LEVI & KORSINSKY, LLP
Adam M. Apton (SBN 316506)
1160 Battery Street East, Suite 100
San Francisco, CA 94111
Tel: (415) 373-1671
Email: aapton@zlk.com

Counsel for Plaintiff

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

WILLIAM ROBBINS, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

v.

GRAIL, INC., ROBERT P. RAGUSA, JOSHUA J. OFMAN, and HARPAL S. KUMAR,

Defendants.

Case No.

CLASS ACTION

COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

DEMAND FOR JURY TRIAL

Plaintiff William Robbins ("Plaintiff"), individually and on behalf of all other persons similarly situated, by his undersigned attorneys, alleges in this Complaint for violations of the federal securities laws (the "Complaint") the following based upon knowledge with respect to his own acts, and upon facts obtained through an investigation conducted by his counsel, which included, *inter alia*: (a) review and analysis of relevant filings made by Grail, Inc. ("Grail" or the "Company") with the United States Securities and Exchange Commission (the "SEC"); (b) review and analysis of Grail's public documents, conference calls, press releases, and stock chart; (c) review and analysis of securities analysts' reports and advisories concerning the Company; and (d) information readily obtainable on the internet.

Plaintiff believes that further substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery. Most of the facts supporting the allegations contained herein are known only to the defendants or are exclusively within their control.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired Grail common stock between May 13, 2025, and February 19, 2026, inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws (the "Class").

2. Defendants provided investors with material information concerning the likelihood of success of Grail's NHS-Galleri trial achieving its primary endpoint of a statistically significant reduction in Stage III & IV cancers. Defendants' statements included, among other things, confidence in the success of Galleri, consistently promoting its effectiveness "in the real world" and the positive predictive value ("PPV") observed in the Pathfinder studies and in NHS-Galleri's top-line results as sources of confidence for its potential. Defendants further routinely touted the design of the NHS-Galleri and how three years were necessary to demonstrate the achievability of the primary endpoint.

3. Defendants provided these overwhelmingly positive statements to investors while, at the same time, disseminating materially false and misleading statements and/or concealing

material adverse facts concerning the true state of Grail's NHS-Galleri trial following the reveal of the top-line results covering the first screening round. Notably, as Defendants have since attested, the trial as executed within the three-year follow-up period was insufficient to demonstrate the achievability of a reduction in Stage III-IV cancers; Defendants disclosed the trial period, and thus the screening duration, was apparently insufficient to demonstrate whether the primary endpoint was achievable. Defendants further repeatedly refused to provide detailed top-line results or other data from the NHS-Galleri study, potentially concealing known trendlines which arguably suggested either a longer timeline would be necessary or otherwise that the probability of achieving the statistical reduction in Stage III & IV cancers by the trial's end had been reduced.

4. On February 19, 2026, Grail announced that the "primary endpoint of statistically significant Stage III-IV reduction was not observed" in the NHS-Galleri Trial. The Company attributed this shortcoming, in part, on "probably need[ing] a longer follow-up time to be able to [compare the study arms] adequately."

5. Investors and analysts reacted immediately to Grail's revelation. The price of Grail's common stock declined dramatically. From a closing market price of $101.53 per share on February 19, 2026, Grail's stock price fell to $50.21 per share on February 20, 2026, a decline of about 50.55% in the span of just a single day.

JURISDICTION AND VENUE

6. Plaintiff brings this action, on behalf of himself and other similarly situated investors, to recover losses sustained in connection with Defendants' fraud.

7. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. §78aa.

9. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b), as Defendant Grail is headquartered in this District and a significant portion of its

business, actions, and the subsequent damages to Plaintiff and the Class, took place within this District.

10. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

THE PARTIES

11. Plaintiff purchased Grail common stock at artificially inflated prices during the Class Period and was damaged upon the revelation of the Defendants' fraud. Plaintiff's certification evidencing his transaction(s) in Grail is attached hereto.

12. Grail, Inc. is a Delaware corporation with its principal executive offices located at 1525 O'Brien Drive, Menlo Park, California 94025. During the Class Period, the Company's common stock traded on the NASDAQ Stock Market (the "NASDAQ") under the symbol "GRAL."

13. Defendant Robert P. Ragusa ("Ragusa") was, at all relevant times, the Chief Executive Officer and Director of Grail.

14. Defendant Joshua J. Ofman ("Ofman") was, at all relevant times, the President of Grail.

15. Defendant Harpal S. Kumar ("Kumar") was, at all relevant times, the Chief Scientific Officer and International President of Grail.

