ (2,027,005)</b>	<b>\$ (1,465,685)</b>
Net loss per share — Basic and Diluted	\$ (11.11)	\$ (63.54)	\$ (47.21)
Weighted-average shares of common stock used in computing net loss per share:	36,753,751	31,901,259	31,049,148

<sup>(1)</sup> Includes related party screening revenue of \$208, \$460 and \$652, respectively.

<sup>(2)</sup> Includes related party cost of screening revenue of \$4,617, \$13,091 and \$8,532, respectively.

<sup>(3)</sup> Includes related party cost of development services revenue of \$275, \$637 and \$238, respectively.

<sup>(4)</sup> Includes related party research and development expenses of \$3,306, \$18,843 and \$19,508, respectively.

<sup>(5)</sup> Includes related party general and administrative expenses of nil, \$104 and \$206, respectively.

See accompanying notes to consolidated financial statements.

**GRAIL, Inc.**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
**(Amounts in thousands)**

(in thousands)	Year Ended		
	December 31, 2025	December 31, 2024	December 31, 2023
<b>Net loss</b>	\$ (408,351)	\$ (2,027,005)	\$ (1,465,685)
Other comprehensive income:			
Net unrealized gain on marketable securities, net of tax	110	266	—
Foreign currency translation adjustment	1,094	119	172
<b>Comprehensive loss</b>	<u>\$ (407,147)</u>	<u>\$ (2,026,620)</u>	<u>\$ (1,465,513)</u>

See accompanying notes to consolidated financial statements.

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

	Common Stock		Member's Equity	Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders'/Member's Equity
	Shares	Amount					
<b>Balance as of January 1, 2023</b>	—	\$ —	\$ 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
<b>Balance as of December 31, 2023</b>	—	—	11,421,446	—	1,066	(7,776,325)	3,646,187
Net loss	—	—	—	—	—	(2,027,005)	(2,027,005)
Stock-based compensation expense	—	—	326	31,607	—	—	31,933
Other comprehensive income	—	—	—	—	385	—	385
Contribution from member, net	—	—	312,000	—	—	—	312,000
Recognition of deferred tax liability in connection with the Spin-Off*	—	—	(447,190)	—	—	—	(447,190)
Reclassification of incentive plan liabilities to additional paid-in capital	—	—	—	54,795	—	—	54,795
Disposal funding received in connection with the Spin-Off*	—	—	932,300	—	—	—	932,300
Issuance of common stock in connection with the Spin-Off and reclassification of contribution from member, net*	31,049,148	31	(12,218,882)	12,218,851	—	—	—
Vesting of restricted stock units	2,844,261	3	—	(3)	—	—	—
<b>Balance as of December 31, 2024</b>	33,893,409	34	—	12,305,250	1,451	(9,803,330)	2,503,405
Net loss	—	—	—	—	—	(408,351)	(408,351)
Stock-based compensation expense	—	—	—	58,283	—	—	58,283
Other comprehensive income	—	—	—	—	1,204	—	1,204
Vesting of restricted stock units	2,491,212	2	—	(2)	—	—	—
Issuance of common stock under ESPP	136,551	—	—	4,525	—	—	4,525
Issuance of common stock and pre-funded warrants in connection with the PIPE, net of issuance costs	2,640,970	3	—	311,316	—	—	311,319
Issuance of common stock in connection with the ATM program, net of issuance costs	1,169,218	1	—	107,476	—	—	107,477
<b>Balance as of December 31, 2025</b>	40,331,360	\$ 40	\$ —	\$ 12,786,848	\$ 2,655	\$ (10,211,681)	\$ 2,577,862

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

See accompanying notes to consolidated financial statements.

**GRAIL, Inc.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(Amounts in thousands)

	Year Ended		
	December 31, 2025	December 31, 2024	December 31, 2023
Cash flows from operating activities			
<b>Net loss</b>	\$ (408,351)	\$ (2,027,005)	\$ (1,465,685)
Adjustments to reconcile net loss to net cash used by operating activities:			
Amortization of intangibles assets	138,334	138,333	138,333
Depreciation	18,010	19,723	20,364
Stock-based compensation expense	58,283	86,084	97,235
Deferred income taxes	(126,153)	(134,251)	(38,153)
Amortization of discount on marketable securities	(21,217)	(3,167)	—
Goodwill and intangible assets impairment	28,000	1,420,936	718,466
Credit loss expense	332	—	—
Cash payment for equity awards	—	(53,807)	(76,910)
Other	1,347	276	2,829
Changes in operating assets and liabilities:			
Accounts receivable <sup>(1)</sup>	1,685	(3,370)	(1,383)
Supplies <sup>(2)</sup>	2,615	3,073	(1,940)
Operating lease right-of-use assets and liabilities, net	1,025	1,747	6,712
Prepaid expenses and other assets <sup>(3)</sup>	3,360	1,823	(908)
Accounts payable <sup>(4)</sup>	(2,733)	(14,635)	2,889
Accrued and other liabilities <sup>(5)</sup>	6,456	(12,916)	2,351
<b>Net cash used by operating activities</b>	<u>(299,007)</u>	<u>(577,156)</u>	<u>(595,800)</u>
Cash flows from investing activities			
Purchases of property and equipment <sup>(6)</sup>	(909)	(5,208)	(12,887)
Purchases of marketable securities	(1,308,340)	(545,803)	—
Proceeds from maturities of marketable securities	1,224,200	—	—
<b>Net cash used in investing activities</b>	<u>(85,049)</u>	<u>(551,011)</u>	<u>(12,887)</u>
Cash flows from financing activities			
Proceeds from issuance of common stock and pre-funded warrants in connection with the PIPE, net of issuance costs	311,319	—	—
Proceeds from issuance of common stock in connection with the ATM program, net of issuance costs	107,477	—	—
Issuance of common stock under ESPP	4,525	—	—
Cash funding received from Illumina	—	1,244,300	464,000
Other	—	—	(234)
<b>Net cash provided by financing activities</b>	<u>423,321</u>	<u>1,244,300</u>	<u>463,766</u>
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(147)	(62)	305
Net increase (decrease) in cash, cash equivalents, and restricted cash	39,118	116,071	(144,616)
Cash, cash equivalents and restricted cash — beginning of period	217,583	101,512	246,128
<b>Cash, cash equivalents and restricted cash — end of period</b>	<u>256,701</u>	<u>217,583</u>	<u>101,512</u>
Represented by:			
Cash and cash equivalents	249,727	214,234	97,287
Restricted cash	6,974	3,349	4,225
<b>Total</b>	<u>\$ 256,701</u>	<u>\$ 217,583</u>	<u>\$ 101,512</u>
<b>Supplemental cash flow information:</b>			
Property and equipment included in accounts payable and accrued liabilities	\$ (42)	\$ —	\$ (1,326)
Operating cash flows from operating leases, net	\$ (17,174)	\$ (19,272)	\$ (18,733)

<sup>(1)</sup> Includes changes in related party accounts receivable of \$(65), \$15 and \$133, respectively.

<sup>(2)</sup> Includes changes in related party supplies of \$(3,130), \$2,725 and \$(871), respectively.

<sup>(3)</sup> Includes changes in related party prepaid and other current assets of \$(77), \$(36) and \$27, respectively.

<sup>(4)</sup> Includes changes in related party accounts payable of nil, \$(168) and \$(2,965), respectively.

<sup>(5)</sup> Includes changes in related party accrued liabilities of \$104, \$9 and \$91, respectively.

<sup>(6)</sup> Includes related party purchases of property and equipment of \$(591), nil and \$(2,644), respectively.

See accompanying notes to Consolidated financial statements.

**GRAIL, Inc.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 1. ORGANIZATION AND DESCRIPTION OF BUSINESS**

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

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

***Separation from Illumina***

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

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

- Separation and Distribution Agreement — governed the terms and conditions of the Spin-Off and sets forth aspects of the Company’s and Illumina’s relationship following the Spin-Off. See *Note 11 — Legal And Regulatory Proceedings* for more information regarding the contingencies related to this agreement.
- Tax Matters Agreement — governs the respective rights, responsibilities and obligations of Illumina and the Company after the Spin-Off with respect to all tax matters and includes restrictions to preserve the tax-free status of the Distribution. See *Note 14 — Taxes* and *Note 11 — Legal And Regulatory Proceedings* regarding income taxes and the contingencies related to this agreement.
- Employee Matters Agreement — addresses employment, compensation, and benefits matters, including the allocation and treatment of assets and liabilities relating to employees and compensation and benefits plans and programs in which GRAIL employees participate, as well as the treatment of cash-based incentive awards in connection with the Spin-Off. See *Note 8 — Stock-Based Compensation* for further details regarding treatment of equity awards.
- Stockholder and Registration Rights Agreement — governs the respective rights, responsibilities and obligations of Illumina and the Company after the Spin-Off with respect to Illumina’s continuing ownership of GRAIL common stock.
- Supply and Commercialization Agreement Amendment — amends the Company’s supply and commercialization agreement with Illumina, which governs the ongoing supply and commercial relationship, including licensing, royalty payments and intellectual property between GRAIL and Illumina. See *Note 16 — Related Party Transactions* for more information regarding the royalty arrangements with Illumina.

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Illumina provided the Company with disposal funding (the “Disposal Funding”) in the amount of \$932.3 million in accordance with the Separation and Distribution Agreement, which was subject to a clawback feature that lapsed on September 24, 2025. See *Note 11 — Legal And Regulatory Proceedings — Contingencies* for 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 its net loss and to become profitable and operate profitably, to manage the Company’s negative cash flows from operations and to generate positive cash flows from operations, and the Company’s ability to obtain financing to support working capital requirements. The Company had \$249.7 million of cash and cash equivalents and \$654.7 million of short-term marketable securities as of December 31, 2025.

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

**NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

***Basis of Presentation and Principles of Consolidation***

After the Spin-Off, the Company became a standalone publicly-traded company, and the Company’s financial statements are presented on a consolidated basis.

Prior to the Spin-Off, the accompanying consolidated financial statements represented the historical operations of the standalone GRAIL legal entity and included purchase accounting adjustments and certain tax adjustments as if the Company filed a separate income tax return and was not included in Illumina’s consolidated return for the period of time the Company was owned by Illumina. All revenues and costs as well as assets and liabilities directly associated with the business activity of the Company were included in the consolidated financial statements. Certain assets and liabilities were reflected at fair value under the new basis of accounting established at the closing of the Acquisition. Management considered the need to allocate any shared costs incurred by the parent, Illumina, to the accompanying consolidated financial statements. However, since the European Commission had adopted an order requiring Illumina and GRAIL to be held and operated as distinct and separate entities, no material allocations were required.

The financial statements for all periods presented, including the historical results of the Company prior to the Spin-Off, are referred to as “Consolidated Financial Statements” and have been prepared in accordance with generally accepted accounting principles in the United States (“U.S. GAAP”) and include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances have been eliminated in consolidation. The Company’s significant accounting policies are summarized below.

***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, 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-

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classified awards, valuation of 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*

The Company is subject to credit risk from its portfolio of cash, cash equivalents and short-term marketable securities held at three accredited financial institutions. As of December 31, 2025, the Company had \$249.7 million of cash and cash equivalents, and short-term marketable securities of \$654.7 million. The Company limits its exposure to credit losses by investing in money market funds and United States ("U.S.") government treasury securities through U.S. banks with high credit ratings. The Company's cash consists of deposits held with banks that may at times exceed federally insured limits, however, its exposure to credit risk in the event of default by the financial institution is limited to the extent of amounts recorded on the consolidated balance sheets. The Company performs evaluations of the relative credit standing of these financial institutions to limit the amount of credit exposure. The Company has not experienced any losses in such accounts.

The Company has policy limits for the amount it can invest in any one type of security, except for securities issued or guaranteed by the U.S. government. The goals of the Company's investment policy, in order of priority, are as follows: minimize risk of the invested capital (including credit risk, interest rate risk and concentration risk), provide liquidity in a timely manner to accommodate operational and capital needs, and subject to the foregoing, seek to generate a reasonable return based on market conditions given these risk and liquidity guidelines. As of December 31, 2025, the Company had no off-balance sheet concentrations of credit risk. Under its investment policy, the Company limits amounts invested in such securities by credit rating, maturity, investment type and issuer, as a result, the Company is not exposed to any significant concentrations of credit risk from these financial instruments.

*Customers*

The Company is subject to credit risk related to its accounts receivable. Accounts receivable primarily arise from testing services performed in the U.S. and are primarily with biopharmaceutical companies, healthcare organizations, employers, digital health platforms, concierge medicine practices, life insurance companies, Centers for Medicare & Medicaid Services, and individuals. The Company does not require collateral. Accounts receivable are recorded net of the allowance for credit losses.

Significant customers are those that represent more than ten percent of total revenue or accounts receivable, net balances for the periods and as of each consolidated balance sheet date presented, respectively.

For the year ended December 31, 2025, no single customer accounted for 10% or more of the Company's revenue. For the years ended December 31, 2024, and December 31, 2023, one customer accounted for 11% and 14% of the Company's revenue.

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As of December 31, 2025, no single customer accounted for 10% or more of the Company's account receivable, net. As of December 31, 2024 one customer accounted for 32% of the Company's account receivable, net.

***Suppliers***

The Company is subject to a concentration risk for equipment, supplies and reagents that are available from a limited number of sources. The Company sources certain laboratory equipment, supplies and reagents used to perform testing services and research and development from single vendors. Historically, the Company has not experienced significant issues sourcing equipment and supplies needed to perform testing services.

***Cash and Cash Equivalents***

Cash and cash equivalents consist of cash on deposit with banks denominated in U.S. Dollars and British Pounds, money market funds, and all highly liquid investments with an original maturity of three months or less.

***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.

***Short-term marketable securities***

The Company classifies its investments as available-for-sale, which consist of high-grade U.S. government treasury bills and are reported at fair value. Management determines the appropriate classification of investments at the time of purchase and re-evaluates such designation as of each balance sheet date. Marketable securities that mature within twelve months from the balance sheet date are classified as short-term marketable securities and those with maturities over twelve months from the balance sheet date are classified as long-term marketable securities. Unrealized holding gains and losses are reflected as a separate component of shareholders' equity in accumulated other comprehensive gain (loss) until realized. Realized gains and losses on the sale of these securities are recognized in net income or loss.

The Company regularly evaluates its investment portfolio under the available-for-sale debt securities impairment model guidance for indications of possible impairment from credit losses or other factors. For available-for-sale debt securities in an unrealized loss position, the Company evaluates whether a current expected credit loss exists based on available information relevant to the credit rating of the security, current economic conditions and reasonable and supportable forecasts. The Company's investment portfolio is composed of low-risk, investment grade securities and thus the Company has not recorded an expected credit loss for its investment portfolio.

***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 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.

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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, prepaid expenses and other current assets, accounts payable, and accrued liabilities approximate fair value due to their short-term nature.

***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. These reserves are re-evaluated on a regular basis and adjusted, as needed. Once a receivable is deemed to be uncollectible, the receivable balance is charged against the reserve. As of December 31, 2025, and December 31, 2024, the Company had \$3.6 million and \$3.8 million of allowance for credit losses.

***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, usage forecasts and evaluation of near-term expirations.

***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:

	<b>Useful Life (in Years)</b>
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.

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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 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 of Illumina’s acquisition of GRAIL (“Closing Date”). Goodwill represented the excess of purchase price paid 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 test. The developed technology underpins both Galleri, designed as a cancer screening test for asymptomatic individuals over 50 years of age, and a diagnostic aid for cancer test 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 under development. IPR&D is considered indefinite-lived and therefore is not amortized until completed and placed into service or expensed upon abandonment of the associated research and development efforts.

Goodwill and IPR&D, which were not amortized, were reviewed for impairment at least annually or more frequently if events or circumstances indicated a potential for impairment. Goodwill and IPR&D were considered impaired if the carrying value of the reporting unit or IPR&D asset exceeded its respective fair value.

The Company performed its goodwill impairment analysis at the reporting unit level. The Company has one reporting unit, which aligns with its reporting structure and availability of discrete financial information. During the goodwill impairment review, the Company assessed qualitative factors to determine whether it was more likely than not that the fair value of the Company’s reporting unit was less than the carrying amount, including goodwill. During the indefinite-lived intangible asset impairment review, the Company assessed the qualitative factors to determine whether it was more likely than not that the fair value of the indefinite-lived intangible asset was less

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than the carrying amount. The qualitative factors considered included, but were not limited to, macroeconomic conditions, industry and market considerations, and the Company's overall financial performance. If the carrying amount of the reporting unit or intangible asset exceeded its fair value, the Company recorded an impairment loss based on the excess.

The Company fully impaired goodwill as of December 31, 2024, resulting in no remaining carrying value. In addition, the Company fully impaired its IPR&D assets as of December 31, 2025, resulting in no remaining carrying value as of that date.

#### ***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.

#### ***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 ("CODM") 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 U.S.

#### ***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 U.S.

#### ***Screening Revenue***

The Company recognizes screening revenue from the sale of cancer screening testing services for patients. Patients obtain tests via healthcare systems, employers, digital health platforms, 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 generally based on our list price, with discounts in certain channels, or, for certain customers, such as larger, higher-volume customers or international distributors, negotiated contractual rates. For certain customers, we also offer rebates. 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

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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, prepayments 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 \$1.9 million and \$1.6 million as of December 31, 2025 and December 31, 2024, all of which is considered short-term and was recorded within other current liabilities on the accompanying consolidated balance sheets.

***Cost of Screening Revenue***

Cost of screening revenue generally consists of cost of materials, labor including salaries and wages, bonus, benefits and stock-based compensation, amortization of GRAIL intangible assets, blood collection kits and shipping, phlebotomy, royalties, electronic medical records, equipment depreciation, and allocations of overhead

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expenses such as facilities and information technology costs. Per the terms of the Separation and Distribution Agreement with Illumina, the royalty arrangement with Illumina is suspended until the earlier of December 24, 2026, or any change of control of the Company, at which time a high-single digit royalty will be payable on screening revenue.