16. Defendants Ragusa, Ofman, and Kumar are sometimes referred to herein as the "Individual Defendants." Grail together with the Individual Defendants are referred to herein as the "Defendants."

17. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Grail's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. Each Individual Defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the

ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of these Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

18. Grail is liable for the acts of the Individual Defendants, and its employees under the doctrine of respondeat superior and common law principles of agency as all the wrongful acts complained of herein were carried out within the scope of their employment with authorization.

19. The scienter of the Individual Defendants, and other employees and agents of the Company are similarly imputed to Grail under respondeat superior and agency principles.

SUBSTANTIVE ALLEGATIONS

A. Company Background

20. Grail is a commercial stage healthcare company with a focus on early cancer detection through screening methodology.

21. The Company developed a multi-cancer early detection test, "Galleri," which is the analysis of a blood sample designed to screen for a multitude of cancers, pinpoint the organ or tissue type of origin, and assist in the screening process.

22. Pertinently, one of Grail Galleri trials was the "NHS-Galleri trial," the primary objective of which was "to show a reduction in late-stage (III-IV) cancers in people who received the Galleri test compared with those who did not."

23. On May 29, 2024, Grail updated investors on its efforts to attain an accelerated implementation of its test as a national screening program through the NHS: "Based on a snapshot of first-year results from the ongoing NHS-Galleri trial, NHS England has decided to await final results from the three-year trial before determining whether to initiate a pilot of the Galleri test in the NHS."

B. The Defendants Materially Misled Investors Concerning NHS-Galleri's Potential to Achieve its Primary Endpoint

May 13, 2025

24. On May 13, 2025, Defendants issued a press release reporting first quarter fiscal 2025 financial results. As part of the release, Defendants further announced "Positive Top-Line Results from the Prevalent Screening Round of the NHS-Galleri Trial," in pertinent part as follows:

> GRAIL recently completed a review of Galleri test performance results in the intervention arm from the prevalent screening round of the registrational NHS-Galleri trial. ***The prevalent screening round is the first round of blood draws (of the three total blood draw rounds in the trial) with one year of follow up.***
>
> ***Data from the prevalent screening round showed a substantially higher positive predictive value (PPV) than that observed in the PATHFINDER study***, which was previously published in *The Lancet*. ***Cancer signal of origin (CSO) accuracy and specificity were consistent with that observed in the PATHFINDER study***. In PATHFINDER, Galleri demonstrated a PPV of 43%, CSO accuracy of 88%, and specificity of 99.5%. There were no serious safety concerns in the NHS-Galleri prevalent screening round, also consistent with the PATHFINDER study.
>
> . . .
>
> ***The NHS-Galleri trial was designed with three consecutive years of screening in order to achieve the primary endpoint, which is the absolute reduction in the number of late stage (stages 3 and 4) cancer diagnoses***. Final clinical utility results from all three years of the trial are expected in mid-2026. GRAIL plans to submit data from the prevalent screening round of the NHS-Galleri trial as part of our premarket approval application in the first half of 2026.

(Emphasis added).

25. Defendant Ragusa was further quoted in the release, indicating the company was "very pleased with these initial results from the NHS-Galleri trial," and reminded investors that the final results were expected in mid-2026.

26. During the contemporaneous earnings call, Defendant Kumar elaborated further on the top-line results, providing, in pertinent part, the following:

> I'm pleased to share high-level Galleri test performance results from the intervention arm of the prevalent screening round of our 140,000 participant 3-year NHS-Galleri registrational trial. The prevalent screening round was the first round of blood draws with 1 year of follow-up.

> ***We were pleased to see a substantially higher PPV than the 43% observed in the PATHFINDER study. We also saw specificity and cancer signal of origin or CSO, consistent with our PATHFINDER study, which was an interventional return of results study evaluating the performance of Galleri***.
>
> . . .
>
> As a reminder, Galleri demonstrated specificity of 99.5% and a CSO accuracy of 88% in PATHFINDER. There were no serious safety concerns in the NHS-Galleri prevalence screening round, also consistent with the PATHFINDER study. As Bob mentioned, ***the top line results from the prevalent screening round of the NHS-Galleri trial are very encouraging***. Results of all the 3 years of the trial are expected in mid-2026. These longitudinal results will be the first clinical utility results of their kind in the MCED field.
>
> The NHS-Galleri trial was designed as 3 annual blood draws plus 12 months of follow-up in order to evaluate Galleri's ability to diagnose cancer at an earlier stage relative to standard of care. ***Cancer screening trials designed to show clinical utility are commonly conducted over 3 or more years using an annual screening interval. Because if screening is only conducted once, results can be influenced by the fact that the first screening round, detects many prevalent late-stage asymptomatic cancers that have not yet been diagnosed. This and other factors are likely to cause final results of the 3-year trial to differ from a review of the first round results***.

(Emphasis added).

27. Defendant Ofman further positively promoted the results and highlighted that the drug "is working," suggesting the NHS-Galleri trial was on track for a positive result.

> Now let's be clear, ***Galleri is working in the real world***. ***We are detecting clinically meaningful cancers and early-stage cancers in asymptomatic adults***.
>
> ***Our signal detection rate in commercial use is very much in line with what we expected based on our prior clinical studies***. The majority of the early-stage cancers Galleri has found are in cancer types where a recommended screening test does not even exist, thereby allowing patients an opportunity to access more effective and even curative treatments.
>
> Now we've described over time the key performance metrics, features and capabilities for multi-cancer early detection tests, which importantly are quite different from those for single cancer screenings. ***Positive predictive value or PPV is a key metric, which discerns among positive test results, how many are true positives***. Specificity, critically important, defines the false positive rate, a very low false positive rate helps reduce unnecessary workups and their associated costs and contribute to driving a high positive predictive value. Our demonstrated specificity at 99.5% equates to a false positive rate of 0.5%.

. . .

> ***Galleri indeed identified cancers across this large intended use population, including early-stage cancers and cancers without recommended screening***. Generally, the test performance in this real-world setting remain consistent with what we've consistently observed in our prior clinical studies.

(Emphasis added).

28. A question-and-answer segment followed the Defendants' prepared remarks on the call. During the following pertinent exchanges, Defendants expanded upon the results and repeatedly reminded investors the second and third screening rounds were where the key primary endpoint of reduced late-stage cancer diagnoses could be analyzed and, to ensure the "integrity" of the trial, Defendants were withholding detailed data, in pertinent part:

> <Q: Tejas Savant – Morgan Stanley – Senior Healthcare Equity Analyst> So the intervention arm from the NHS-Galleri, that data that you just shared. How should we be thinking about the read across from that to your next year's final NHS-Galleri readout, like particularly in terms of that higher PPV you highlighted? And can you put a finer point on when in the second half of the year, we can expect PATHFINDER 2 data?
>
> <A: Robert P. Ragusa> Yes. So on the second question, we're looking to mid next year to have the readout on the full 3-year study. We also have Harpal on the call today. So Harpal, maybe answering the first part of that question.
>
> <A: Harpal S. Kumar> Yes, sure. Thank you for the question. So look, the -- it's important just to reiterate that ***the results we've shared today are from the first screening round only. And as we've tried to describe, it's really important that the first round of a screening program, what you typically see is that you are finding a lot of prevalent cancers in the population that have not yet been diagnosed***. They are asymptomatic, but they can often be very late stage. And so as we go through to the second and third rounds, and those prevalent cancers in the population have already been diagnosed, ***we would expect to see some differences in the second and third round as indeed has other screening programs in the past. But we're not in a position today to be able to predict what those results will be***. But we will have those results in mid-'26.
>
> . . .
>
> <Q: Kyle Alexander Mikson – Canaccord Genuity Corp. – Director & Senior Equity Research Analyst> Just on NHS first, just given the data here and the partnership in the study keep progressing. How are the recent conversations with NHS going? And do you -- what do you expect they're going to do, I guess, with Galleri commercialization in the country following the full readout in 2026.

And then secondly for maybe Harpal, on the PPV for the subset here that you provided, is that like a modeled number? Or is that like a concrete metric? I just want to kind of understand if it's like how the number should be used, and if it's like -- how materially higher it is compared to like PATHFINDER, for example?

<A: Robert P. Ragusa> Harpal, you want to take?

<A: Harpal S. Kumar> Yes, sure. Thanks, Bob. So let me quickly take the second question first. So when we say the PPV was substantially higher in the first round, that's a concrete number. ***We're not sharing what that number is, but we can say it's substantially higher than the 43% that we saw in PATHFINDER***. So it's not a modeled number.

With respect to the conversations with the NHS, I mean, just to say that we are in constant dialogue with the NHS and with the national screening committee in the U.K. and with the government in the U.K., ***they are clear that they want to wait to see final results from all 3 rounds of the study before they will make a decision as to if and when to roll out a screening program in the U.K. or in England particularly***. So I can't give you anything more concrete than that at this point, other than to say we're in constant dialogue.

<A: Robert P. Ragusa> Harpal, maybe go through a little bit of ***why not reveal the numbers right now?***

<A: Harpal S. Kumar> Yes, sure. So I mean, it's important to reiterate that the NHS-Galleri trial was designed as a 3-year screening study. In other words, we do 3 rounds of screening. And that's very common in screening trials and studies of screening because for the reasons that I stated earlier on the call, ***if you only look at one round of screening, then what you'll typically find in that first round is a lot of prevalent asymptomatic cancers in the population, which can often be late stage, but haven't yet been diagnosed***.