***Cost of Development Services Revenue***

Cost of development services revenue generally consists of materials and patient sample acquisition, labor including salaries and wages, bonus, benefits and stock-based compensation, royalties, equipment depreciation, and allocations of overhead expenses such as facilities and information technology costs. Per the terms of the Separation and Distribution Agreement with Illumina, the royalty arrangement with Illumina is suspended until the earlier of December 24, 2026 or any change of control of the Company, at which time a high-single digit royalty will be payable on development services revenue.

***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 in the consolidated balance sheets and within research and development 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***

Research and development 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. 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 \$15.1 million, \$17.7 million and \$21.9 million for the years ended December 31, 2025, December 31, 2024, and December 31, 2023.

***Stock-Based Compensation Expense***

The Company's stock-based compensation expense includes expenses related to restricted stock units ("RSUs"), performance stock units ("PSUs"), deferred stock units ("DSUs"), performance stock options ("PSOs"), Employee Stock Purchase Plan ("ESPP") and Cash-Based Equity Awards. Forfeitures are accounted for as incurred.

The grant date fair values of RSUs and PSUs are generally determined based on the closing market price of GRAIL's common stock on the date of the grant and in the case of DSUs resulting from deferrals of director cash fees, based on the closing market price of GRAIL's common stock on the date that such cash fees would have been otherwise paid. Generally, awards of RSUs are granted subject to service conditions and PSUs are granted subject to service and performance based-conditions, with vesting periods ranging between 18 and 48 months.

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Stock-based compensation expense is recognized based on the fair value of the award on a straight-line basis over the requisite service periods of the RSUs. The fair value of the PSUs begins to be recognized when it is probable that the performance-based condition will be met.

The fair value of shares to be issued under the ESPP, is derived using the Black-Scholes-Merton option-pricing model at the commencement of 6-month purchase periods in May and November of each year. Stock-based compensation for the ESPP is expensed using a straight-line attribution method over the offering period. Additionally, forfeitures are accounted for as incurred.

The fair value of PSOs that continue to be subject to service conditions was 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 was determined by weighting the historical and implied volatility of peer companies' common stock. The expected term was the Company's best estimates based on the vesting period and contractual term. Given that cash dividends were never declared or paid on the Illumina nor GRAIL common stock, the expected dividend yield is determined to be 0%. The risk-free interest rate was based upon U.S. Treasury securities with remaining terms similar to the expected term of the stock-based awards. The fair value of the PSOs begins to be recognized when it is probable that the performance-based condition will be met.

A cash-based equity incentive award (the "Cash-Based Equity Award") program was adopted following Illumina's acquisition of GRAIL in 2021 to provide GRAIL employees with dollar-denominated long-term incentive awards that were indexed to the value of GRAIL. In connection with the Spin-Off, in accordance with the Employee Matters Agreement, the Cash-Based Equity Awards, which were cash-settled, liability-classified awards, were modified to become RSUs that will be settled in shares of the Company's common stock upon vesting (the "Award Modification"). Unvested PSOs that were previously held by certain GRAIL employees to purchase Illumina common stock were converted to options to purchase GRAIL common stock in connection with the Spin-Off.

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

There were no Cash-Based Equity Awards outstanding as of December 31, 2024. See *Note 8 — Stock-Based Compensation* for further details.

#### **Deferred Offering Costs**

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After the consummation of an equity financing, these costs are recorded as a reduction of additional paid-in capital. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations.

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**Pre-funded Warrants**

Pre-funded warrants are classified as a component of stockholders' equity within additional paid-in capital and are recorded at the issuance date. The pre-funded warrants are equity classified because they (i) are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, (ii) are immediately exercisable, (iii) do not embody an obligation for the Company to repurchase its shares, (iv) permit the holders to receive a fixed number of shares of common stock upon exercise, (v) are indexed to the Company's common stock and (vi) meet the equity classification criteria. In addition, such pre-funded warrants do not provide any guarantee of value or return. The value of the pre-funded warrants is known at issuance, as their sales price approximates their fair value, and net proceeds from the sale are recorded as a component of additional paid-in capital.

**Defined Contribution Plan**

The Company sponsors a defined contribution plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan") pursuant to which, eligible employees can elect to contribute eligible compensation to the 401(k) Plan, subject to certain limitations. On January 1, 2023, the 401K Plan was modified to provide for a 100% employer match of employee contributions up to a maximum of three thousand dollars per employee. For the years ended December 31, 2025 and December 31, 2024, the Company contributed \$2.6 million and \$3.9 million to match employee contributions. The Company pays the administrative costs for the 401(k) plan.

**Benefit from Income Taxes**

Income taxes are accounted for under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the future tax consequences of events that have been included in the consolidated financial statements. Deferred tax assets are recognized for deductible temporary differences and tax credit carryforwards, and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portions or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment.

We recognize the impact of a tax position in our consolidated financial statements only if that position is more likely than not of being sustained upon examination by taxing authorities, based on the technical merits of the position. Due to the complexity of some of the uncertainties, the ultimate resolution may result in payments that are materially different from our current estimate of the tax liability. These differences, as well as any interest and penalties, will be reflected in the provision for income taxes in the period in which they are determined.

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

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underlying \$447.2 million of tax attributes were adjusted through an entry of \$447.2 million to additional paid in capital.

***Net Loss Per Share***

The Company calculates basic net loss per share by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period. The weighted-average shares number of shares of common stock outstanding as of December 31, 2025 included pre-funded warrants, as the shares underlying the warrants are issuable for little cash consideration and are immediately exercisable. Diluted net loss per share is computed based on the sum of the weighted average number of common shares and potentially dilutive common shares outstanding during the period. In loss periods, basic and diluted net loss per share are identical since the effect of potentially dilutive common shares is antidilutive and therefore excluded. Potentially dilutive common shares consist of shares issuable under equity awards. Potentially dilutive common shares from equity awards are determined using the average share price for each period under the treasury stock method. In addition, proceeds from exercise of equity awards and the average amount of unrecognized compensation expense for equity awards are assumed to be used to repurchase shares.

***Restructuring Charges***

Restructuring charges consist primarily of severance, benefits, payroll taxes, and other related costs. The Company records a liability for ongoing employee termination benefits when it is probable that an employee is entitled to them and the amount of the benefits can be reasonably estimated. One-time employee termination costs are recognized when management has communicated the termination plan to employees, unless future service is required, in which case the costs are recognized ratably over the future service period. All other related costs are recognized when incurred. Restructuring charges are recognized as an operating expense within the consolidated statements of operations and are classified based on each employee's respective function.

***Foreign Currency***

The functional currency of the foreign subsidiary is the British Pound. Adjustments resulting from translating the financial statements of the United Kingdom subsidiary 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.

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**Reclassification**

Certain amounts within the segment disclosure in the footnote to the consolidated financial statements for the respective periods ended December 31, 2024 and December 31, 2023 have been conformed to the current period presentation.

**Recent Accounting Pronouncements**

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

*Recently Adopted Accounting Pronouncements*

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. This update improves income tax disclosure requirements, primarily through enhanced transparency and decision usefulness of disclosures. The Company adopted the standard on its effective date in 2025, on a retroactive basis, and has included the required disclosures in *Note 14 — Taxes*.

*Accounting Pronouncements Not Yet Adopted*

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

In May 2025, the FASB issued No. ASU 2025-04, Compensation—Stock Compensation (Topic 718) and Revenue from Contracts with Customers (Topic 606). This update address diversity in practice and improves the operability of accounting for share-based consideration granted to customers. The amendments clarify how to distinguish between service and performance conditions for vesting, require entities to estimate forfeitures for all share-based consideration payable to customers, and specifies that variable consideration guidance in ASC 606 does not apply when measuring such awards. This guidance is effective for fiscal years beginning after December 15, 2026, and interim reporting periods within those annual reporting periods, with early adoption permitted. The transition method may be modified retrospective or on a retrospective basis. The Company is currently evaluating the impact of this guidance on its consolidated financial statements and related disclosures.

In July 2025, the FASB issued ASU No. 2025-05, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets. This update provides entities with a practical expedient related to developing reasonable and supportable forecasts as part of estimating expected credit losses, in which entities may elect to assume that current conditions as of the balance sheet date do not change for the remaining life of the asset. This guidance is effective for fiscal years beginning after December 15, 2025 and interim reporting periods within those annual reporting periods. Early adoption is permitted. The Company is currently evaluating the impact of this guidance on its consolidated financial statements and related disclosures.

In September 2025, the FASB issued ASU No. 2025-06, Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software. This update removes all references to software development project stages and requires entities to start capitalizing software costs when both of the following occur: (i) management has authorized and committed to funding the software project and (ii) it is probable that the project will be completed and the software will be used to perform the function intended. This guidance is effective for fiscal years beginning after December 15, 2027 and interim

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reporting periods within those annual reporting periods. Early adoption is permitted. The transition method may be prospective, modified, or retrospective. The Company is currently evaluating the impact of this guidance on its consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU No. 2025-10 (ASC Topic 832), Accounting for Government Grants Received by Business Entities. This ASU establishes the accounting and presentation for government grants received by a business entity. This guidance is effective for fiscal years beginning after December 15, 2028 and interim reporting periods within those annual reporting periods. Early adoption is permitted. This ASU provides for adoption either on a modified prospective, modified retrospective, or retrospective basis. The Company is currently evaluating the impact of this guidance on its consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU No. 2025-11, Interim Reporting (Topic 270): Narrow-Scope Improvements. This update enhances consistency in interim reporting for all entities by clarifying interim disclosure requirements and the form and content of interim financial statements in accordance with GAAP. This guidance is effective for interim reporting periods with annual reporting periods beginning after December 15, 2027. Early adoption is permitted and must be applied either prospectively or retrospectively to any or all prior periods presented in the financial statements. The Company is currently evaluating the impact of this guidance on its consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU No. 2025-12, Codification Improvements. This update includes a series of technical amendments intended to clarify guidance, correct unintended application issues, and improve consistency and operability across various Topics within the FASB Accounting Standards Codification. This guidance is effective for fiscal years beginning after December 15, 2026 and interim reporting periods within those annual reporting periods. Early adoption is permitted. The Company is currently evaluating the impact of this update on its consolidated financial statements and related disclosures.

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**NOTE 3. REVENUE**

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

(in thousands)	Year Ended		
	December 31, 2025	December 31, 2024	December 31, 2023
<b>United States</b>			
Screening	\$ 136,760	\$ 108,536	\$ 75,000
Development Services	333	2,280	3,679
<b>International<sup>(1)</sup></b>			
Screening	1,841	91	—
Development Services	8,238	14,688	14,426
<b>Total</b>	\$ 147,172	\$ 125,595	\$ 93,105

<sup>(1)</sup> International region includes revenue earned from customers located outside of the United States.

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

(in thousands)	Year Ended		
	December 31, 2025	December 31, 2024	December 31, 2023
<b>Screening</b>			
Commercial	\$ 133,933	\$ 108,467	\$ 75,000
Government <sup>(1)</sup>	4,668	160	—
<b>Development Services</b>			
Commercial	8,571	16,968	18,105
<b>Total</b>	\$ 147,172	\$ 125,595	\$ 93,105

<sup>(1)</sup> Government screening revenue primarily consists of revenue earned as part of our REACH/Galleri-Medicare clinical study.

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**NOTE 4. GOODWILL AND INTANGIBLE ASSETS**

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

**Goodwill Impairment**

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

(in thousands)

	<b>Goodwill</b>
Balance as of January 1, 2023	\$ 1,497,402
Impairment	(608,466)
Balance as of December 31, 2023	888,936
Impairment	(888,936)
Balance as of December 31, 2024	\$ —

**2023 Goodwill Impairment**

In Q3 2023, Illumina 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 which led the Company 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 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%. The Company recognized a goodwill impairment of \$608.5 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.

**2024 Goodwill Impairment**

In Q2 2024, prior to the Spin-Off, the approval of the Spin-Off by Illumina's board of directors represented a potential indicator of impairment, which also aligned with the timing of Illumina's annual goodwill impairment test date for 2024. The assessment was performed using a market approach to determine the fair value of goodwill which utilized the valuation ranges prepared by the divestment financial advisors engaged by Illumina in connection with the Spin-Off. The valuation ranges were determined using revenue multiples from public company peers for 2024 and 2025. The implied discount rate for the goodwill impairment assessment was 51.5%. The Company recognized a goodwill impairment of \$888.9 as a result of the impairment assessment, primarily due to changes to the forecast of GRAIL's value and the method for valuing GRAIL.

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

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**Intangible Assets**

Intangible assets identified in connection with Illumina's acquisition of the Company include developed technology, trade names and IPR&D and were measured at fair value as of the Closing Date.

The following roll-forward indicates the fair values assigned to finite-lived intangible assets and the resulting amortization:

(in thousands)	As of					
	December 31, 2025			December 31, 2024		
	Gross Carrying Amount	Accumulated Amortization	Net Intangible Assets	Gross Carrying Amount	Accumulated Amortization	Net Intangible Assets
Developed Technologies	\$ 2,410,000	\$ (580,185)	\$ 1,829,815	\$ 2,410,000	\$ (446,297)	\$ 1,963,703
Trade Names	40,000	(19,259)	20,741	40,000	(14,813)	25,187
<b>Total Finite-Lived Intangible Assets</b>	<b>\$ 2,450,000</b>	<b>\$ (599,444)</b>	<b>\$ 1,850,556</b>	<b>\$ 2,450,000</b>	<b>\$ (461,110)</b>	<b>\$ 1,988,890</b>

The following roll-forward indicates the carrying value of the indefinite-lived intangible asset from the Acquisition and the impairment expenses recorded:

(in thousands)	IPR&D
Balance as of January 1, 2023	\$ 670,000
Impairment	(110,000)
Balance as of December 31, 2023	560,000
Impairment	(532,000)
Balance as of December 31, 2024	28,000
Impairment	(28,000)
Balance as of December 31, 2025	\$ —

In conjunction with the Q3 2023 goodwill impairment assessment described above, the Company also evaluated the IPR&D intangible asset 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%. 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 conjunction with Illumina's Q2 2024 goodwill impairment assessment, the IPR&D intangible asset of the GRAIL reporting unit was evaluated for potential impairment by Illumina prior to the Spin-Off. The evaluation for a potential impairment of the IPR&D intangible asset was performed by comparing its carrying value to the assessed estimated fair value, which was determined by the income approach, using a discounted cash flow model. Estimates and assumptions used in the income approach included projected cash flows and a discount rate. The discount rate selected at the time of the IPR&D intangible impairment assessment was 46.5%. Based on the impairment test performed, Illumina assessed and determined that the carrying value of GRAIL's IPR&D intangible asset exceeded its estimated fair value. As a result of push down accounting, the Company recognized an impairment of \$420.0 million primarily due to changes to revenue projections and the discount rate utilized.

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In Q2 2024, subsequent to the Spin-Off, the Company performed a portfolio review and determined to decrease investment in the development of the IPR&D asset, which impacted the amount and timing of expected future cash flows attributable to IPR&D. This determination was driven by the impact of the Company's post-Spin-Off capital structure, constitution of the Company's Board at the time of the Spin-Off as the key decision maker for the determination, and increased ability to revisit the Company's business strategy and portfolio as a standalone public company without regulatory oversight. This represented a potential impairment indicator. An impairment assessment was performed using a discounted cash flow model utilizing the updated projected cash flows and discount rate. The discount rate selected was 20.0%. Based on the impairment test performed, the Company assessed and determined that the carrying value of the IPR&D intangible asset exceeded its estimated fair value. As a result, the Company recognized an additional impairment of \$112.0 million, primarily due to a decrease in projected cash flows.

In Q2 2025, the Company identified a change in market conditions in relation to its IPR&D asset which is in development. The change is expected to impact the amount of future cash flows attributable to the technology underlying the IPR&D asset. This represented a potential impairment indicator. An impairment assessment was performed using a discounted cash flow model utilizing the updated projected cash flows and discount rate. The discount rate selected was 21.0%. 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 \$28.0 million, resulting in the write off of the entire carrying value of the IPR&D asset.

The estimates and assumptions updated in each of the evaluations described above 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 Goodwill and IPR&D intangible assets.

During 2024, the Company performed a recoverability test of its finite-lived intangible assets, and no impairment was identified. In 2025, the Company determined that no triggering events occurred that would require performing a recoverability test, and accordingly, no impairment charge was recorded. See Note 17, Subsequent Events, for information regarding a possible impairment indicator related to the Company's finite-lived intangible assets identified during the three months ending March 31, 2026.

Amortization expense related to finite-lived intangible assets was \$138.3 million for each of the years ended December 31, 2025, December 31, 2024, and December 31, 2023.