By going to a second and third round, you start to see what the impact of a, if you like, a more established or steady-state screening program might be. And so it's ***really important that we safeguard those upcoming readouts and the integrity of the trial as a whole. It's also really important that we safeguard the interest of the participants taking part in the trial. And so for all of those reasons, we're not sharing more detailed information at this stage***, but we are now getting closer to having the final results middle of next year, and we look forward to sharing all of those, both with all of you, but also with the NHS at that time.

(Emphasis added).

August 12, 2025

29. On August 12, 2025, Defendants published their second quarter results and again conducted an associated earnings call. During the call, Defendant Ofman briefly discussed the NHS-Galleri study, stating, in pertinent part:

> You will recall in May that we completed a review of Galleri test performance results in the intervention arm from the prevalent screening round of the registrational NHS Galleri trial. ***Data from the prevalence screening round showed a substantially higher positive predictive value than that observed in the first PATHFINDER study***. Specificity and CSO accuracy were consistent with that observed in the first PATHFINDER study. And again, there were no serious safety concerns observed in PATHFINDER 2, also consistent with the first PATHFINDER study. ***These top line findings from NHS Galleri and PATHFINDER 2 confirm and extend what we already know about our multi-cancer early detection technology***. The technology has been validated through many robust studies, including intended-use populations and through hundreds of thousands of commercial and clinical study test results showing very consistent results.

(Emphasis added).

30. Defendant Kumar then elaborated on the specifics of the primary endpoint of the study, confirming it was initially powered to "deliver a statistically significant result" in the time provided for the study while simultaneously omitting any new information Defendants learned in the time since creation of the trial and particularly following Grail's internal review of the concealed first round screening results, in pertinent part, as follows:

> <Q: Yuko Oku – Equity Analyst> Great. And if I could squeeze 1 more in, if I may. Could you elaborate on the statistical powering of the NHS Galleri study? What difference is the [trial powered] to detect on the primary endpoint of reduction in the incidence of late-stage cancer versus the control arm? And what result will be viewed as meaningful benefit?
>
> . . .
>
> <A: Harpal S. Kumar> Yes. Sure. So I mean the study is powered to show a significant reduction in late-stage cancer. So we -- the primary endpoint is a reduction in Stage III and IV cancers. And we look first at the 12 cancers that represent about 2/3 of all cancer mortality and then we go on to look at all cancers from there. So we will be looking at that late-stage reduction. We don't have a specific reduction in mind, but it's -- ***but the size of the study was set to be able to deliver a statistically significant result in terms of that reduction. So we will see what that reduction ends up being***. We're interested, obviously, both in reduction of Stage III and IV cancers, but also Stage IV cancers because ultimately, people

> primarily die of Stage IV cancer. ***So if we can see significant reductions in those late-stage cancers, we believe this will provide substantial benefit to the population***.

(Emphasis added).

31. Defendants further promoted the upcoming NHS-Galleri final readout as a key entry point for the company's position in the global market in the following pertinent exchange:

> <Q: Colleen Wohlrab Babington – Wolfe Research LLC – Research Analyst> This is Colleen on for Doug. As the NHS data reads out next year, we think that could serve as a strong evidence package for other international opportunities with single-payer systems. How are your conversations with territories across the globe looking deploy Galleri?
>
> Also, if international volume grows sufficiently, will you have to do a tech transfer to international labs?
>
> <A: Robert P. Ragusa> Yes, it's a great question. So ***we get a tremendous amount of inbound interest, as you can imagine, from around the globe***. And with that, we've had numerous conversations. We also believe, as you rightly pointed out that in middle of next year, from an efficiency standpoint, effectiveness standpoint, ***in the middle of next year when we read out the NHS Galleri study, we think that's going to be a great calling card to really have significant discussions with a lot of countries around the globe***, both due to just the sheer size of the study, but also the rigor and reputation those studies done on the NHS. I think that reputational advantage will go a long way as we have those conversations.
>
> Harpal, anything you want to add with that?
>
> <A: Harpal S. Kumar> I think you've largely covered it, Bob. I mean as you said, this is a ***very large study conducted extremely well*** in a health system that is very well respected around the world. So we fully expect that the results from this study will be and are being observed by countries right across the world. We're getting, as Bob said, a lot of inbound interest from pretty much every country around the world, and ***we expect that the results in the middle of next year will provide us with the data to really turn those conversations into meaningful opportunities as we look forward.*** And as you alluded to, ***should give us a substantial growth opportunity as we look forward***.