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
2026	\$ 138,333
2027	138,333
2028	138,333
2029	138,333
2030	136,852
Thereafter	1,160,372
<b>Total</b>	<b>\$ 1,850,556</b>

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**NOTE 5. BALANCE SHEET COMPONENTS**

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

(in thousands)	As of December 31,	
	2025	2024
<b>Property and equipment, net</b>		
Laboratory equipment	\$ 54,113	\$ 53,550
Computer hardware	3,993	4,682
Furniture and fixtures	2,515	2,577
Computer software	1,072	1,072
Leasehold improvements	59,769	59,764
Construction-in-process	804	1,296
Property and equipment, gross	122,266	122,941
Less accumulated depreciation and amortization	(70,453)	(53,880)
<b>Total property and equipment, net</b>	\$ 51,813	\$ 69,061

(in thousands)	As of December 31,	
	2025	2024
<b>Accounts Receivable, net</b>		
Trade accounts receivable, gross	\$ 21,899	\$ 24,099
Allowance for credit losses	(3,604)	(3,787)
<b>Total accounts receivable, net</b>	\$ 18,295	\$ 20,312

(in thousands)	As of December 31,	
	2025	2024
<b>Accrued liabilities</b>		
Accrued compensation expenses	\$ 36,299	\$ 34,530
Accrued clinical studies and research and development expenses	15,656	13,027
Accrued legal and professional service expenses	3,650	2,966
Accrued other expenses	8,340	6,718
<b>Total accrued liabilities</b>	\$ 63,945	\$ 57,241

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**NOTE 6. FAIR VALUE MEASUREMENTS, CASH EQUIVALENTS AND MARKETABLE SECURITIES**

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

December 31, 2025				
(in thousands)	Fair Value	Level 1	Level 2	Level 3
<b>Financial Assets:</b>				
Money market funds	\$ 63,195	\$ 63,195	\$ —	\$ —
U.S. government treasury bills	184,041	184,041	—	—
Total cash equivalents	247,236	247,236	—	—
U.S. government treasury bills	654,703	654,703	—	—
Total short-term marketable securities	654,703	654,703	—	—
<b>Total</b>	<b>\$ 901,939</b>	<b>\$ 901,939</b>	<b>\$ —</b>	<b>\$ —</b>

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

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

December 31, 2025			
(in thousands)	Amortized Cost	Gross Unrealized Gains	Estimated Fair Value
Money market funds	\$ 63,195	\$ —	\$ 63,195
U.S. government treasury bills	838,368	376	838,744
<b>Total</b>	<b>\$ 901,563</b>	<b>\$ 376</b>	<b>\$ 901,939</b>

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

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

There were no marketable securities in an unrealized loss position as of December 31, 2025 and December 31, 2024. Accordingly, no credit loss impairment was recognized as of December 31, 2025 and December 31, 2024.

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**NOTE 7. COMMON STOCK*****Private Investment of Public Equity (the "PIPE")***

On October 18, 2025, the Company entered into a securities purchase agreement (the "Purchase Agreement") with certain investors for the private placement of (i) 2,640,970 shares of GRAIL's common stock at a price of \$70.05 per share and (ii) pre-funded warrants to purchase an aggregate of 1,998,573 shares of GRAIL's common stock (the "Pre-Funded Warrants") at a purchase price of \$70.049 per Pre-Funded Warrant, which represents the per share price for the common stock less the \$0.001 exercise price. The PIPE closed on October 21, 2025, at which time the Company received aggregate net proceeds of \$311.3 million, after deducting issuance costs of \$13.7 million.

All of the Pre-Funded Warrants issued in the PIPE were outstanding as of December 31, 2025.

***At the Market Equity Distribution Program (the "ATM Program")***

On November 14, 2025, the Company entered into an equity distribution agreement ("Equity Distribution Agreement"), with certain sales agents, establishing an ATM Program under which the Company may offer and sell shares of its common stock, having an aggregate offering price of \$300.0 million or up to 6,900,000 shares of common stock.

During 2025, the Company issued 1,169,218 shares of its common stock and the Company received aggregate net proceeds of \$107.5 million, after deducting issuance costs of \$3.2 million. As of December 31, 2025, \$189.3 million worth of shares of common stock remained available for sale pursuant to the ATM Program.

***Samsung Stock Purchase Agreement (the "Samsung SPA")***

On October 16, 2025, the Company entered into a stock purchase agreement (the "Samsung SPA"), by and among the Company, Samsung C&T Corporation ("Samsung C&T"), Samsung Electronics Singapore Pte. Ltd. (together with Samsung C&T, the "Samsung Investors") and Samsung Electronics Co., Ltd. ("Samsung Electronics"), providing for the issuance and sale by the Company to the Samsung Investors in a private placement of an aggregate of 1,570,308 shares of GRAIL's common stock, at a purchase price of \$70.05 per share, upon the terms and conditions set forth in the Samsung SPA, including closing conditions, for aggregate gross proceeds of approximately \$110.0 million (the "Samsung Investment").

The Company is also subject to a number of obligations described in the Samsung Stock Purchase Agreement. The Samsung Stock Purchase Agreement contains customary representations, warranties and agreements by the Company, indemnification obligations of the Company and the Samsung Investors for liabilities under the Securities Act of 1933, as amended (the "Securities Act"), and other obligations of the parties.

The Company intends to use the net proceeds from the Samsung Investment to fund its commercial activities and reimbursement efforts, as well as for working capital and other general corporate purposes.

**GRAIL, Inc.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 8. STOCK-BASED COMPENSATION**

The components of stock-based compensation expense for both equity and liability-classified awards recognized in our consolidated statements of operations was as follows:

(in thousands)	Year Ended		
	December 31, 2025	December 31, 2024	December 31, 2023
RSUs	\$ 54,564	\$ 29,774	\$ 1,127
ESPP	3,059	—	—
PSOs	660	1,514	577
Cash-based equity awards	—	54,796	95,531
Stock-based compensation expense, before taxes	58,283	86,084	97,235
Related income tax benefits	(13,708)	(20,890)	(23,455)
Stock-based compensation expense, net of taxes	<u>\$ 44,575</u>	<u>\$ 65,194</u>	<u>\$ 73,780</u>

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

(in thousands)	Year Ended		
	December 31, 2025	December 31, 2024	December 31, 2023
Cost of screening revenue (exclusive of amortization of intangible assets)	\$ 2,226	\$ 1,724	\$ 1,932
Cost of development services revenue	36	230	38
Research and development	15,986	30,701	39,792
Sales and marketing	10,871	15,310	17,506
General and administrative	29,164	38,119	37,967
Stock-based compensation expense, before taxes	58,283	86,084	97,235
Related income tax benefits	(13,708)	(20,890)	(23,455)
Stock-based compensation expense, net of taxes	<u>\$ 44,575</u>	<u>\$ 65,194</u>	<u>\$ 73,780</u>

Unamortized compensation cost and weighted average service period of all unvested equity classified awards as of December 31, 2025 was as follows:

	Unamortized Compensation Costs	Weighted Average Service Period
	<i>(in thousands)</i>	<i>(in years)</i>
RSUs and PSUs	\$ 76,895	1.5
PSOs	432	1.2
ESPP	1,719	0.4
Total unamortized compensation costs	<u>\$ 79,046</u>	

**GRAIL, Inc.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**2024 Incentive Award Plan**

The GRAIL, Inc. 2024 Incentive Award Plan (the “2024 Plan”) was adopted by the Company and approved by Illumina, in its capacity as GRAIL’s sole stockholder, in May 2024 to facilitate the grant of cash and equity incentive awards to non-employee directors, employees, and consultants of the Company and its subsidiaries and to enhance the ability of the Company and any of its subsidiaries to obtain and retain the services of these individuals following the Spin-Off. This plan authorizes the issuance of stock options, stock appreciation rights, restricted stock, restricted stock units, dividend equivalents, performance-based awards, and other stock or cash based awards. The 2024 Plan is subject to an annual increase on the first day of each calendar year ending on January 1, 2034, equal to the lesser of (i) 5% of the aggregate number of shares outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares as is determined by the GRAIL board of directors.

**2024 Deferred Compensation Plan**

The GRAIL, Inc. Deferred Compensation Plan for Directors (the “2024 Deferred Compensation Plan”) was adopted by the Company’s board of directors on July 15, 2024 to provide the Company’s non-employee directors with an opportunity to defer payment of all or a portion of their eligible compensation, consisting of cash fees and/or equity awards granted during a given year. Each director may make an irrevocable deferral election with respect to all or a portion of their eligible compensation in accordance with the terms and conditions of the 2024 Deferred Compensation Plan, deferring payment until the earlier of (i) a fixed date elected by the director (if any), (ii) the director’s separation from service, (iii) a “change in control” (as defined in the 2024 Plan) or (iv) the director’s death or permanent disability. If a director elects to defer all or a portion of their cash fees, the Company will issue a number of deferred stock units (“DSUs”) to the director equal to the portion of cash fees deferred divided by the fair market value of a share of the Company’s common stock on the date that such fees would have otherwise been paid, rounded down to the nearest whole share. If a director elects to defer their equity awards, the Company will issue a number of DSUs to the director equal to the number of shares of Company common stock underlying the deferred awards and subject to the same vesting, forfeiture and other restrictions that would have otherwise applied to such equity award absent the deferral. All DSUs will be issued under the 2024 Plan. As of December 31, 2025, three of our directors elected to defer their 2025 cash fees and two of our directors elected to defer their equity awards granted in 2025.

A summary of the Company’s shares available for grant under the 2024 Plan, was as follows:

	<b>Shares Available for Grant</b>
	<i>(in thousands)</i>
<b>Balance as of December 31, 2024</b>	<b>479,339</b>
Annual increase	1,694,670
Awarded	(2,152,456)
Forfeited	491,833
<b>Balance as of December 31, 2025</b>	<b>513,386</b>

**GRAIL, Inc.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**2024 Inducement Award Plan**

The GRAIL, Inc. 2024 Inducement Award Plan (the “2024 Inducement Plan”) was adopted by the Company’s board of directors on August 9, 2024. The 2024 Inducement Plan was adopted to enhance the ability of the Company and any of its subsidiaries to attract, retain and motivate eligible employees by providing these employees with equity ownership opportunities and/or equity-linked compensatory opportunities. The 2024 Inducement Plan is used exclusively for the grant of equity awards to prospective employees who (i) were not previously employees of the Company, or (ii) are returning to the Company following a bona fide period of non-employment, in any case, in connection with and as an inducement material to such prospective employee’s entering into employment with the Company pursuant to Nasdaq Listing Rule 5635(c)(4). The 2024 Inducement Plan authorizes the issuance of stock options, stock appreciation rights, restricted stock, restricted stock units, dividend equivalents, performance-based awards, and other stock or cash based awards. On May 14, 2025, the Company registered an additional 500,000 shares of common stock that may be issued pursuant to awards granted under the 2024 Inducement Plan. The 2024 Inducement Plan does not have a specified limit on the number of shares authorized for issuance.

**2024 Employee Stock Purchase Plan**

The GRAIL, Inc. 2024 Employee Stock Purchase Plan (the “ESPP”) was adopted by the Company and approved by Illumina, in its capacity as the Company’s sole stockholder, in May 2024. The number of shares of common stock available under the ESPP is subject to an annual increase on the first day of each calendar year ending on January 1, 2034, equal to the lesser of (i) 1% of the aggregate number of shares outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares as is determined by the Company’s board of directors.

Under the ESPP, eligible employees are offered the opportunity to purchase shares by participating in a 6-month offering period commencing in May and November of each year. Employees who participate in the ESPP may elect to have up to 15% of their eligible compensation withheld to purchase shares of the Company’s common stock. The purchase price of the Company’s common stock will be equal to 85% of the lower of (i) the fair market value of the Company’s common stock at the beginning of the applicable 6-month offering period or (ii) the fair market value of the Company’s common stock at the end of the applicable 6-month offering period. Our first offering period began in May 2025 with our first purchase date in November 2025. There were no shares issued under the ESPP during the year ended December 31, 2024.

A summary of the Company’s shares available for grant under the ESPP, was as follows:

	<b>Shares Available for Grant</b>
	<i>(in thousands)</i>
<b>Balance as of December 31, 2024</b>	414,021
Annual increase	338,934
Issued <sup>(1)</sup>	(136,551)
<b>Balance as of December 31, 2025</b>	616,404

<sup>(1)</sup> Represent \$4.5 million in cash received for the issuance of common stock under the ESPP

**GRAIL, Inc.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Equity-Classified Awards**

**Restricted Stock Units**

During the year ended December 31, 2025, the Company granted two PSU awards (the “PSU Awards”) under the 2024 Plan with vesting conditions tied to achievement of Company-specific performance and continued service.

The PSU Awards have differing vesting schedules. The first PSU Award, covering 26,000 shares, vests as to one-third of the shares subject thereto upon the achievement of a Company-specific performance condition, with the remaining two-thirds of the shares subject thereto vesting in substantially equal installments on each of the first and second anniversaries of the initial vesting date, subject to continued service through the applicable vesting date. The second PSU Award, covering 5,000 shares, vests as to 60% of the shares subject thereto upon the achievement of a Company-specific performance condition, with the remaining 40% of the shares subject thereto vesting on the first anniversary of the initial vesting date, subject to continued service through the applicable vesting date.

The PSU Awards had an aggregate grant-date fair value of \$1.6 million and expire, to the extent unvested, in May and November 2035, respectively.

As of December 31, 2025, it was not probable that the performance conditions associated with the PSU Awards will be achieved and, therefore, no stock-based compensation expense has been recognized in the consolidated financial statements. In February 2026, the performance condition of the first PSU Award was met. As a result, the Company will commence recognizing stock-based compensation expense in the consolidated financial statements for this PSU Award in Q1 2026.

A summary of the Company’s RSUs, PSUs, and DSUs, issued under the 2024 Plan and 2024 Inducement Award Plan, were as follows:

	Restricted Stock Units <sup>(1)</sup> <i>(in thousands)</i>	Weighted-Average Grant-Date Fair Value Per Share
<b>Outstanding at January 1, 2024</b>	—	\$—
Conversion	6,485	\$15.37
Awarded	2,833	\$13.07
Released	(2,844)	\$15.37
Forfeited	(951)	\$15.22
<b>Outstanding at December 31, 2024</b>	5,523	\$14.22
Awarded <sup>(1)</sup>	2,407	\$40.79
Released	(2,491)	\$15.21
Forfeited	(576)	\$22.83
<b>Outstanding at December 31, 2025</b>	4,863	\$25.84

<sup>(1)</sup> Includes 31,000 PSU awarded and 30,865 DSUs vested but unreleased related to three directors that had elected to defer their 2025 cash fees and two directors that had elected to defer release of their equity awards

The aggregate fair value of restricted stock units outstanding as of December 31, 2025 and December 31, 2024 was \$416.2 million and \$98.6 million. The fair value of all RSUs that vested during the years ended December 31, 2025, December 31, 2024, and December 31, 2023 was \$93.8 million, \$45.5 million, and \$0.5 million.

**GRAIL, Inc.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Performance Stock Options**

The Company has two PSOs outstanding. The outstanding PSOs, have contractual terms of ten years from the respective grant dates, 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.

The performance condition for one of the outstanding awards of PSOs covering 63,484 shares that has an exercise price of \$14.00 per share was met on November 1, 2024, meaning that this option now vests and becomes exercisable in thirty-six equal monthly installments on the monthly anniversaries of November 1, 2024, subject to continued service through the vesting date. As of December 31, 2025, 22,925 shares subject to this PSO were vested and exercisable.

The second outstanding award of PSOs covers 40,831 shares has an exercise price of \$12.80 per share and will commence vesting upon meeting certain performance-based conditions; achievement of this performance condition is not considered probable as of December 31, 2025. As such, there has been no expense recognized for this PSO.

PSOs activity, issued under the 2024 Plan, were as follows:

	Performance Options	Weighted-Average Exercise Price Per Share	Weighted-Average Contractual Term
	<i>(in thousands)</i>		<i>(in years)</i>
Outstanding at December 31, 2025	104	\$13.53	4.2
Vested and Exercisable at December 31, 2025	23	\$14.00	4.2

The aggregate intrinsic value of the PSOs outstanding as of December 31, 2025 and December 31, 2024 was \$7.5 million and \$0.5 million.

**Fair Value Valuation Assumptions**

The fair value of employee stock purchase rights under the ESPP have been estimated with the following assumptions using the Black-Scholes-Merton option-pricing model:

	December 31, 2025
Weighted-average assumptions:	
Expected life (in years)	0.5
Risk-free interest rate	4.0%
Expected volatility	97.4%
Expected dividend	—%
Weighted-average estimated grant date fair value per share	\$59.31

The expected term represents the term from the first day of the offering period to the purchase date. The risk-free interest rate assumption was based upon observed interest rates of Treasury bills appropriate for the expected term. For the Company's first offering, the expected stock price volatility was estimated using the average of the Company's historical volatility and the average historical volatility of comparable peer companies, as the Company had limited trading history as a public company. For the current offering and future offerings, the expected stock price volatility is estimated using the Company's historical volatility, as sufficient trading history has been established and is considered representative of expected future stock price trends. Expected dividend yield was 0% as the Company has not paid and does not anticipate paying dividends on its common stock.

**GRAIL, Inc.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Liability-classified Awards**

***Performance-Based Award***

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

***Cash-Based Equity Awards***

The Cash-Based Equity Award program was adopted following Illumina's acquisition of GRAIL in 2021 to provide GRAIL employees with dollar-denominated long-term incentive awards that increased or decreased in value based on corresponding changes in GRAIL's calculated value. GRAIL's standalone value calculation was estimated by the Company based on its analysis and input from independent valuation advisors. To estimate the value of GRAIL for the purposes of the Cash-Based Equity Awards, various assumptions were used, including long-range financial projections, as well as the discount rate and terminal growth rate. The awards generally vested in four equal installments on the first four anniversaries of the grant date, subject to continued employment through the applicable vesting date. In April 2024, Illumina's Compensation Committee and Board of Directors (as applicable) approved an adjustment of the ordinary course payouts for all outstanding Cash-Based Equity Awards providing that the Cash-Based Equity Awards would be paid based on their nominal (face) values without adjustment based on changes in equity value. Subsequent to this adjustment to the Cash-Based Equity Awards and continuing until the Award Modification, the Cash-Based Equity Awards were expensed based on such nominal (face) value in accordance with their applicable vesting schedules. The payments in respect of the Cash-Based Equity Awards between the adoption of such adjustment and the Distribution Date were paid out in cash at the applicable Cash-Based Equity Awards' nominal (face) value. Payments in respect of the Cash-Based Equity Awards before such adjustment were paid out in cash based on the adjusted value of the Cash-Based Equity Award on the applicable vesting date.

**GRAIL, Inc.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

During the second quarter of 2024, one-time Cash-Based Equity Awards were granted to GRAIL employees, including executives, for retention purposes (“2024 Transition Incentive Awards”) with a total grant date fair value of \$40.2 million. Each 2024 Transition Incentive Awards vested entirely in one year or less from its grant date, subject to the applicable holder’s continued service through the vesting date. In connection with the Spin-Off, the 2024 Transition Incentive Awards were converted into RSUs covering 2.5 million shares in accordance with the Employee Matters Agreement by dividing the aggregate award value by the volume-weighted average share price over the first four trading days following the Spin-Off. On the modification date, June 28, 2024, these 2024 Transition Incentive Awards in the amount of \$4.4 million were reclassified to Additional Paid-In Capital.

In connection with the Spin-Off, all outstanding Cash-Based Equity Awards, with the exception of the 2024 Transition Incentive Awards described above, were modified and converted into RSUs in accordance with the Employee Matters Agreement, with the number of RSUs determined by dividing the Aggregate Award Value (as discussed below) for such Cash-Based Equity Award by the volume-weighted average share price of GRAIL stock on the first four trading days following the Spin-Off. All other terms and conditions of the awards, including vesting and payment terms, were unaffected by the conversion. For each Cash-Based Equity Award, the “Aggregate Award Value” was equal to, (i) for the portion of such award originally scheduled to vest in 2024, the initial grant value of such portion, and (ii) for the remaining unvested portion of such award, the initial grant value of such portion adjusted up or down based on a percentage, with such percentage determined by (A) GRAIL’s average closing market capitalization for the four trading days immediately following the distribution date minus the aggregate equity value of GRAIL at the time the Cash-Based Equity Award was granted, as reflected in the consolidated financial statements of Illumina (the “Baseline Equity Value”), divided by (B) the Baseline Equity Value.

Upon modification, the awards became equity-classified. The value of tranches of the Cash-Based Equity Awards (exclusive of the 2024 Transition Incentive Awards described above) was reduced and, as a result, there was no incremental compensation cost. Approximately 1,300 grantees were impacted by this modification. On the modification date, June 28, 2024, the liability-classified awards were reclassified to Additional Paid-In Capital at their fair value in the amount of \$50.3 million. Due to the higher value of the 2024 tranche of the Cash-Based Equity Awards, compensation cost was recognized over the vesting period to ensure compensation cost had been recognized at least equal to the amount that was legally vested. As the result of this modification, the Cash-Based Equity Awards that were outstanding on the Distribution Date (in addition to the 2024 Transition Incentive Awards) were converted to 4.0 million RSUs that were settled in shares of the Company’s common stock. There were no Cash-Based Equity Award outstanding as of December 31, 2025.

Cash-Based Equity Award activity for the periods presented was as follows:

	Year Ended
	December 31, 2024
(in thousands)	
<b>Beginning balance</b>	\$ 292,189
Granted	66,864
Cancelled	(11,751)
Vested and paid in cash	(53,807)
Change in fair value	(9,535)
Conversion of outstanding awards to GRAIL RSUs	(283,960)
<b>Outstanding balance</b>	\$ —

**GRAIL, Inc.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 9. LEASES**

The Company has entered into operating leases for facilities utilized for commercial and research and development. Operating leases have remaining lease terms which range from less than 1 year to 8 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:

	Year Ended		
	December 31, 2025	December 31, 2024	December 31, 2023
(in thousands)			
Operating lease costs	\$ 17,767	\$ 18,577	\$ 24,357
Variable lease costs	4,061	4,666	3,676
<b>Total lease costs</b>	<b>\$ 21,828</b>	<b>\$ 23,243</b>	<b>\$ 28,033</b>

The Company's weighted average remaining lease term and weighted average discount rate for operating leases were as follows:

	As of December 31,	
	2025	2024
Weighted-average remaining lease term	6.9 years	7.3 years
Weighted average discount rate	2.6 %	2.5 %

Future undiscounted lease payments under operating leases as of December 31, 2025 were as follows:

(in thousands)	Amount
2026	\$ 13,590
2027	8,442
2028	8,232
2029	8,448
2030	8,260
Thereafter	23,871
<b>Total undiscounted lease payments</b>	<b>70,843</b>
Less: Imputed interest	(6,290)
Less: Tenant improvement allowance*	(9,690)
<b>Total operating lease liabilities</b>	<b>\$ 54,863</b>

\* Tenant improvement allowance is estimated to be received as follows: approximately \$0.3 million in 2026 and \$9.4 million thereafter.

Excluded from the lease obligation table above is a commercial lease agreement (the "Lease") entered into by and between the Company and Sunnyvale Office Acquisition, LLC, as of September 11, 2025, pursuant to which the Company agreed to lease an aggregate of approximately 75,556 square feet for a new corporate headquarters in Sunnyvale, California, which will be recognized as an operating lease upon the lease commencement date. The actual timing of lease commencement for accounting purposes, as well as the Company's obligation to begin making payments and recognizing rental and other expenses, is dependent upon when the space is made available to the Company and the Company obtains control of the underlying asset. The Company's current estimate of the total estimated undiscounted lease payments, excluding the renewal option and option to expand into additional space, for this leased office space is approximately \$61.7 million.

**GRAIL, Inc.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 10. COMMITMENTS AND CONTINGENCIES**

The future non-lease commitments over the next five years and thereafter were as follows:

	<u>As of December 31, 2025</u>
(in thousands)	<u>Purchase Commitments</u>
2026	\$ 25,023
2027	23,927
2028	3,633
2029	258
<b>Total</b>	<b>\$ 52,841</b>

*Licensing Agreements*

The Company has entered into licensing agreements related to its research efforts. These agreements contain minimum annual royalty payments which are cancellable at the Company's discretion, therefore they are not reflected in the above chart. Additionally, some of these licensing agreements 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, and laboratory supplies 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. Two such milestones were achieved within 2024 and \$1.0 million paid as of December 31, 2024. The remaining milestones are based on net sales over a minimum threshold in specified geographic regions, which were not probable of achievement as of December 31, 2025.

*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 material 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.

**GRAIL, Inc.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**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.

***Federal Securities Class Actions***

On November 11, 2023, the first of three securities class action complaints was filed against Illumina and certain of its current and former executive officers in the United States District Court for the Southern District of California. The first-filed case is captioned Kangas v. Illumina, Inc. et al., the second-filed case is captioned Roy v. Illumina, Inc. et al., and the third-filed case is captioned Louisiana Sheriffs' Pension & Relief Fund v. Illumina, Inc. et al. (collectively, the "Actions"). The complaints generally allege, among other things, that defendants made materially false and misleading statements and omitted material facts relating to Illumina's acquisition of Grail. The complaints seek unspecified damages, interest, fees, and costs. On January 9, 2024, four movants filed motions to consolidate the Actions and to appoint a lead plaintiff ("Lead Plaintiff Motions"). On April 11, 2024, the Court issued an order consolidating the Actions into a single action (captioned in re Illumina, Inc. Securities Litigation No. 23-cv-2082-LL-MMP), and appointed Universal-Investment-Gesellschaft mbH, UI BVK Kapitalverwaltungsgesellschaft mbH, and ACATIS Investment Kapitalverwaltungsgesellschaft mbH as lead plaintiffs. (the "Lead Plaintiffs"). On June 21, 2024, the Lead Plaintiffs filed a consolidated amended complaint. The amended complaint alleges that GRAIL, in addition to Illumina, and certain of their respective current and former directors and others violated sections 10(b) and 20(a) of the Securities Exchange Act and SEC Rule 10b-5 in connection with Illumina's acquisition of GRAIL and disclosures concerning the same. GRAIL has an indemnification obligation for certain current and former directors and officers involved in the matter pursuant to indemnification agreements entered into by these individuals and GRAIL. On September 13, 2024 the plaintiffs further amended the complaint. On November 12, 2024, the Company moved to dismiss Lead Plaintiffs' second amended complaint for failure to state a claim under Sections 10(b) and 20(a) of the Exchange Act. Lead Plaintiffs filed their opposition to the motion to dismiss on December 20, 2024, and the Company filed its reply in support of its motion to dismiss on February 3, 2025. On September 26, 2025, the court granted the motion to dismiss for failure to state a claim with leave to amend, and ordered the plaintiffs to file an amended complaint, if any, by October 27, 2025. On October 27, 2025, the Lead Plaintiffs filed their third amended complaint. On December 12, 2025, the Company filed a motion to dismiss Lead Plaintiffs' third amended complaint. In light of the fact that the lawsuits are in an early stage, the Company cannot predict the ultimate outcome of the suits.

***Other Legal Matters***

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

The Company is involved in various lawsuits and claims arising in the ordinary course of business, including actions with respect to employment matters. In connection with these matters, the Company assesses, on a regular basis, the probability and range of possible loss based on the developments in these matters. A liability is recorded in the consolidated financial statements if it is believed to be probable that a loss has been incurred and the amount of the loss can be reasonably estimated. Since litigation is inherently unpredictable and unfavorable resolutions could occur, assessing contingencies is highly subjective and requires judgments about future events. The Company regularly reviews outstanding legal matters to determine the adequacy of the liabilities accrued and related disclosures. The Company may change its estimates if its assessment of the various factors changes and the amount of ultimate loss may differ from estimates, resulting in a material effect on the Company's business,

**GRAIL, Inc.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

financial condition, results of operations, and/or cash flows. As of December 31, 2025, the Company is unable to estimate a range of possible loss in excess of the amounts accrued.

**Contingencies**

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

In connection with the Spin-Off, Illumina provided the Company with disposal funding in the amount of \$932.3 million in accordance with the Separation and Distribution Agreement, which was subject to a clawback feature that lapsed on September 24, 2025.

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

**NOTE 12. RESTRUCTURING**

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

	Year Ended December 31, 2025		
	Severance and related benefit costs	Other Costs	Total
(in thousands)			
Research and development	\$ (47)	\$ 111	\$ 64
Sales and marketing	(83)	—	(83)
General and administrative	(31)	16	(15)
Total	<u>\$ (161)</u>	<u>\$ 127</u>	<u>\$ (34)</u>

	Year Ended December 31, 2024		
	Severance and related benefit costs	Other Costs	Total
(in thousands)			
Research and development	\$ 8,783	\$ 297	\$ 9,080
Sales and marketing	4,858	—	4,858
General and administrative	3,897	478	4,375
Total	<u>\$ 17,538</u>	<u>\$ 775</u>	<u>\$ 18,313</u>

**GRAIL, Inc.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

(in thousands)	Severance and related benefit costs	Other Costs	Total
Restructuring charges	\$ 17,538	\$ 775	\$ 18,313
Cash payments made	(16,732)	(454)	(17,186)
Non-cash charges	—	(99)	(99)
Amount recorded in accrued liabilities as of December 31, 2024	806	222	1,028
Restructuring charges	(161)	127	(34)
Cash payments made	(645)	(349)	(994)
Amount recorded in accrued liabilities as of December 31, 2025	\$ —	\$ —	\$ —

**NOTE 13. NET LOSS PER SHARE**

Prior to the Spin-Off, the Company had no common shares issued and outstanding. In connection with the Spin-Off, on June 24, 2024, there were 31.0 million shares of GRAIL common stock distributed to Illumina stockholders. This share amount is utilized for the calculation of basic and diluted earnings per share for all periods presented prior to the Spin-Off. For the year ended December 31, 2023 these shares are treated as issued and outstanding for purposes of calculating historical earnings per share.

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

(in thousands, except share and per share data)	Year Ended		
	December 31, 2025	December 31, 2024	December 31, 2023
<b>Numerator</b>			
Net loss	\$ (408,351)	\$ (2,027,005)	\$ (1,465,685)
<b>Denominator</b>			
Weighted average shares of common stock—basic and diluted	36,753,751	31,901,259	31,049,148
<b>Net loss per share</b>			
Basic	\$ (11.11)	\$ (63.54)	\$ (47.21)
Diluted	\$ (11.11)	\$ (63.54)	\$ (47.21)

Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share, as the inclusion of all potential shares of common stock outstanding would have been anti-dilutive.

The following common stock equivalents were excluded from the calculation of diluted net loss per share for the periods presented as they had an anti-dilutive effect:

	Year Ended		
	December 31, 2025	December 31, 2024	December 31, 2023
Unvested restricted stock units	4,831,956	5,523,029	6,564,282
Unvested performance options	104,315	104,315	104,315
Unvested performance stock units	31,000	—	—
Shares issuable under ESPP	74,453	—	—
Total	5,041,724	5,627,344	6,668,597

**GRAIL, Inc.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 14. TAXES**

Loss before income taxes summarized by region was as follows:

	Year Ended		
	December 31, 2025	December 31, 2024	December 31, 2023
(in thousands)			
United States	\$ (540,192)	\$ (2,165,006)	\$ (1,509,885)
Foreign	5,688	2,645	2,249
<b>Loss before benefit from income taxes</b>	<b>\$ (534,504)</b>	<b>\$ (2,162,361)</b>	<b>\$ (1,507,636)</b>

The benefit from income taxes consisted of the following:

	Year Ended		
	December 31, 2025	December 31, 2024	December 31, 2023
(in thousands)			
<b>Current taxes:</b>			
Federal	\$ 1,125	\$ —	\$ —
Foreign	—	(1,628)	(3,798)
<b>Total current income tax expense/(benefit)</b>	<b>\$ 1,125</b>	<b>\$ (1,628)</b>	<b>\$ (3,798)</b>
<b>Deferred taxes:</b>			
Federal	\$ (111,750)	\$ (92,184)	\$ (22,019)
State	(15,528)	(41,544)	(16,134)
<b>Total deferred income tax benefit</b>	<b>(127,278)</b>	<b>(133,728)</b>	<b>(38,153)</b>
<b>Benefit from income taxes</b>	<b>\$ (126,153)</b>	<b>\$ (135,356)</b>	<b>\$ (41,951)</b>

The benefit from income taxes reconciles to the amount computed by applying the federal statutory rate to loss before income taxes as follows:

	Year Ended					
	December 31, 2025		December 31, 2024		December 31, 2023	
(in thousands)						
Tax at federal statutory rate	\$ (112,246)	21.0 %	\$ (454,122)	21.0 %	\$ (316,603)	21.0 %
State, net of federal benefit <sup>(1)</sup>	(11,190)	2.1 %	(29,235)	1.4 %	(13,283)	0.9 %
<b>Tax credits</b>						
Research tax credits	(3,589)	0.7 %	(7,145)	0.3 %	(1,827)	0.1 %
Change in valuation allowance	111	— %	166,475	(7.7)%	160,664	(10.7)%
<b>Nontaxable or nondeductible items</b>						
Goodwill impairment	—	— %	186,641	(8.6)%	127,778	(8.5)%
Stock compensation	(5,920)	1.1 %	88	— %	134	— %
Other	6,681	(1.3)%	1,942	(0.1)%	1,186	— %
<b>Total tax benefit from income taxes</b>	<b>\$ (126,153)</b>	<b>23.6 %</b>	<b>\$ (135,356)</b>	<b>6.3 %</b>	<b>\$ (41,951)</b>	<b>2.8 %</b>

<sup>(1)</sup> State taxes in California, Georgia, New York, New York City, and Illinois made up the majority (greater than 50 percent) of the tax effect in this category.

**GRAIL, Inc.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

Significant components of deferred tax assets and liabilities were as follows:

(in thousands)	December 31, 2025	December 31, 2024
<b>Deferred tax assets:</b>		
Net operating losses	\$ 147,070	\$ 43,707
Tax credits	14,047	7,963
Other accruals and reserves	6,671	5,727
Stock compensation	9,992	9,320
Capitalized U.S. research and development expenses	16,497	23,088
Other amortization	53,792	57,401
Operating lease liabilities	13,689	16,539
Property & equipment	392	2,063
Other	876	1,026
<b>Total gross deferred tax assets</b>	<b>263,026</b>	<b>166,834</b>
Valuation allowance on deferred tax assets	(6,938)	(7,744)
<b>Total deferred tax assets</b>	<b>\$ 256,088</b>	<b>\$ 159,090</b>
<b>Deferred tax liabilities:</b>		
Purchased intangible amortization	\$ (461,714)	\$ (488,874)
Operating lease right-of-use assets	(12,957)	(16,076)
<b>Total deferred tax liabilities</b>	<b>(474,671)</b>	<b>(504,950)</b>
<b>Deferred tax liability, net</b>	<b>\$ (218,583)</b>	<b>\$ (345,860)</b>

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, 2025, the Company was not able to conclude it is more likely than not certain deferred tax assets will be realized. Therefore, a valuation allowance of \$6.9 million was recorded against certain federal, state, and foreign deferred tax assets.

As of December 31, 2025, the net operating loss carryforwards for federal and state tax purposes were \$567.0 million and \$424.2 million. Net operating loss carryforwards for state tax purposes will begin to expire in 2034 unless utilized prior. The federal and state tax credit carryforwards were \$13.0 million and \$6.8 million. The federal credits will begin to expire in 2044 unless utilized prior. The state credits do not expire and can be carried forward indefinitely. GRAIL's UK subsidiary had \$16.0 million of UK net operating losses that can generally be carried forward indefinitely provided that the UK 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.

**GRAIL, Inc.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

The following table summarizes the gross amount of uncertain tax positions:

(in thousands)	Year Ended		
	December 31, 2025	December 31, 2024	December 31, 2023
Balance at beginning of year	\$ 3,859	\$ 59,295	\$ 51,843
Decreases related to the Spin-Off	—	(59,295)	—
Decreases related to prior year tax positions	(46)	—	—
Increases related to current year tax positions	3,823	3,859	7,452
<b>Balance at end of year</b>	<b>\$ 7,636</b>	<b>\$ 3,859</b>	<b>\$ 59,295</b>

Included in the balance of uncertain tax positions as of December 31, 2025, December 31, 2024, and December 31, 2023 were \$7.1 million, \$3.6 million, and \$54.4 million, 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.

The following table presents the disaggregation of income taxes paid by jurisdiction:

(in thousands)	December 31, 2025
Federal	\$ —
New York	492
Massachusetts	176
South Carolina	148
New York City	139
North Carolina	80
Tennessee	73
All Other States	23
<b>Total taxes paid</b>	<b>\$ 1,131</b>

Tax years 2019 to 2025 remain subject to future examination by the major tax jurisdictions in which the Company is subject to tax.