(Emphasis added).

September 9, 2025

32. On September 9, 2025, Defendant Ragusa presented on behalf of Grail as the Morgan Stanley 23rd Annual Global Healthcare Conference. During the interview, Defendant

Ragusa provided some brief updates and reminders as to the timing and importance of the final readout for NHS-Galleri, in pertinent part, as follows:

> <Q: Yuko Oku – Morgan Stanley – Equity Analyst> Okay. To start, could you provide a quick overview of GRAIL's mission for folks that are not as familiar with the story? And what are you focused on over the next 12 months?
>
> <A: Robert P. Ragusa> . . . And so what we're looking forward to the next 12 months. So we've just read out over the summer, our NHS Galleri study, where we found substantially higher positive predictive value than PATHFINDER. So PATHFINDER [was] already at 43%. In our PATHFINDER-2 study, we gave the top line results, again, substantially higher positive predictive value and higher cancer detection rate. And in both studies, the specificity or false positive rate was consistent as well as the cancer signal of origin accuracy was very consistent and no adverse events in those studies.
>
> So we're really looking forward to it. We submitted and are hopeful we'll be able to present at ESMO in October with our PATHFINDER-2 full data readout. And then in the middle of next year, the full readout on the NHS Galleri study. So again, PATHFINDER-2 was 35,000 people and NHS Galleri 140,000 people. So large studies. And then the other big thing next year is we're looking in the first half of 2026 to submit our final module for our PMA to the FDA.
>
> . . .
>
> <Q: Yuko Oku – Morgan Stanley – Equity Analyst> So I want to jump into NHS Galleri. You shared top line results from NHS Galleri trial as well, which also showed substantially higher PPV in the first round of blood draws than observed in PATHFINDER, though PPV may decline in the subsequent blood draws. Similar to the question on PATHFINDER-2, are there any key differences in the population enrolled in NHS Galleri, or is -- or its design that may have driven PPV higher than in the PATHFINDER?
>
> <A: Robert P. Ragusa> Yes, it's a good question. So in NHS Galleri, similar to PATHFINDER-2, we went to extraordinary lengths to make sure that we had a population that was representative of the U.K. So we looked across ethnicity to make sure we had the match ethnicity mix as well as socioeconomic scale. So in the U.K., they actually have scales for in quadrants. And so we made sure those all match. So we're very comfortable that the population is very representative, likely one of the things that changed the incidents that would have impacted the PPV.
>
> Anytime you have that culling effect in the first round, you could have an impact on PPV as you go into future rounds. That's definitely a possibility. But ***the important element within the NHS Galleri that sets us aside is an interventional longitudinal 3-year study with a year of follow-up. So it's actually looking for clinical utility. So we're looking for stage shifts, so reduction in late-stage cancers in the intervention arm compared to the control arm. So look at Stage 3 and 4 reduction versus the control arm*** as well as the Stage 4 reduction versus the control

> arm. ***So we should be able to get a measure of clinical utility out of that.*** And that will all come out in the middle of next year.
>
> . . .
>
> <Q: Yuko Oku> Great. And then just in the last couple of minutes here, I want to wrap up with a bigger picture question. What about GRAIL's story do you feel is underappreciated by investors?
>
> <A: Robert P. Ragusa> Yes. So I think -- I'm not sure about underappreciated, but if we look -- if we kind of just look to the future, one of the big things we have coming out is what we've already done in terms of GRAIL being the only NSAID with demonstrated capability in the intended-to-us population of people being screened for cancer. We have -- mid next year, we have the readout on clinical utility. ***So it will be great to see out of the NHS Galleri study, the clinical utility. We'll be in process of FDA approval. So we submit in the first half of next year. We expect about a 1-year process for that to get the FDA approval.***

(Emphasis added).

October 20, 2025

33. On October 20, Defendants conducted a special call to largely discuss results of a distinct Galleri study, Pathfinder 2. During the question-and-answer segment, Defendants briefly discussed how Pathfinder 2's success increases their confidence in a positive output for the NHS-Galleri study in response to the following pertinent inquiry:

> <Q: Douglas Anthony Schenkel – Wolfe Research, LLC – MD, Senior Research Analyst, and Head of Life Science & Diagnostic Tools> A few topics, on clinical utility, as we've seen in the past, FDA approval does not always translate to CMS reimbursement. Ultimately, the key dynamic will be likely stage shift, as you acknowledged in your prepared remarks as a proxy for survival benefit. Is there anything in PATHFINDER 2 that makes you more comfortable about a positive outcome on this metric when we head to NHS Galleri? Or ultimately, do we just need to wait for the readout?
>
> And building off of that, given FDA requirements outlined at the FDA panel on MCED in 2023, what boxes have you checked with the FDA and what remains to be done? So essentially trying to get at the clinical utility question, which would be key to reimbursement and then separately, the regulatory question in the U.S. with the FDA.
>
> <A: Joshua J. Ofman> No. Doug, really good questions. Let's take the clinical utility one first. There's nothing directly that can be inferred from the PATHFINDER 2 study to the stage shift or the reduction in late-stage detection. That is the primary endpoint of the NHS Galleri, but ***there are many aspects of***

PATHFINDER 2 that give us more confidence in the overall performance of Galleri. And those specifically are the dramatically increased cancer detection rate when added to standard of care screening, and secondly, the much higher PPV that we've been observing as well as the episode sensitivity, which is quite high.

For those of you who may not have been following this, when case-controlled studies report high sensitivity, they very rarely translate into that level of performance in actual interventional studies, and we've seen that even in the MCED field with the one interventional study that was done in 65-year-old women, where the performance of the assay from the case-control study simply did not come close to replicating. So we're very pleased with that episode sensitivity, those numbers coming out of PATHFINDER 2 relative to what we had seen in prior studies.

So I think those three things together, Doug, ***give us a lot of confidence in the performance, but they don't directly speak to stage shift or the reduction in late-stage cancer because that will much more be related to the case mix of cancers in that individual study and the stage distribution in that individual study***.

I'll turn it over to Harpal in a minute to comment more on the NHSCU. But on the FDA, based on the 2023 panel, it became -- it was quite clear what the FDA said in respect to the meaningful necessity of having the CSO directed workup. And given what we've seen now with Galleri and PATHFINDER 2 with very high CSO accuracy and very rapid diagnostic resolution, we feel really confident about that finding.

The other thing the FDA emphasized was the false positives being one of the biggest harms related to screening. And with our 0.4% false positive rate, we feel very good about that. And the other thing they mentioned, of course, as it relates to safety, was the over-diagnosis. And we've published now multiple times that low shedding tumors that are indolent are not typically detected well by Galleri. So Galleri is very unlikely to contribute to the problem of overdiagnosis of indolent cancer. So on those three dimensions, we feel very good. And then I'll ask Harpal to comment more on the clinical utility question.

<A: Harpal S. Kumar> Yes. I mean I think you've largely covered it, Josh. But you're right, Doug, that ***your primary endpoint in NHS Galleri will be looking at that reduction of late-stage cancers. And in order to find a reduction, you have to have a randomized controlled trial***. And that's, of course, what an NHS Galleri is.

I think just to add one point to what Josh said, one of the things that encourages me greatly from PATHFINDER 2 is that more than half of the cancers were found at stages 1 and 2. And that's in a cohort of cancers where 3/4 are currently unscreened. And so ***I think to the extent that you can take any guidance from a study that doesn't have a comparator arm, I think those points really do encourage me as well***.

(Emphasis added).

November 12, 2025

34. On November 12, 2025, Defendants conducted an earnings call corresponding to the release of Grail's third quarter results. Pertinently, while Defendant Ofman briefly addressed the NHS-Galleri study by reminding investors of the high PPV finding in the previously released top-line results.

> Our PMA submission will include these data from the first 25,000 enrolled in PATHFINDER 2 to complete 12 months of follow-up, plus findings from the prevalent round of screening from the NHS Galleri randomized clinical trial as well as the results of a bridging study between the version of Galleri used in the 2 registrational trials to the updated version that we plan to submit to the FDA for premarket approval.
>
> As a reminder, ***we announced positive top line results from the prevalent round of screening in the NHS Galleri trial in May*** of this year, namely that data from the prevalent screening round ***showed a substantially higher positive predictive value than that was observed in the first PATHFINDER study***.

(Emphasis added).

35. During the question-and-answer segment, Defendant Kumar discussed the purpose behind the NHS-Galleri study and the NHS' own previous determination to await full results. In pertinent part, Defendant Kumar reiterated to investors that the reduction of stage 3 and 4 cancers could not be "look[ed] at" as a preliminary metric and similarly would not be shared with the public until such time:

> <Q: Douglas Anthony Schenkel – Wolfe Research, LLC – MD, Senior Research Analyst and Head of Life Science & Diagnostic Tools> So I want to actually talk about NHS England a little bit more, and then I have a COGS-specific question. So starting on NHS England, looking back to May 2024, when the statement was issued saying that early results were not compelling enough to justify a large-scale pilot, were they referring to any clinical utility data from year 1 or to test level performance metrics such as PPV, sensitivity and/or specificity? Can you share a little bit more on what prompted that decision?
>
> And then on the same topic, has anyone besides GRAIL and the NHS evaluation team seen the year 1 NHS Galleri data. I'm just curious if anyone else has seen it? And then if not, at what venue do you anticipate releasing that data more broadly, keeping in mind that you've said the FDA module submission is expected to be, I think, completed in Q1. So it would seem like that data would need to be released soon.