**GRAIL, Inc.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 15. SEGMENT INFORMATION**

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

The following table is representative of the significant expense categories regularly provided to the CODM when managing the Company's single reporting segment. A reconciliation to the consolidated net loss for the years ended December 31, 2025, December 31, 2024 and December 31, 2023 is included in the table below:

(in thousands)	Year Ended		
	December 31, 2025	December 31, 2024	December 31, 2023
<b>Revenue:</b>			
Screening revenue	\$ 138,601	\$ 108,627	\$ 74,999
Development services revenue	8,571	16,968	18,106
Total revenue	147,172	125,595	93,105
<b>Costs and operating expenses:</b>			
Cost of screening revenue (exclusive of amortization of intangible assets) <sup>(1)(2)</sup>	73,251	63,284	47,966
Cost of development services revenue <sup>(1)(2)</sup>	2,605	6,444	6,861
Compensation	231,188	314,042	311,375
Depreciation and intangible assets amortization expense	149,794	153,228	148,920
Stock-based compensation	56,021	84,130	95,265
Professional services	36,821	63,443	48,994
Clinical studies	28,012	43,890	54,590
Goodwill and intangible assets impairment	28,000	1,420,936	718,466
Cloud computing and information technology	25,019	30,233	31,868
Facilities	21,666	25,983	30,276
Laboratory supplies and research collaborations	12,802	41,341	41,863
Other segment expenses <sup>(3)</sup>	44,156	67,799	72,043
Total costs and operating expenses	709,335	2,314,753	1,608,487
Loss from Operations	(562,163)	(2,189,158)	(1,515,382)
<b>Other income (expense):</b>			
Interest income	28,652	26,733	7,954
Other income (expense), net	(993)	64	(208)
Benefit from income taxes	126,153	135,356	41,951
<b>Net Loss</b>	<b>\$ (408,351)</b>	<b>\$ (2,027,005)</b>	<b>\$ (1,465,685)</b>

<sup>(1)</sup> Cost of screening revenue (exclusive of amortization of intangible assets) and cost of development services revenue include stock-based compensation expense. See Note 8 — *Stock-Based Compensation* for further details.

<sup>(2)</sup> Cost of screening revenue (exclusive of amortization of intangible assets) and cost of development services revenue include \$6.6 million, \$4.8 million and \$9.8 million of depreciation expense for the year ended December 31, 2025, December 31, 2024 and December 31, 2023.

<sup>(3)</sup> Other segment expenses include costs related to contractors and temporary labor, marketing expenses, and legal expenses.

**GRAIL, Inc.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 16. RELATED PARTY TRANSACTIONS**

***Illumina Purchases and Sales***

The Company was a subsidiary of Illumina, Inc. between August 19, 2021 to June 23, 2024. Subsequent to the Spin-Off, Illumina retained 4,502,126 shares which represented a 14.5% stake in the Company as of the Spin-Off. During the fourth quarter of 2025, Illumina sold 2,000,000 shares of the Company's common stock, reducing its ownership to 2,502,126 shares, which represented approximately 6.0% of the Company's outstanding common stock as of December 31, 2025. On February 17, 2026, Illumina filed a Schedule 13G reporting beneficial ownership of 1,302,126 shares of our common stock.

As a result of the reduction in ownership, Illumina no longer meets the definition of a related party. Accordingly, following Illumina's disposition on November 17, 2025, transactions and balances with Illumina are no longer considered related-party transactions.

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 for the periods during which Illumina qualified as a related party of the Company, as follows:

(in thousands)	As of December 31, 2024
Accounts receivable	\$ 65
Supplies	3,130
Prepaid expenses and other current assets	77
Property and equipment, net	2,227
Accrued liabilities	104

(in thousands)	Year Ended		
	December 31, 2025 <sup>(1)</sup>	December 31, 2024	December 31, 2023
Screening revenue	\$ 208	\$ 460	\$ 652
Cost of screening revenue	4,617	13,091	8,532
Cost of development services revenue	275	637	238
Operating expenses—Research and development	3,306	18,843	19,508
Operating expenses—General and administrative	—	104	206

<sup>(1)</sup> Included transactions from January 1, 2025 through November 17, 2025

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

**GRAIL, Inc.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 17. SUBSEQUENT EVENTS*****2024 Incentive Award Plan***

On January 1, 2026, in accordance with the automatic evergreen provision of the 2024 Incentive Award Plan the maximum number of shares that can be issued under the plan was increased to 12,368,055. Subsequent to December 31, 2025, the Company granted 1.7 million RSUs of Class A common stock to employees. The RSUs are subject to continued service, vest annually over a service period 4 years, and had a fair market value on the grant date of \$88.5 million.

***2024 Employee Stock Purchase Plan***

On January 1, 2026, in accordance with the automatic evergreen provision of the 2024 Employee Stock Purchase Plan the maximum number of shares that can be issued under the plan was increased to 1,156,269.

***Potential Impairment of Long-Lived Intangible Assets***

On February 19, 2026, the Company issued a press release announcing top-line results from its NHS-Galleri trial, showing that, although the primary endpoint of statistically significant Stage 3 and 4 reduction was not observed, adding Galleri to standard of care screening resulted in a substantial reduction in Stage 4 cancer diagnoses, increased Stage 1 and 2 detection of deadly cancers, and four-fold higher cancer detection rate when compared to standard of care alone. Immediately following the release of this information, the Company's market capitalization decreased materially. This decrease in market capitalization represents a possible impairment indicator that could result in an impairment of our long-lived intangible assets, which had a balance of \$1.9 billion as of December 31, 2025. As a result, the Company expects to perform an interim impairment test during the first quarter of 2026 as this is the period in which such information was available to management. The Company has not yet completed this interim impairment test as of the date of this filing. See Note 2 Summary of Significant Accounting Policies for information about how long-lived intangible assets are tested for impairment.

## **Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure**

None.

### **Item 9A. Controls and Procedures**

#### ***Limitation on Effectiveness of Controls and Procedures***

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

#### ***Evaluation of Disclosure Controls and Procedures***

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

#### ***Management's Annual Report on Internal Control over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in the Exchange Act Rules 13a-15(f). Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the framework in Internal Control Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the results of our assessment under the framework in the Internal Control—Integrated Framework (2013), our management concluded that our internal control over financial reporting was effective as of December 31, 2025. This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for “emerging growth companies”.

#### ***Changes in Internal Control over Financial Reporting***

There were no changes in our internal controls over financial reporting during the fourth quarter of December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

### **Item 9B. Other**

#### **(a) Disclosure in lieu of reporting on a Current Report on Form 8-K.**

#### **Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

On March 10, 2026, the Board of Directors appointed Joshua Ofman, M.D., MSHS, age 61, to serve as Chief Executive Officer of the Company, effective June 1, 2026 (the “Transition Effective Date”). The Board also appointed Dr. Ofman to serve as a Class III director, effective on March 12, 2026, immediately following the filing of this Annual Report on Form 10-K and a Registration Statement on Form S-8 relating to the registration of certain shares under our Employee Stock Purchase Plan and Incentive Award Plan, to hold office until the 2027 annual meeting of stockholders. We intend to nominate Dr. Ofman for reelection to the Board at the 2027 annual meeting of stockholders.

Dr. Ofman has served as the Company's President since June 2021 and previously served as the Company's Chief Medical Officer from November 2021 until June 2022, as the Company's 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. Dr. Ofman has previously served on the Board of Directors of two privately held biotechnology companies. Previously, Dr. Ofman spent more than 15 years at Amgen, where he last served in the role of Senior Vice President, Global Value, Access and Policy. Prior to that, Dr. 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. Dr. 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.

There are no arrangements or understandings between Dr. Ofman and any other persons pursuant to which Dr. Ofman was appointed as Chief Executive Officer. Dr. Ofman has no direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K, and there are no family relationships between Dr. Ofman and any director or executive officer of the Company.

The material terms of any compensatory arrangements entered into with Dr. Ofman in connection with his appointment as Chief Executive Officer will be disclosed once determined in a subsequent periodic or current report, as required.

On March 12, 2026, Robert Ragusa announced his retirement as Chief Executive Officer of the Company and as a Class III director, in each case, effective on the Transition Effective Date (June 1, 2026).

In connection with Mr. Ragusa's retirement, the Company and Mr. Ragusa entered into a Transition Agreement, dated as of March 10, 2026 (the "Transition Agreement"). A copy of the Transition Agreement is filed as Exhibit 10.15 to this Annual Report on Form 10-K and is incorporated herein by reference.

Pursuant to the Transition Agreement, Mr. Ragusa will continue to serve as our Chief Executive Officer until the Transition Effective Date and, following the Transition Effective Date, will serve as a senior executive advisor until March 12, 2027 (such period the "Transition Period"). During the Transition Period, Mr. Ragusa will assist and cooperate with the Company with respect to the transition of the position of Chief Executive Officer to Dr. Ofman.

Pursuant to the Transition Agreement, Mr. Ragusa will continue to receive the same compensation and benefits as currently in effect until the Transition Date. During the Transition Period, we will pay or provide to Mr. Ragusa: (i) an annualized base salary of \$300,000, (ii) continued participation in health and welfare benefits or comparable subsidized healthcare continuation coverage, (iii) a pro-rated bonus under the Company's Variable Compensation Plan for portion of calendar year 2026 preceding the Transition Date, subject to Mr. Ragusa's continued employment through the end of the Transition Period, execution of a release of claims, and continued compliance with restrictive covenants, and (iv) continued vesting of outstanding and unvested equity awards (without eligibility for accelerated vesting, except as described below).

If the Company terminates Mr. Ragusa's employment without Cause (as defined in the Transition Agreement) prior to March 12, 2027, subject to his execution of a release of claims and continued compliance with restrictive covenants, Mr. Ragusa will be entitled to receive: (i) continued payment of his base salary through March 12, 2027, (ii) subsidized healthcare continuation coverage through March 2027, (iii) his pro-rated bonus (if earned), and (iv) accelerated vesting solely as to the portion of his outstanding and unvested equity awards that would have vested had his employment continued through March 12, 2027.

The Transition Agreement includes a general release of claims in favor of the Company and provides that Mr. Ragusa will continue to comply with certain restrictive covenants, including confidentiality, non-disparagement, non-competition, and non-solicitation provisions contained therein.

The foregoing description of the Transition Agreement is qualified in its entirety by reference to a copy of the Transition Agreement which is hereby incorporated herein by reference.

**(b) Insider Trading Arrangements and Policies.**

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

On December 2, 2025, Dr. Joshua Ofman, President of the Company, modified a Rule 10b5-1 trading arrangement intended to satisfy the affirmative defense of Rule 10b5-1(c) (as modified, the “2026 Ofman Trading Arrangement”). The 2026 Ofman Trading Arrangement modifies the 2025 Ofman Trading Arrangement, as defined in our Quarterly Report on Form 10-Q for the three months ended March 31, 2025, and provides for the sale of up to 86,452 shares of common stock, subject to price limitations, until February 20, 2027.

On December 11, 2025, Mr. Aaron Freidin, Chief Financial Officer of the Company, modified a Rule 10b5-1 trading arrangement intended to satisfy the affirmative defense of Rule 10b5-1(c) (as modified, the “2026 Freidin Trading Arrangement”). The 2026 Freidin Trading Arrangement modifies the 2025 Freidin Trading Arrangement, as defined in our Quarterly Report on Form 10-Q for the three months ended March 31, 2025, and provides for the sale of up to 21,000 shares of common stock, subject to price limitations, until March 19, 2027.

**Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections**

Not applicable.

## PART III

### Item 10. Directors, Executive Officers and Corporate Governance

#### Information about our Directors

The following table presents information concerning our board of directors.

Name	Age	Position(s)
William Chase	58	Director
Sarah Krevans	67	Director
Steve Mizell	66	Director
Robert Ragusa	66	Chief Executive Officer and Director
Gregory (Greg) Summe	69	Director and Chairperson of the Board

The following are brief biographies describing the backgrounds of our directors.

**William Chase** has served as a member of our Board since June 2024. Mr. Chase most recently served for 7 years in roles as Executive Vice President, Finance and Administration and Executive Vice President and Chief Financial Officer at AbbVie Inc. ("AbbVie") from October 2018 until July 2019, where he oversaw all financial, investor, and IT activities and played a critical role in the development of the company's strategy and licensing and acquisition actions. Prior to AbbVie, Mr. Chase served nearly 25 years in positions of increasing responsibility at Abbott Laboratories, including roles as Corporate Vice President, Licensing & Acquisitions, Corporate Vice President and Treasurer, and Controller, Abbott International. He currently serves as a director and as chair of the audit committee on the boards of each of Intellia Therapeutics, Inc., a publicly-traded biotechnology company, since April 2023, and Parexel International, a privately-held biopharmaceutical services company, since November 2021. Mr. Chase holds a B.S. from the University of Illinois and an M.B.A. from the University of Chicago Booth School of Business. We believe that Mr. Chase is qualified to serve as a member of our board of directors because of his extensive experience in the biotechnology and pharmaceutical industry and his extensive financial and accounting experience.

**Sarah Krevans** has served as a member of our Board since October 21, 2024. Ms. Krevans is the former President and CEO of Sutter Health, a Northern California based not-for-profit, where she served as CEO from 2016 until 2022. She was responsible for Sutter Health's integrated network of 14,000 clinicians, 24 hospitals, outpatient services, research facilities, and home health and hospice care. Previously, Ms. Krevans served as chief operating officer and president of the Sutter Health Sacramento Sierra Region. She also held executive roles at Kaiser Permanente and served as deputy director of Maine's Bureau of Medical Services and acting director of Medicaid, health planning and licensure programs. Ms. Krevans has served as a Board Member for The Acacium Group since 2021 and is the Chair for CaringBridge, where she has served as a director since 2022. She also serves as an Advisory Board Member for Alignment Health Plan. Ms. Krevans served on Boards of many not-for-profit organizations and served as Chair of the California Hospital Association in 2022 and as a director from 2016 until 2022. Ms. Krevans earned master's degrees in business administration and in public health from the University of California, Berkeley, and a bachelor's degree from Boston University. We believe that Ms. Krevans is qualified to serve as a member of our board of directors because of her experience in U.S. healthcare delivery systems and her extensive industry and leadership experience.

**Steve Mizell** has served as a member of our Board since June 2024. Mr. Mizell is the former Executive Vice President and Chief Human Resources Officer at Merck & Co., Inc., where was employed from October 2018 until his retirement on July 1, 2024. He was responsible for talent acquisition and development, employee health and wellness, total rewards, and human capital management for over 68,000 employees across the world. Mr. Mizell previously served as Executive Vice President & Chief Human Resources Officer at Monsanto Company from 2004 until 2018, where he created an industry-leading workplace for more than 20,000 employees globally. Before that, Mr. Mizell served as Senior Vice President and Chief Corporate Resources Officer for AdvancePCS Inc. and previous to that held several key human resources management roles at companies across the energy, defense, manufacturing, communications and technology sectors. He currently serves on the boards of Allegion Plc., a

publicly-traded security products company, since February 2020, and Group 1 Automotive, Inc., a publicly-traded automotive retailer since March 2021, and has earned a Directorship Certification® from the National Association of Corporate Directors. Mr. Mizell holds a B.S. from Georgia Institute of Technology and an M.S. from Carnegie Mellon University. We believe that Mr. Mizell is qualified to serve as a member of our board of directors because of his extensive experience in risk management, human capital management and leadership.

**Gregory Summe** has served as Chair of our Board since June 2024. Mr. Summe is the Founder of investment fund Glen Capital Partners LLC and has served as the Managing Partner since June 2014. Mr. Summe previously served as Managing Director and Vice Chairman of Global Buyout at The Carlyle Group from October 2009 until June 2014. Prior to The Carlyle Group, Mr. Summe served for over a decade as Chairman, CEO, and President of PerkinElmer, Inc., a leading diagnostics and life sciences company. He also served as a Senior Advisor at Goldman Sachs Capital Partners and was the President of AlliedSignal, Inc.'s Automotive, Jet Engine, and General Avionics businesses. Previously, he was the General Manager of General Electric Commercial Motors and a Partner at McKinsey and Company. He currently serves on the boards of NXP Semiconductors N.V., a publicly-traded semiconductor company, since December 2015, Avantor, Inc., a publicly-traded Life Sciences company, since May 2020 and is the chairman, Wheels Up, a publicly traded private aviation company since September 2024 and is a Senior Advisor at Star Mountain Capital, LLC. Mr. Summe previously served on the boards of State Street Corp., a publicly traded financial services company from 2001 until May 2025, Virgin Orbit Holdings, Inc., a publicly-traded space launch services company, from January 2022 until August 2023, and NextGen Acquisition Corp I & II from July 2020 until December 2021. Mr. Summe holds a B.S. from the University of Kentucky, an M.S. from the University of Cincinnati, and an M.B.A. from the Wharton School of the University of Pennsylvania. We believe that Mr. Summe is qualified to serve as a member of our board of directors because of his extensive corporate leadership, industry, and finance experience.

The biography of Robert Ragusa is set forth under the section below “—Information about our Executive Officers.”

#### Information about our Executive Officers.

The following table presents information concerning our executive officers.

Name	Age	Position(s)
Robert Ragusa	66	Chief Executive Officer and Director
Aaron Freidin	47	Chief Financial Officer
Joshua Ofman	61	President

The following are brief biographies describing the backgrounds of our executive officers.

**Robert Ragusa** has served as our Chief Executive Officer since October 2021 and as a member of our Board since June 2024. 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 from April 2010 until December 2013, 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 2016, 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 24 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.

**Joshua 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. Dr. Ofman has previously served on the Board of Directors of two privately held biotechnology companies. Previously, Dr. 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, Dr. 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. Dr. 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.

#### **Code of Ethics**

The Company has adopted a Code of Business Conduct and Ethics that is intended to serve as a code of ethics for purposes of Item 406 of Regulation S-K. Its Code of Business Conduct and Ethics is posted on its website <https://investors.grail.com/> and the Company intends to disclose on its website any amendments to, or waivers from, such code to the extent required to be disclosed pursuant to SEC or Nasdaq rules.

The remaining information required by this Item will be included in the Company’s definitive proxy statement to be filed with the SEC within 120 days after December 31, 2025, in connection with the solicitation of proxies for the Company’s 2026 Annual Meeting of Shareholders (the “2026 Proxy Statement”), and is incorporated herein by reference.

#### **Item 11. Executive Compensation**

The information required by this Item will be included in the 2026 Proxy Statement, and is incorporated herein by reference.

#### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The information required by this Item will be included in the 2026 Proxy Statement, and is incorporated herein by reference.

#### **Item 13. Certain Relationships and Related Transactions, and Director Independence**

The information required by this Item will be included in the 2026 Proxy Statement, and is incorporated herein by reference.

#### **Item 14. Principal Accountant Fees and Services**

The information required by this Item will be included in the 2026 Proxy Statement, and is incorporated herein by reference.

## PART IV

### Item 15. Exhibits, Financial Statement Schedules

#### (a) Documents filed as part of this report

##### (1) Financial Statements:

Consolidated Financial Statements of GRAIL, Inc. are included in Part II, Item 8 of this Annual Report.

##### (2) Financial Statement Schedules:

Financial statement schedules are omitted as the required information is either inapplicable or the information is presented in our Consolidated Financial Statements or notes thereto.

##### (3) Exhibits

The exhibits listed in the Exhibit Index in (b) below are filed or incorporated by reference as part of this Annual Report.

##### a. Exhibit Index

The following documents are filed as exhibits hereto:

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed / Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
2.1	<a href="#">Separation and Distribution Agreement, dated June 21, 2024, by and among Illumina, Inc. and GRAIL, Inc.</a>	8-K	001-42045	2.1	6/24/24	
3.1	<a href="#">Certificate of Incorporation of GRAIL, Inc., dated June 21, 2024</a>	8-K	001-42045	3.1	6/24/24	
3.2	<a href="#">Amended and Restated Bylaws of GRAIL, Inc., Dated June 21, 2024</a>	8-K	001-42045	3.2	6/24/24	
3.3	<a href="#">Certificate of Conversion</a>	8-K	001-42045	3.3	6/24/24	
4.1	<a href="#">Description of Securities</a>	10-K	001-42045	4.1	3/5/25	
4.2	<a href="#">Form of Pre-Funded Warrant to Purchase Common Stock</a>	8-K	001-42045	4.1	10/20/25	
4.3	<a href="#">Form of Indenture</a>	S-3ASR	333-291503	4.2	11/13/25	
10.1	<a href="#">Tax Matters Agreement between GRAIL, LLC and Illumina, Inc.</a>	8-K	001-42045	10.1	6/24/24	
10.2	<a href="#">Employee Matters Agreement between GRAIL, LLC and Illumina, Inc.</a>	8-K	001-42045	10.2	6/24/24	
10.3	<a href="#">Stockholder and Registration Rights Agreement between GRAIL, LLC and Illumina, Inc.</a>	8-K	001-42045	10.3	6/24/24	
10.4	<a href="#">Agreement and Plan of Merger, dated as of September 20, 2020, among Illumina, Inc., SDG Ops, Inc., SDG Ops, LLC and GRAIL, Inc.</a>	10-12B	001-42045	10.4	5/6/24	
10.5	<a href="#">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</a>	10-12B	001-42045	10.5	5/6/24	
10.6†	<a href="#">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, August 18, 2021 and on May 18, 2023</a>	10-12B	001-42045	10.6	5/6/24	

10.7†	<a href="#">Fourth Amendment to the Amended and Restated Supply and Commercialization Agreement by and between Illumina, Inc. and GRAIL, LLC</a>	8-K	001-42045	10.7	6/24/24
10.8#	<a href="#">GRAIL, Inc. 2024 Incentive Award Plan</a>	8-K	001-42045	10.1	7/2/24
10.9#	<a href="#">Form Restricted Stock Unit Agreement</a>	10-12B/A	001-42045	10.9	5/29/24
10.10#	<a href="#">Form of Stock Option Agreement</a>	10-12B/A	001-42045	10.10	5/29/24
10.11#	<a href="#">Form of Indemnification Agreement between GRAIL, LLC and each of its directors and executive officers</a>	10-12B/A	001-42045	10.11	5/29/24
10.12#	<a href="#">GRAIL, Inc. 2024 Employee Stock Purchase Plan</a>	8-K	001-42045	10.2	7/2/24
10.13#	<a href="#">Form of Cash-Based Equity Appreciation Award Agreement</a>	10-12B/A	001-42045	10.13	5/29/24
10.14#	<a href="#">Employment Offer Letter, between GRAIL, LLC and Robert Ragusa, dated October 14, 2021</a>	10-12B/A	001-42045	10.14	5/29/24
10.15#	<a href="#">Transition, Separation and Release Agreement, between GRAIL, Inc. and Robert Ragusa, dated March 11, 2026</a>				*
10.16#	<a href="#">Form of Amended Offer Letter,</a>	8-K	001-42045	10.1	5/16/25
10.17†	<a href="#">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</a>	10-12B/A	001-42045	10.17	5/29/24
10.18†	<a href="#">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</a>	10-12B/A	001-42045	10.18	5/29/24
10.19†	<a href="#">License Agreement by and between The Chinese University of Hong Kong and Cirina Limited (No. TC1711655), dated as of May 29, 2017</a>	10-12B/A	001-42045	10.19	5/29/24
10.20†	<a href="#">License Agreement by and between The Chinese University of Hong Kong and Cirina Limited (No. TC1711656), dated as of May 29, 2017</a>	10-12B/A	001-42045	10.20	5/29/24
10.21†	<a href="#">License Agreement by and between The Chinese University of Hong Kong and Cirina Limited (No. TC1711657), dated as of May 29, 2017</a>	10-12B/A	001-42045	10.21	5/29/24
10.22	<a href="#">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</a>	10-12B/A	001-42045	10.22	5/29/24
10.23	<a href="#">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</a>	10-12B/A	001-42045	10.23	5/29/24
10.24	<a href="#">Lease Agreement by and between PP Office Owner 1, L.P. and GRAIL, Inc., dated as of June 4, 2020</a>	10-12B/A	001-42045	10.24	5/29/24
10.25#	<a href="#">GRAIL, Inc. Non-Employee Director Compensation Program</a>	8-K	001-42045	10.3	7/2/24
10.26	<a href="#">Lease, dated September 11, 2025, by and between GRAIL, Inc. and Sunnyvale Office Acquisition, LLC</a>	8-K	001-42045	10.1	9/18/25
10.27	<a href="#">Stock Purchase Agreement, dated as of October 16, 2025, by and among GRAIL, Inc., Samsung C&amp;T Corporation, Samsung Electronics Singapore Pte., Ltd. and Samsung Electronics Co., Ltd.</a>	8-K	001-42045	10.1	10/16/25
10.28	<a href="#">Securities Purchase Agreement, dated as of October 18, 2025, by and among GRAIL, Inc. and the Investors named therein</a>	8-K	001-42045	10.1	10/20/25
10.29	<a href="#">Registration Rights Agreement, dated as of October 18, 2025, by and among GRAIL, Inc. and the Investors named therein</a>	8-K	001-42045	10.2	10/20/25

10.30	<a href="#">Equity Distribution Agreement, dated as of November 14, 2025, by and among GRAIL, Inc., Morgan Stanley &amp; Co. LLC and TD Securities (USA) LLC.</a>	8-K	001-42045	10.1	11/14/2025	
19.1	<a href="#">Insider Trading Policy.</a>	10-K	001-42045	19.1	3/5/25	
21.1	<a href="#">List of subsidiaries of GRAIL, Inc.</a>	10-12B	001-42045	21.1	5/6/24	
23.1	<a href="#">Consent of Independent Registered Public Accounting Firm</a>					*
31.1	<a href="#">Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>					*
31.2	<a href="#">Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>					*
32.1	<a href="#">Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>					**
32.2	<a href="#">Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>					**
97.1	<a href="#">Policy for Recovery of Erroneously Awarded Compensation</a>	10-K	001-42045	97.1	3/5/2025	
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document					*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					*
*	Filed herewith.					
**	Furnished herewith.					
#	Indicates a management or compensatory plan.					
†	Pursuant to Item 601(b)(10) of Regulation S-K, portions of this exhibit have been omitted as the registrant has determined that the omitted information is (i) not material and (ii) the type of information that the registrant customarily and actually treats as private or confidential.					

**Item 16. Form 10-K Summary**

None.

**SIGNATURE**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GRAIL, Inc.

Dated: March 12, 2026

By: /s/ Robert Ragusa

Name: Robert Ragusa

Title: Chief Executive Officer (Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated

<b><u>Name</u></b>	<b><u>Title</u></b>	<b><u>Date</u></b>
<u>/s/ Robert Ragusa</u> Robert Ragusa	Chief Executive Officer and Director (Principal Executive Officer)	March 12, 2026
<u>/s/ Aaron Freidin</u> Aaron Freidin	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 12, 2026
<u>/s/ William Chase</u> William Chase	Director	March 12, 2026
<u>/s/ Steven Mizell</u> Steven Mizell	Director	March 12, 2026
<u>/s/ Sarah Krevans</u> Sarah Krevans	Director	March 12, 2026
<u>/s/ Gregory Summe</u> Gregory Summe	Director and Chairperson of the Board	March 12, 2026

## TRANSITION, SEPARATION AND RELEASE AGREEMENT

This Transition, Separation and Release Agreement (the “*Agreement*”) is entered into by and between Robert Ragusa (“*Executive*”) and GRAIL, Inc. (the “*Company*”), effective as of the Effective Date (as defined below). The purpose of this Agreement is to provide for the orderly transition of Executive’s duties to Executive’s successor, senior advisory support for a transition period to Executive’s successor, and full and final resolution of all matters relating to Executive’s employment with the Company and the transition and termination thereof.

### 1. Continued Employment, Transition.

(a) Continued CEO Employment Period. From the Effective Date until June 1, 2026 (the “*Transition Date*” and such period, the “*Pre-Transition Period*”), unless earlier terminated by Executive or the Company in accordance with the terms and conditions set forth in Executive’s offer letter with the Company, dated October 14, 2021 (the “*Offer Letter*”), Executive shall continue in employment as the Company’s Chief Executive Officer and member of the board of directors of the Company (the “*Board*”) on Executive’s existing terms and conditions of employment, as outlined in the Offer Letter.

(b) Transition Period. Effective June 1, 2026, Executive’s service in the role of Chief Executive Officer shall terminate and Executive shall resign from any officer and director roles held by Executive with the Company and its affiliates, including as a member of the Board and simultaneously transition to the employment role of Senior Executive Advisor (for clarity, without termination of employment) on the terms and conditions set forth in this Agreement. Executive shall execute such documentation and take such other actions as may be reasonably necessary to effectuate the foregoing. Executive shall continue in the role of Senior Executive Advisor from the Transition Date through March 12, 2027 (the “*Transition Period*” and, together with the Pre-Transition Period, the “*Employment Period*” and such date, the “*Transition Period End Date*”), or such earlier date as either the Company or Executive may terminate Executive’s employment in accordance with the terms and conditions set forth herein (in any case, the “*Separation Date*”).

(c) Position; Duties.

(i) *Pre-Transition Period.* During the Pre-Transition Period (or until any earlier termination of employment), Executive shall continue in his role as the Company’s Chief Executive Officer with the same duties, authority and responsibilities, including those contemplated by the Offer Letter, as in effect as of the Effective Date. During the Pre-Transition Period, Executive shall serve as a full-time executive officer and member of the Board, consistent with his employment prior to the Effective Date, and shall devote his full business time and attention to his duties and responsibilities in accordance with the Offer Letter.

(ii) *Transition Period.* During the Transition Period, Executive shall have such duties and responsibilities as are assigned by the Company’s Chief Executive Officer, consistent with his position as Senior Executive Advisor with such duties and responsibilities intended to ensure a smooth transition of the Chief Executive Officer role and provide support across existing initiatives and operations under the supervision of the Company’s Chief Executive Officer, including without limitation (in each, case, unless otherwise directed by the Company’s Chief Executive Officer): (i) providing strategic counsel and continuity support, (ii) supporting preparation for earnings calls, (iii) transferring institutional knowledge, including regarding Board engagement and governance, (iv) coordinating the new Chief Executive Officer’s participation in investor conferences and other external engagements, (v) transitioning and stewarding key external relationships, and (vi) advising on laboratory operations and supply chain matters (collectively, the “*Transition Services*”). During the Transition Period, Executive

shall devote such time and attention to the Transition Services as may be reasonably required to fully perform such Transition Services. For clarity, the scope of Executive's role, duties and authorities may be limited during the Transition Period as determined in the sole discretion of the Company's Chief Executive Officer, and Executive shall not undertake any duties, activities or communications unless and until expressly authorized or directed by the Company's Chief Executive Officer.

(d) *Termination of Employment Agreement; Acknowledgements.* Effective as of the Transition Date, the Offer Letter shall, without further action by the Company, Executive, or any other party, terminate and cease to be of any further force or effect. For clarity, neither the termination of the Offer Letter, Executive's transition from Chief Executive Officer to Senior Executive Advisor, the appointment of a successor Chief Executive Officer of the Company, nor any other action, term or condition contemplated by this Agreement, in any case, shall give rise to Good Reason (within the meaning of the Offer Letter) or otherwise trigger any severance or other payments under the Offer Letter or otherwise (other than any payments or benefits expressly contemplated by this Agreement).

## **2. Compensation; Benefits.**

(a) *Base Salary.* During the Pre-Transition Period, Executive's base salary shall continue at the annualized rate in effect on the Effective Date. During the Transition Period, Executive will be paid an annualized base salary of \$300,000. The base salary shall be paid in accordance with the Company's normal payroll procedure as in effect from time to time, but no less often than bi-monthly.

(b) *Benefits.* During the Pre-Transition Period, Executive's benefits eligibility shall continue as in effect on the Effective Date and as contemplated by the Offer Letter. During the Transition Period, Executive's benefits eligibility shall, solely if and to the extent permitted under the applicable benefit plan or program, continue in effect on the same terms as applied during the Pre-Transition Period, *provided*, that if Executive becomes ineligible to participate as an active employee under the terms of any Company "group health plan" during the Transition Period, then, subject to Executive's valid election to continue healthcare coverage under Section 4980B of the Code, the Company shall continue to provide Executive and Executive's eligible dependents, through the end of the calendar month in which the Transition Period ends (the "**COBRA Period**"), with coverage under its group health plans at the same levels and the same cost to Executive as applied immediately prior to the Effective Date (subject to adjustments applicable to active employee participants generally), *provided, further*, that if the Company is unable to continue to cover Executive under its group health plans without incurring penalties (including without limitation, pursuant to Section 2716 of the Public Health Service Act or the Patient Protection and Affordable Care Act), jeopardizing the tax-qualified status of any plan, and/or causing all or any portion of the health benefits provided to become taxable to Executive, then, in any such case, an amount equal to each remaining Company subsidy shall thereafter be paid to Executive in substantially equal taxable monthly installments over the COBRA Period (or the remaining portion thereof) (in any event, the "**COBRA Payments**"). For clarity, to the extent that Executive ceases to be eligible for any other benefit or perquisite plan or program during the Transition Period, the Company shall have no obligation to provide or replicate any such other benefits or perquisites.

(c) *Variable Compensation Plan.* Notwithstanding anything to the contrary in the Offer Letter or otherwise, subject to and conditioned upon Executive's: (i) continued employment in good standing through the end of the Transition Period, (ii) timely execution following the Separation Date of a general release of claims substantially consistent with the provisions of Section 6 below (the "**Release**") that becomes effective and irrevocable within thirty (30) (or to the extent required by law, sixty (60)) days following the Separation Date, and (iii) continued compliance with the terms and conditions of Sections 8 and 9 hereof, Executive shall remain eligible to earn a bonus under the Company's Variable Compensation Plan ("**VCP**"), determined by reference to Executive's Pre-Transition Period base salary and target bonus and attainment of applicable performance goals, pro-rated based on the portion of

calendar year 2026 elapsed through the Transition Date (the “*Pro-Rata VCP Bonus*”). The Pro-Rata VCP Bonus shall be paid as and when bonuses under the VCP are paid to the Company’s executives generally (but for clarity, in no event no event later than May 15, 2027).

(d) Incentive Equity Awards. Each Company incentive equity award granted to Executive that is outstanding as of the Effective Date shall remain outstanding and eligible to vest in accordance with its terms through the end of the Transition Period; *provided*, that notwithstanding anything to the contrary contained in the Offer Letter, in any incentive equity award agreement or otherwise, in no event shall any accelerated vesting apply with respect to any such Company incentive equity award held by Executive in any context.

### **3. Termination of Employment**

(a) Termination of Offices, Employment. Executive’s status as an officer of the Company and member of the Board shall terminate on the Transition Date. Executive’s employment with the Company shall terminate on the Separation Date. For clarity, Executive’s employment during the Employment Period is and shall remain “at will,” meaning that either the Company or Executive may terminate Executive’s employment with the Company at any time for any lawful reason (subject, during the Pre-Transition Period only, to the terms and conditions of the Offer Letter). The Company and Executive further acknowledge and agree that the termination of Executive’s employment hereunder shall constitute a “separation from service” within the meaning of Section 409A (as defined below).

(b) Accrued Obligations. Within thirty (30) days following the Separation Date (or any earlier date as may be required by applicable law), the Company will pay to Executive (i) all accrued salary, and (ii) any unreimbursed business expenses incurred and substantiated by Executive, in each case, in accordance with Company policy prior to the Separation Date (collectively, the “*Accrued Obligations*”).