. . .

<A: Harpal S. Kumar> Sure. Thank you, Doug. So on NHS England's decision last year, important to reiterate that what they would have wanted to see in order to initiate a pilot at that stage was very exceptional data. And they looked at a few specific metrics, of which PPV was definitely one. ***To remind everyone, it isn't possible to look at the sort of broad utility measure of Stage 3 and 4 reduction with only 1 year of data. That has to come with 3 years of data***. But PPV was certainly one. And you'll have seen our announcement earlier this year that the PPV in that first round was substantially greater than we saw in our first PATHFINDER study, which to remind everyone was 43%.

So ***it gives you a sense of some of the information that was seen at the time. But again, to reiterate what the NHS would have wanted to see was truly exceptional data in order to accelerate*** -- and the point is they were looking about an acceleration of an implementation rather than waiting until the final study results. And what they said at the time was, ***it wasn't exceptional enough to accelerate that implementation*** and so that they wanted to wait for the final study results.

In answer to your second question, no, ***only the NHS evaluation team have seen that data so far***.

To the third question, yes, it will be the data from the prevalent round only from the intervention arm will be part of our FDA PMA submission package in Q1 next year, but ***that does not mean it will be in the public domain at that point. There won't be any data in the public domain from NHS Galleri until we have the final study results.***

(Emphasis added).

November 13, 2025

36. On November 13, 2025, Defendants conducted their annual Analyst/Investor Day call. During the call, investors heard prepared remarks from Peter Sasieni, a member of the Grail Advisory Board, who provided some additional details regarding the study design of NHS-Galleri, in pertinent part:

So the ***main endpoint is a reduction in advanced stage cancer. And this is a little bit controversial***, so I want to talk about it a little bit. And the first is that I think it's really important to think about causal reasoning. Much of my career, I worked on cervical cancer, HPV vaccination. So I want to talk about that for a minute. We now know that cervical cancer is caused by HPV infection.

If you have a persistent infection, it can start to lead to a precancerous lesion, cervical neoplasia. If that's not treated, it can go on and to become invasive cervical

> cancer. And if you had a cervical cancer and you didn't treat it or even if you did, you can get death from cervical cancer. If you can prevent the infection, you'll be able to prevent the death of cervical cancer.
>
> No one said that you had to wait and show a reduction in mortality from cervical cancer in order to introduce HPV vaccination. And in fact, it was only 17 -- no, slightly less, about 15 years after we introduced HPV vaccination that we were able to show a reduction in cervical cancer as a result of that vaccination. Similar arguments go for cancer screening. ***Cancer progresses through stages. For most cancers, prognosis gets substantially worse for the more advanced stages. If you find a cancer earlier, screening will lead to fewer advanced stage cancers*** than the -- because the advanced stage cancers have substantially worse prognosis, you're going to likely to reduce cancer-specific mortality.
>
> . . .
>
> So how are we doing this? So first of all, we're going to test for a reduction in Stage II and Stage IV cancers from these 12 prespecified cancers that account for 2/3 of cancer mortality in the U.S. and the U.K. If that's significant, the result is significant. The trial has shown that it can reduce advanced stage cancers from these 12 types. But if it is, we want to look further, does it have an effect on other types than the -- other than 12 types or does it have an effect overall.

(Emphasis added).

37. The above statements in Paragraphs 24 to 36 were false and/or materially misleading. Defendants created the false impression that they possessed reliable information pertaining to the probability of achieving the primary endpoint of a statistically significant reduction in Stage III-IV cancers in the Company's NHS-Galleri trial, while also concealing material adverse facts which reduced the possibility of such an outcome. In truth, Grail's optimism in achieving the primary endpoint of its NHS-Galleri study fell short of reality; the confidence management provided in light of the "Positive Top-Line Results" from the trial's first screening round and the Pathfinder studies was misplaced and ignored potential trendlines in unreleased top-line data and other information learned since the inception of the study that suggested three years would be less sufficient than previously though to demonstrate the achievability of the primary endpoint.