(c) Termination without Cause. If the Separation Date occurs prior to the Transition Period End Date by reason of the Company’s termination of Executive’s employment without Cause (as defined in the Offer Letter), then, subject to and conditioned upon Executive’s (i) timely execution following the Separation Date of a Release that becomes effective and irrevocable within thirty (30) (or to the extent required by law, sixty (60)) days following the Separation Date, and (ii) continued compliance with the terms and conditions of Sections 8 and 9 hereof:

- (i) The Company shall pay to Executive the Base Salary that would have been payable during the remainder of the Transition Period had the Employment Period ended on the Transition Period End Date, in accordance with the payment timing set forth in Section 2(a).
- (ii) The COBRA Payments shall continue for the remainder of the COBRA Period as though the Employment Period had ended on the Transition Period End Date.
- (iii) The Company shall pay to Executive the Pro-Rata VCP Bonus upon the later to occur of (i) the date on which bonuses under the VCP are paid to the Company’s executives generally or (ii) the first regularly scheduled payment date to occur following the date on which the Release becomes effective and irrevocable (but in no event later than March 15<sup>th</sup> of the calendar year following the calendar year in which the Separation Date occurs).
- (iv) Any Company equity awards held by Executive shall become vested (and, as applicable, exercisable) on an accelerated basis as of the Separation Date with respect to the number of shares subject to such Company equity award that

would have vested had Executive's employment continued through the Transition Period End Date.

(d) **Incentive Equity Awards.** Each Company equity award held by Executive as of the Separation Date shall, to the extent then unvested (after taking into consideration the accelerated vesting described in Section 3(c) above, if applicable), lapse and be forfeited without payment therefor.

(e) **Return of Company Property.** Executive represents and warrants he shall, prior to the Separation Date, return to the Company any and all property and equipment of the Company, including (i) all keys, files, lists, books and records (and copies thereof) of, or in connection with, the Company's business, equipment (including, but not limited to, computer hardware, software and printers, wireless handheld devices, cellular phones and pagers), access or credit cards, Company identification, and all other property belonging to the Company in Executive's possession or control, and (ii) all documents and copies, including hard and electronic copies, of documents in Executive's possession relating to any Confidential Information (as defined below), including without limitation, internal and external business forms, manuals, correspondence, notes and computer programs, and that Executive shall not make or retain any copy or extract of any of the foregoing; provided, however, that Executive may retain Executive's telephone and address book and copies of Executive's own personnel, payroll and benefit documents (provided that such documents do not contain any Confidential Information and that the Company has the prior opportunity to review, redact and/or retain any such documents containing Confidential Information).

4. **Tax Withholding and Other Deductions.** All compensation payable to Executive hereunder shall be subject to all required tax withholding and deductions, and the Company is hereby authorized to withhold and deduct such amounts from all payments hereunder.

5. **Certain Acknowledgments.** Executive acknowledges that, upon receipt of the Accrued Obligations (and subject to payment of Executive's pro-rated 2026 VCP award if earned, as provided above), Executive will have received all monies and other benefits due to Executive in connection with his employment with and separation from the Company, and that Executive shall have no right, title, or interest in or entitlement to any other payments or benefits in connection therewith, other than as expressly set forth in this Agreement. Executive further represents that he has not sustained a work-related injury or illness that he has not previously reported to the Company.

6. **Release of Known and Unknown Claims.**

(a) **General Release.** In exchange for the consideration set forth in this Agreement, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Executive agrees unconditionally and forever to release and discharge the Company and the Company's affiliated, related, parent and subsidiary corporations, as well as their respective past and present parents, subsidiaries, affiliates, associates, members, stockholders, employee benefit plans, attorneys, agents, representatives, partners, joint venturers, predecessors, successors, assigns, insurers, owners, employees, officers, directors and all persons acting by, through, under, or in concert with them, or any of them (hereinafter the "***Releasees***") from any and all manner of claims, actions, causes of action, in law or in equity, demands, rights, or damages of any kind or nature which he may now have, or ever have, whether known or unknown, fixed or contingent, including any claims, causes of action or demands of any nature (hereinafter called "***Claims***"), that Executive now has or may hereafter have against the Releasees by reason of any and all acts, omissions, events or facts occurring or existing prior to Executive's execution of this Agreement. The Claims released hereunder specifically include, but are not limited to, any claims for fraud; breach of contract; breach of implied covenant of good faith and fair dealing; inducement of breach; interference with contract; wrongful or unlawful discharge or demotion; violation of public policy; sexual or any other type of assault and battery; invasion of privacy; intentional

or negligent infliction of emotional distress; intentional or negligent misrepresentation; conspiracy; failure to pay wages, benefits, vacation pay, severance pay, commissions, equity, attorneys' fees, or other compensation of any sort; failure to accommodate disability, including pregnancy; discrimination or harassment on the basis of pregnancy, race, color, sex, gender, national origin, ancestry, religion, disability, handicap, medical condition, marital status, sexual orientation, age or any other protected category; any claim under Title VII of the Civil Rights Act of 1964, as amended, by the Civil Rights Act of 1991, 42 U.S.C. § 2000 et seq.; Equal Pay Act, as amended, 29 U.S.C. § 206(d); the Civil Rights Act of 1866, 42 U.S.C. § 1981; the Family and Medical Leave Act of 1993, 29 U.S.C. § 2601 et seq.; the Americans with Disabilities Act of 1990, 42 U.S.C. § 12101 et seq.; the False Claims Act, 31 U.S.C. § 3729 et seq.; Age Discrimination in Employment Act (as amended, the "**ADEA**"); Older Workers Benefit Protection Act; the Executive Retirement Income Security Act, as amended, 29 U.S.C. § 1001 et seq.; the Worker Adjustment and Retraining Notification Act ("**WARN**"), as amended, 29 U.S.C. § 2101 et seq.; the Fair Labor Standards Act, 29 U.S.C. § 215 et seq.; the California Fair Employment and Housing Act, as amended, Cal. Lab. Code § 12940 et seq.; the California Equal Pay Law, as amended, Cal. Lab. Code §§ 1197.5(a), 1199.5; the Moore-Brown-Roberti Family Rights Act of 1991, as amended, Cal. Gov't Code §§ 12945.2, 19702.3; the California WARN Act, Cal. Lab. Code § 1400 et seq.; the California False Claims Act, Cal. Gov't Code § 12650 et seq.; the California Corporate Criminal Liability Act, Cal. Penal Code § 387; the California Labor Code; and any federal, state or local laws of similar effect.

(b) Claims Not Released. This release shall not apply to: the Company's obligations to provide any compensation, benefits and continued incentive equity award vesting during the Employment Period as set forth in this Agreement; Executive's right to indemnification under any applicable indemnification agreement with the Company, including, but not limited to, pursuant to any Side A Difference-in-Conditions policy that the Company may elect to maintain from time to time, as applicable; the Company's governing documents or applicable law; Executive's right to assert claims for workers' compensation or unemployment benefits; Executive's right to bring to the attention of the Equal Employment Opportunity Commission or similar state or local human rights agency ("**EEOC**") claims of discrimination, harassment, or retaliation (*provided*, that Executive releases his right to secure any damages for any such alleged conduct); any right to communicate directly with, cooperate with, or provide information to, any federal, state or local Government Agencies (as defined below); any right to file an unfair labor practice charge under the National Labor Relations Act ("**NLRA**"); Executive's vested rights under any retirement or welfare benefit plan of the Company; Executive's rights in his capacity as an equityholder of the Company; or any other rights that may not be waived by an Executive under applicable law.

(c) Unknown Claims. Executive acknowledges that Executive has been advised of and is familiar with the provisions of California Civil Code Section 1542, which provides as follows:

"A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY."

Executive, being aware of said Code Section, hereby expressly waives any rights he may have thereunder, as well as under any other statutes or common law principles of similar effect.

(d) ADEA Release. Executive acknowledges that he is releasing any claims he may have under the ADEA (as defined above). To accept this Agreement, Executive must execute this Agreement no later than the date that is twenty-one (21) days after receipt (the "**Review Period**"). Executive agrees that the Review Period shall not be extended due to changes to this Agreement, whether material or not. The Company hereby advises Executive to consult with an attorney prior to signing this

Agreement. After Executive signs this Agreement, Executive has up to seven (7) days to revoke the Agreement (such seven (7) day period, the “**Revocation Period**”). In order to effectively revoke this Agreement, Executive must send written notice of the decision to do so to the Company, to the attention of Abram Barth, General Counsel, at abarth@grailbio.com, and such written notice must be received by the Company prior to the expiration of the Revocation Period. If Executive fails to return his executed Agreement to the Company by the last day of the Review Period or if Executive timely revokes this Agreement, this Agreement shall be null and void and of no effect. If Executive timely returns his executed Agreement to the Company and the Revocation Period expires without revocation, this Agreement shall become effective, irrevocable, and enforceable on the eighth (8th) day after Executive executes this Agreement (the “**Effective Date**”).

(e) **Representations.** Executive represents and warrants that there has been no assignment or other transfer of any interest in any Claim which he may have against Releasees, or any of them, and Executive agrees to indemnify and hold Releasees, and each of them, harmless from any liability, Claims, demands, damages, costs, expenses and attorneys’ fees incurred by Releasees, or any of them, as the result of any such assignment or transfer or any rights or Claims under any such assignment or transfer. It is the intention of the parties that this indemnity does not require payment as a condition precedent to recovery by the Releasees against Executive under this indemnity. Executive agrees that if he hereafter commences any suit arising out of, based upon, or relating to any of the Claims released hereunder or in any manner asserts against Releasees, or any of them, any of the Claims released hereunder, then Executive agrees to pay to Releasees, and each of them, in addition to any other damages caused to Releasees thereby, all attorneys’ fees incurred by Releasees in defending or otherwise responding to said suit or Claim.

(f) **No Actions.** Executive represents and warrants to the Company that Executive has no pending actions, Claims or charges of any kind against any Releasee. Executive agrees that if Executive hereafter commences, joins in, or in any manner seeks relief through any suit arising out of, based upon, or relating to any of the Claims released hereunder or in any manner asserts against the Releasees any of the Claims released hereunder, then Executive will pay to the Releasees against whom such Claim(s) is asserted, in addition to any other damages caused thereby, all attorneys’ fees incurred by such Releasees in defending or otherwise responding to said suit or Claim; *provided*, that Executive shall not be obligated to pay the Releasees’ attorneys’ fees to the extent such fees are attributable to Executive’s right to file a charge with the EEOC, but as stated above, Executive hereby waives any right to any damages or individual relief resulting from any such charge.

(g) **No Admission.** Executive understands and agrees that neither the payment of money nor the execution of this Agreement shall constitute or be construed as an admission of any liability whatsoever by the Releasees.

7. **Protection of Confidential Information.** Executive acknowledges and agrees that Executive has had access to and contributed to information and materials of a highly sensitive nature (including Confidential Information (as defined below)) of the Company and its current and future direct and indirect subsidiaries and parent and related entities. Executive agrees that unless Executive first secures the written consent of the Company, Executive shall not use for Executive or anyone else, and shall not, and shall cause Executive’s affiliates and representatives not to, disclose to others, any Confidential Information, except to the extent such use or disclosure is (i) used in the proper performance of Executive’s duties under this Agreement during the Employment Period, (ii) required by law or any order issued by any governmental authority (in which event Executive shall, to the extent practicable, inform the Company in advance of any such required disclosure, shall cooperate with the Company in all reasonable ways in obtaining a protective order or other protection in respect of such required disclosure, and shall limit such disclosure to the extent reasonably possible while still complying with such

requirements) (iii) made to attorneys, accountants, or financial or other advisors of Executive who need to know such Confidential Information, know of the existence and terms of this Agreement and are bound by confidentiality obligations no less protective of the Confidential Information than the terms contained herein, or (iv) protected by Section 11 below. Executive shall, and shall cause Executive's applicable affiliates and representatives to, use all reasonable care to safeguard Confidential Information and to protect it against disclosure, misuse, espionage, loss and theft. As used herein, "**Confidential Information**" means all information (whether or not specifically identified as confidential), in any form or medium, that is disclosed to, or developed or learned by, Executive to the extent relating to the business, operations, affairs, products, services or research of the Company or any of their partners, affiliates, officers, directors or key employees, including, without limitation: (A) internal business information of the Company and its subsidiaries (including, without limitation, information relating to strategic plans or practices, business, accounting, financial or marketing plans, practices or programs, training practices or programs, salaries, bonuses, incentive plans or other compensation and benefits information or accounting and business methods); (B) identities of, individual requirements of, specific contractual arrangements with, or information about, the Company, its affiliates, their respective customers or their respective confidential information; (C) any confidential or proprietary information of any third party that the Company or its subsidiaries have a duty to maintain confidentiality of, or use only for certain limited purposes; (D) industry research compiled by, or on behalf of the Company, without limitation, identities of potential target companies, management teams, or transaction sources identified by, or on behalf of, Executive or the Company; (E) compilations of data or analyses, processes, methods, track and performance records, data or data bases relating thereto; and (F) information related to the intellectual property of the Company and its subsidiaries, or updates of any of the foregoing; provided that "**Confidential Information**" shall not include any information that (x) Executive can demonstrate has become generally known to the public other than as a result of the acts or omissions of Executive or Executive's affiliates in breach of any confidentiality obligations, or (y) is independently developed by Executive or Executive's affiliates or representatives following the date hereof outside of Executive's performance of his duties and responsibilities to the Company under this Agreement and without use of or reference to the Confidential Information.

8. **Non-Disparagement**. Following the Effective Date, except as protected by Section 11 below, Executive agrees not to publish or disseminate, directly or indirectly, any statements, whether written or oral, that are or could reasonably be expected to be harmful to or reflect negatively on any of the Company or any of its affiliates, or that are otherwise disparaging of any of the Company's, its affiliates or any of their past or present officers, directors, employees, advisors, agents, policies, procedures, practices, decision-making, conduct, professionalism or compliance with standards. The Company agrees to instruct its directors and executive officers to refrain from making disparaging statement regarding Executive, other than (i) in connection with providing truthful testimony or other response in connection with any legal, judicial or governmental investigation or proceeding or (ii) statements made in response to Executive's statements in the event that Executive's statements are in breach of Executive's non-disparagement obligations. In responding to inquiries about Executive from prospective employers, the Company's Human Resources Department will confirm only Executive's dates of employment and title.

#### 9. **Non-Competition/Non-Solicitation**.

(a) **Pre-Transition Period Non-Competition**. During the Pre-Transition Period, Executive shall devote Executive's best efforts and full business time and attention to the business and affairs of the Company, its subsidiaries and its affiliates, and, unless provided otherwise pursuant to a prior unanimous written consent or approval by a majority of the Board, Executive shall not (i) serve as an employee or consultant for any other entity, (ii) serve on the board of directors or similar body of any

other entity that engages in the Restricted Business (as defined below), or (iii) engage, directly or indirectly, in any other business activity (whether or not pursued for pecuniary advantage) that is or may be competitive with, or that might place Executive in a competing position to, that of the Company or any of its subsidiaries or affiliates. (and, without limitation of the foregoing, for clarity, shall not engage in any of the activities restricted under Section 9(b) below). Notwithstanding the foregoing, during the Pre-Transition Period, it shall not be a violation of this Agreement for Executive to: (A) continue to serve in the roles (at existing levels/capacities) listed on Schedule A hereto, (B) serve on boards, committees or similar bodies of charitable or nonprofit organizations or educational institutions, and (C) manage Executive's personal investments (real estate or otherwise), in each case, so long as such activities do not violate this Section 9, create a potential business or fiduciary conflict, or, individually or in the aggregate, materially interfere or conflict with the performance of Executive's duties and responsibilities under this Agreement.

(b) Transition Period Non-Competition. During the Employment Period, and without limiting Executive's obligations during the Pre-Transition Period, Executive shall not, and shall cause Executive's affiliates not to, in each case, directly or indirectly, own, manage, control, participate in, consult with, render services similar in nature to the services provided to the Company or its subsidiaries for, permit his, her or its name to be used in or in any other manner engage in the business or enterprise in which a material component of such business or enterprise (i.e., comprising more than 20% of the annual revenue or spending of such business or enterprise) involves the research, development, validation, manufacture, marketing, sale or provision of multi-cancer early detection screening or diagnostic tests or related technologies, together with associated laboratory, software, data, and clinical-support services (the "**Restricted Business**"): (i) for or on behalf of any person or entity that was a customer (or affiliate thereof) of the Company or its subsidiaries during Executive's employment and continues to be a customer of the Company (or affiliate thereof) as of the time such services are offered, or (ii) otherwise in any state within the United States in which the Company or its subsidiaries are engaged in the Restricted Business during the Employment Period. For purposes of this Section 9(b), the term "participate" includes any direct or indirect interest in any enterprise, whether as an officer, director, employee providing services substantially similar to the services provided to the Company or its subsidiaries, partner, sole proprietor, agent, representative, independent contractor providing services substantially similar to the services provided to the Company or its subsidiaries, seller, franchisor, franchisee, creditor or owner; provided that the foregoing activities shall not restrict (A) continued service in the roles (at existing levels/capacities) listed on Schedule A hereto or (B) passive ownership of less than two percent (2%) of the equity securities of a publicly-held entity whose equity securities are traded on a national securities exchange or in the over the counter market, so long as Executive does not have the right or ability to directly or indirectly manage or otherwise direct the operations of such entity (including through the ability to appoint any representatives to the board of directors thereof).

(c) Business Relations Non-Solicitation. During the Employment Period, Executive shall not, and shall cause Executive's affiliates not to, directly or indirectly, on Executive's behalf or on behalf of others (other than on behalf of the Company), (x) induce or attempt to induce any customers, vendors, licensees, licensors or other business relations of the Company or its subsidiaries with whom Executive had personal interactions or had access to Confidential Information while employed by the Company (collectively, "**Business Relations**") to cease doing business with the Company or its subsidiaries or otherwise materially adversely modify its business relationship with the Company or its subsidiaries or (y) otherwise materially interfere with the relationship between the Company or its subsidiaries, on the one hand, and any Business Relations, on the other hand.

(d) Employee Non-Solicitation. During the Employment Period and during the twelve (12) month period immediately following the Separation Date, Executive shall not induce or

attempt to induce any Restricted Persons (as defined below) to leave the employ of or engagement by the Company or its subsidiaries, or otherwise materially interfere with the relationship between the Company or its subsidiaries and any such Restricted Person, or (y) solicit to hire or engage, either directly or on behalf of any other person or entity, any such person who is a Restricted Person; *provided*, that nothing contained in this Section 9(d) shall prohibit Executive from (placing general advertisements or conducting any other form of general solicitation that is not specifically targeted at any Restricted Persons without any direct or indirect prior solicitation or encouragement from Executive prior to such hiring or engagement in violation of this Agreement). For purposes of this Section 9(d), “**Restricted Persons**” shall mean any officer, director, manager or employee of the Company or any of its subsidiaries whom Executive supervised, with whom Executive had personal interactions, or with respect to whom Executive had access to Confidential Information while employed by the Company.

10. **Equitable Remedies.** The Executive acknowledges and understands that Sections 7, 8 and 9 of this Agreement are of a special and unique nature, the breach of which cannot be adequately compensated for in damages by an action at law, and that any breach or threatened breach of such provisions would cause the Company irreparable harm. In the event of a breach or threatened breach by Executive of the provisions of this Agreement, the Company shall be entitled to an injunction restraining Executive from such breach without the need to post bond therefor. Nothing contained in this Section 10 shall be construed as prohibiting the Company from pursuing, or limiting the Company’s ability to pursue, any other remedies available for any breach or threatened breach of this Agreement by Executive.

11. **Certain Exceptions.** Notwithstanding anything in this Agreement or the Release to the contrary, nothing contained in this Agreement shall prohibit Executive (or Executive’s attorney) from (i) filing a charge with, reporting possible violations of federal law or regulation to, participating in any investigation by, or cooperating with the U.S. Securities and Exchange Commission (“**SEC**”), the Financial Industry Regulatory Authority (“**FINRA**”), the EEOC, the National Labor Relations Board (“**NLRB**”), the Occupational Safety and Health Administration, the U.S. Commodity Futures Trading Commission, the U.S. Department of Justice or any other securities regulatory agency, self-regulatory authority or federal, state or local regulatory authority (collectively, “**Government Agencies**”), or making other disclosures that are protected under the whistleblower provisions of applicable law or regulation, (ii) communicating directly with, cooperating with, or providing non-privileged information (including trade secrets) in confidence to any Government Agencies for the purpose of reporting or investigating a suspected violation of law, or from providing such information to Executive’s attorney or in a sealed complaint or other document filed in a lawsuit or other governmental proceeding, (iii) receiving an award for information provided to any Government Agency, (iv) exercising any rights Executive may have under Section 7 of the NLRA, such as the right to engage in concerted activity, including collective action or discussion concerning wages or working conditions, or (v) discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination based on a protected characteristic or any other conduct that Executive has reason to believe is unlawful, in each case, without notice to or cooperation with the Company. Pursuant to 18 USC Section 1833(b), (1) Executive will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made: (x) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or (y) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal, and (2) if Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, he may disclose the trade secret to his attorney and use the trade secret information in the court proceeding, if he (a) files any document containing the trade secret under seal and (b) does not disclose the trade secret, except pursuant to court order. Further, nothing in this Agreement is intended to or shall preclude Executive from providing truthful testimony in response to a valid subpoena, court order, regulatory request or other judicial, administrative or legal process or otherwise as required by law. If

Executive is required to provide testimony, then unless otherwise directed or requested by a Governmental Agency or law enforcement or as protected above, Executive shall notify the Company in writing as promptly as practicable after receiving any such request of the anticipated testimony and at least ten (10) days prior to providing such testimony (or, if such notice is not possible under the circumstances, with as much prior notice as is possible) to afford the Company a reasonable opportunity to challenge the subpoena, court order or similar legal process.

12. **Ongoing Cooperation.** Executive agrees that, during and after the Employment Period, Executive will assist and cooperate with the Company and its affiliates: (i) concerning reasonable requests for information about the business of the Company or its affiliates or Executive's involvement and participation therein, (ii) in connection with the defense, prosecution or investigation of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company or its subsidiaries or affiliates, including any proceeding before any arbitral, administrative, judicial, legislative, or other body or agency, including testifying in any proceeding to the extent such claims, actions, investigations or proceedings relate to services performed or required to be performed by Executive, pertinent knowledge possessed by Executive, or any act or omission by Executive, and (iii) and in connection with any investigation or review by any federal, state or local regulatory, quasi- or self-regulatory or self-governing authority or organization (including, without limitation, the SEC and FINRA) as any such investigation or review relates to services performed or required to be performed by Executive, pertinent knowledge possessed by Executive, or any act or omission by Executive. Executive's full cooperation shall include, but not be limited to, being available to meet and speak with officers or employees of the Company, its affiliates and/or their counsel at reasonable times and locations, executing accurate and truthful documents, appearing at the Company's request as a witness at depositions, trials or other proceedings without the necessity of a subpoena, and taking such other actions as may reasonably be requested by the Company and/or its counsel to effectuate the foregoing. In requesting such services, the Company will consider other commitments that Executive may have at the time of the request, shall reimburse Executive for reasonable, documented out-of-pocket expenses incurred in connection with such cooperation to the extent that such expenses are approved by the Company in advance and, to the extent such cooperation is provided after the Separation Date, and exceeds ten hours in the aggregate shall compensate Executive for such time in excess of ten hours at an hourly rate of \$167.00.

13. **Arbitration.** Executive acknowledges and agrees that the arbitration provisions set forth in this Section 13 supersede and replace the arbitration provisions set forth in the Offer Letter for all purposes hereunder and with respect to the Offer Letter.

(a) **JAMS Arbitration.** Executive and the Company agree that, except for any claims excluded in Section 13(g) below, any dispute, controversy or claim, however significant, arising out of or in any way relating to Executive's employment with or termination of employment from the Company, including without limitation any dispute, controversy or claim arising out of or in any way relating to any provision of this Agreement (including the validity, scope and enforceability of this arbitration clause), to the fullest extent authorized by applicable law, shall be submitted to final and binding arbitration before a single neutral arbitrator in accordance with the rules of Judicial Arbitration and Mediation Services ("**JAMS**") pursuant to its Employment Arbitration Rules and Procedures, which are available at <http://www.jamsadr.com/rules-employment-arbitration/>, and the Company will provide a copy upon Executive's request, as the exclusive remedy for resolving any and all such disputes.

(b) **Tribunal; Location; Individual Capacity.** The tribunal will consist of a sole neutral arbitrator selected by mutual agreement of the parties (or, absent such mutual agreement, in accordance with the rules of JAMS) and the place of arbitration will be San Francisco, California. Each party shall be entitled to all types of remedies and relief otherwise available in court (subject to the limitations set forth herein). The parties agree that any arbitration pursuant to this Agreement shall be

brought on an individual, rather than class, collective, or representative basis, and waive the right to pursue any claim subject to arbitration on a class, collective, or representative basis.

(c) Jurisdiction. The parties to this Agreement hereby expressly and irrevocably submit themselves to the personal jurisdiction of the Superior Court of the State of California (the "**Superior Court**") for the purpose of compelling arbitration pursuant to this Agreement and for the purpose of any judicial proceedings seeking to confirm, modify or vacate any arbitration award. The arbitration provisions of this Agreement shall be governed by and enforceable pursuant to the Federal Arbitration Act. In all other respects for provisions not governed by the Federal Arbitration Act, this Agreement shall be construed in accordance with the laws of the State of California, without reference to conflicts of law principles.

(d) Fees. To the extent required by applicable law, the fees of the arbitrator and all other costs that are unique to arbitration shall be paid by the Company initially, but if Executive initiates a claim subject to arbitration, Executive shall pay any filing fee up to the amount that Executive would be required to pay if Executive initiated such claim in the Superior Court. The arbitrator may if it deems appropriate in its discretion award costs and expenses, including, but not limited to, attorneys' fees and/or witness fees incurred in connection with such arbitration to the prevailing party.

(e) WAIVER OF TRIAL BY JURY OR COURT. EXECUTIVE AND THE COMPANY UNDERSTAND THAT BY AGREEING TO ARBITRATE ANY ARBITRATION CLAIM, THEY WILL NOT HAVE THE RIGHT TO HAVE ANY ARBITRATION CLAIM DECIDED BY A JURY OR A COURT, BUT SHALL INSTEAD HAVE ANY ARBITRATION CLAIM DECIDED THROUGH ARBITRATION.

(f) WAIVER OF OTHER RIGHTS. EXECUTIVE AND THE COMPANY WAIVE ANY CONSTITUTIONAL OR OTHER RIGHT TO BRING CLAIMS COVERED BY THIS AGREEMENT OTHER THAN IN THEIR INDIVIDUAL CAPACITIES. EXCEPT AS MAY BE PROHIBITED BY LAW, THIS WAIVER INCLUDES THE ABILITY TO ASSERT CLAIMS AS A PLAINTIFF OR CLASS MEMBER IN ANY PURPORTED CLASS OR REPRESENTATIVE PROCEEDING.

(g) Excluded Claims. Notwithstanding the foregoing, this Section 13 shall not preclude either party from seeking a temporary restraining order or a preliminary injunction from a court of competent jurisdiction if such relief is not available in a timely fashion through arbitration. Further, this arbitration agreement shall not apply to: (i) claims for unemployment and workers' compensation benefits; (ii) sexual harassment and sexual assault disputes arising under federal, state, local, or tribal law, unless Executive elects to arbitrate such disputes; (iii) claims arising under the NLRA or which are brought before the NLRB; (iv) claims brought before the EEOC, if Executive is required to exhaust Executive's administrative remedies; provided, that any appeal from an award or denial of an award by the EEOC or any further action upon receipt of a right-to-sue letter shall be arbitrated pursuant to the terms of this Section 11; and (v) any other claim, which by law cannot be subject to mandatory arbitration.

(h) Representation by Counsel. The parties acknowledge that they are entering into this arbitration provision voluntarily, and are represented by counsel. If any part of this arbitration provision is deemed unenforceable, it is entirely severable from the rest and shall not affect or limit the validity or enforceability of the remainder of the provision, or the Agreement.

#### 14. Code Section 409A.

(a) General. To the extent applicable, this Agreement shall be interpreted in accordance with Section 409A of the Code and Department of Treasury regulations and other interpretive

guidance issued thereunder, including without limitation any such regulations or other such guidance that may be issued after the Effective Date (collectively, "**Section 409A**"). Notwithstanding any provision of this Agreement to the contrary, in the event that following the Effective Date, the Company determines that any compensation or benefits payable under this Agreement may be subject to Section 409A, the Company and Executive shall work together in good faith to such amendments to this Agreement or adopt other policies or procedures (including amendments, policies and procedures with retroactive effect), or take any other actions as may be necessary or appropriate to preserve the intended tax treatment of the compensation and benefits payable hereunder, including without limitation actions intended to (i) exempt the compensation and benefits payable under this Agreement from Section 409A, and/or (ii) comply with the requirements of Section 409A, *provided*, that this Section 14 does not, and shall not be construed so as to, create any obligation on the part of the Company to adopt any such amendments, policies or procedures or to take any other such actions. In no event shall the Company, its affiliates or any of their respective officers, directors or advisors be liable for any taxes, interest or penalties imposed under Section 409A or any corresponding provision of state or local law.

(b) **Separate Payments; Six-Month Delay.** Any right under this Agreement to a series of installment payments shall be treated as a right to a series of separate payments. All payments to be made under this Agreement in connection with a termination of employment shall only be made upon the Executive's "separation from service" (within the meaning of and to the extent required by Section 409A). Notwithstanding anything to the contrary in this Agreement, no compensation or benefits shall be paid to Executive during the six-month period following Executive's "separation from service" with the Company (within the meaning of Section 409A) if the payment of such amounts at the time or times indicated in this Agreement would be a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code. If the payment of any such amounts is delayed as a result of the previous sentence, then on the first business day following the end of such six-month period (or if earlier, upon Executive's death), the Company shall pay Executive a lump-sum amount equal to the cumulative amount that would have otherwise been payable to Executive during such period (without interest).

15. **Governing Law.** This Agreement shall be construed under the laws of the State of California, both procedural and substantive.

16. **Waiver.** The failure to enforce any provision of this Agreement shall not be construed to be a waiver of such provision or to affect the validity of this Agreement or the right of any party to enforce this Agreement.

17. **Headings.** The headings in this Agreement are provided solely for convenience, and are not intended to be part of, nor to affect or alter the interpretation or meaning of, this Agreement.

18. **Severability.** If any sentence, phrase, section, subsection or portion of this Agreement is found to be illegal or unenforceable, such action shall not affect the validity or enforceability of the remaining sentences, phrases, sections, subsections or portions of this Agreement, which shall remain fully valid and enforceable.

19. **Assignment.** This Agreement is personal to Executive and shall not be assignable by Executive. The rights of the Company under this Agreement may be assigned by the Company, in its sole discretion, including to any of its affiliates or any person, firm, corporation or other business entity which at any time, whether by purchase, merger or otherwise, directly or indirectly, acquires all or substantially all of the assets or business of the Company. This Agreement shall inure to the benefit of, and be binding on, the Company and its successors and assigns.

20. **Ambiguities.** Both parties have participated in the negotiation of this Agreement and, thus, it is understood and agreed that the general rule that ambiguities are to be construed against the drafter shall not apply to this Agreement. In the event that any language of this Agreement is found to be

ambiguous, each party shall have an opportunity to present evidence as to the actual intent of the parties with respect to any such ambiguous language.

21. **Entire Agreement/Integration.** This Agreement, together with the Offer Letter (solely until the first to occur of the Transition Date or the Separation Date), the individual agreements evidencing any outstanding incentive equity awards granted to Executive by the Company and the Release, constitutes the entire agreement between Executive and the Company concerning the subject matter hereof. No covenants, agreements, representations, or warranties of any kind, other than those set forth herein, have been made to any party hereto with respect to this Agreement. All prior discussions and negotiations have been and are merged and integrated into, and are superseded by, this Agreement. No amendments to this Agreement will be valid unless written and signed by Executive and an authorized representative of the Company.

22. **Consultation with Counsel.** Executive acknowledges (i) that Executive has thoroughly read and considered all aspects of this Agreement, that Executive understands all its provisions and that Executive is voluntarily entering into this Agreement, (ii) that he has been represented by, or had the opportunity to be represented by independent counsel of his own choice in connection with the negotiation and execution of this Agreement and has been advised to do so by the Company, and (iii) that he has read and understands the Agreement, is fully aware of its legal effect, and has entered into it freely based on his own judgment.

23. **Notices.** All notices, requests and other communications hereunder shall be in writing and shall be delivered by courier or other means of personal service (including by means of a nationally recognized courier service or professional messenger service), or sent by email or facsimile and also mailed first class, postage prepaid, by certified mail, return receipt requested, in all cases addressed to:

If to Executive:

At Executive's last known address evidenced on the Company's payroll records or email address evidenced on the Company's records.

If to the Company:

GRAIL, Inc.

1525 O'Brien Drive

Menlo Park, CA 94025

Attention: Abram Barth

**PLEASE READ THIS AGREEMENT CAREFULLY. THIS AGREEMENT CONTAINS A RELEASE OF ALL KNOWN AND UNKNOWN CLAIMS. EXECUTIVE AGREES TO THE TERMS OF THIS AGREEMENT AND VOLUNTARILY ENTERS INTO IT WITH THE INTENT TO BE BOUND HEREBY.**

If the above accurately reflects Executive's understanding, please date and sign the enclosed copy of this Agreement in the places indicated below and return that copy to Abram Barth (abarth@grailbio.com) by March 31, 2026.

Dated: March 11, 2026 Robert Ragusa

/s/ Robert Ragusa

Dated: March 10, 2026 GRAIL, Inc.

/s/ Gregory Summe

Name: Gregory Summe

Position: Chair of the Board

**Schedule A**

*Permitted Outside Activities*

1. Service as a member of the board of directors of Twist Bioscience Corporation.

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-8 No. 333-280424) pertaining to the 2024 Incentive Award Plan and 2024 Employee Stock Purchase Plan of GRAIL, Inc.,
- (2) Registration Statement (Form S-8 No. 333-281890) pertaining to the 2024 Employment Inducement Incentive Award Plan of GRAIL, Inc.,
- (3) Registration Statement (Form S-8 No. 333-285580) pertaining the 2024 Employee Stock Purchase Plan of GRAIL, Inc.,
- (4) Registration Statement (Form S-8 No. 333-287266) pertaining to the 2024 Employee Inducement Incentive Award Plan of GRAIL, Inc., and
- (5) Registration Statement (Form S-3ASR No. 333-291503) and related Prospectus of GRAIL, Inc.;

of our report dated March 12, 2026, with respect to the consolidated financial statements of GRAIL, Inc. included in this Annual Report (Form 10-K) of GRAIL, Inc. for the year ended December 31, 2025.

/s/ Ernst & Young LLP

San Mateo, California

March 12, 2026

**CERTIFICATION**

I, Robert Ragusa, certify that:

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

Date: March 12, 2026

/s/ Robert Ragusa

Robert Ragusa  
Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION**

I, Aaron Freidin, certify that:

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

Date: March 12, 2026

/s/ Aaron Freidin

Aaron Freidin  
Chief Financial Officer  
(Principal Financial Officer)

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

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

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 12, 2026

/s/ Robert Ragusa

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Robert Ragusa  
Chief Executive Officer  
(Principal Executive Officer)

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

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

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 12, 2026

/s/ Aaron Freidin

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Aaron Freidin  
Chief Financial Officer  
(Principal Financial Officer)