C. The Truth Emerged When Grail Disclosed Top-Line Results of the NHS-Galleri Trial during its Q4 2025 Earnings Call

February 19, 2026

38. On February 19, 2026, Defendants issued a release reporting on the results of the "Landmark NHS-Galleri Trial." While Defendants elected to title the release positively, indicating the trial "Demonstrates a Substantial Reduction in Stage IV Cancer Diagnoses, Increased Stage I and II Detection of Deadly Cancers, and Four-Fold Higher Cancer Detection Rate," the trial ultimately failed to achieve its primary endpoint. In pertinent part, the release provided:

> The primary endpoint of statistically significant Stage III-IV reduction ***was not observed***. However, there was a favorable trend toward fewer Stage III-IV cancers in a pre-specified group of 12 deadly cancers* in the intervention arm after the prevalent screening round.

(Emphasis added).

39. Despite the release confirming that the "primary objective" of the trial was "to show a reduction in late-stage (III-IV) cancers in people who received the Galleri test compared with those who did not," none of the individual quoted in the release discussed the primary endpoint miss.

40. Contemporaneous with the trial results, Defendants announced fourth quarter and full year 2025 results. In pertinent part, the quarterly release reiterated that the NHS-Galleri trial failed to achieve its primary endpoint and described the results as follows:

> Announced topline results from the landmark, randomized, controlled NHS-Galleri trial, which evaluated annual screening with the Galleri® test in England's National Health Service (NHS) over three years in 142,000 demographically representative participants aged 50 to 77. The results show that adding Galleri to standard of care screening resulted in a substantial reduction in Stage IV cancer diagnoses, increased Stage I and II detection of deadly cancers, and four-fold higher cancer detection rate when compared to standard of care alone. ***While there was a trend towards reduction in combined Stage III and IV, the trial did not meet the primary endpoint of a statistically significant reduction.***

(Emphasis added).

41. An earnings call was conducted to discuss both of the releases, including the key primary endpoint miss, of the NHS-Galleri study. In pertinent part, Defendant Ragusa summarized the reveal as follows, stating:

> We issued a press release this afternoon with top line results from our NHS-Galleri trial. We observed a substantial reduction in Stage IV cancer diagnosis, increased Stage I and II detection of deadly cancers and a fourfold higher cancer detection rate, outcomes that matter for patient care.
>
> While there was a trend towards reduction in combined Stage III and IV, ***the trial did not meet the primary endpoint of statistically significant reduction***. These data show the benefit of multi-cancer screening with Galleri and provide the strongest evidence for the recommended annual screening interval. Harpal will talk through the top line NHS-Galleri trial results shortly.

(Emphasis added).

42. Defendant Kumar then provided his prepared remarks, providing more detail as to the results of the study, in pertinent part, as follows:

> Detailed results from the NHS-Galleri trial will be submitted for presentation at the upcoming ASCO meeting in Chicago in late May. ***The design of the NHS-Galleri trial was informed by a large body of evidence showing that across multiple cancer types, reductions in late-stage disease are strongly associated with reductions in cancer mortality***. While ***we did not observe a statistically significant reduction in combined Stage III and IV cancers through the trial, which was the primary endpoint of the study***, there was a favorable trend after the prevalent screening round, and we saw compelling evidence of Galleri's benefit.
>
> Comparing the two arms of the study, Stage IV diagnoses in the prespecified group of 12 deadly cancers decreased with each year of sequential Galleri screening, with a greater than 20% reduction in the second and third rounds. Similar reductions were observed across all cancers. The reduction in Stage IV cancer diagnoses is a critically important outcome, which we believe can lead to more effective intervention for patients, particularly given the substantial and growing arsenal of effective treatments for many Stage III cancers. In fact, there is a dramatic improvement in survival for many types of cancer at Stage III as compared with Stage IV.
>
> These results are the first time a multi-cancer early detection test has demonstrated population scale stage shift and reduction in metastatic disease in a randomized trial. Screening with Galleri increased the overall cancer detection rate fourfold compared to standard of care and identified substantially more Stage I and II cancers in types that are typically detected at late stage.
>
> Screening with the Galleri test also resulted in a substantial reduction in the number of cancers detected clinically through emergency presentation, which are associated

> with significantly higher mortality and health care costs. And these benefits came with a strong safety profile. No serious safety concerns were reported in any of the approximately 70,000 participants who received the Galleri test across 3 rounds of testing.

(Emphasis added).

43. During the question-and-answer period of the call that followed, Defendants discussed the significance of the results of the NHS-Galleri study, regulatory hurdles, and provided retrospective analyses of the study design during the following pertinent exchanges:

> <Q: Douglas Anthony Schenkel – Wolfe Research, LLC – MD, Senior Research Analyst and Head of Life Science & Diagnostic Tools> I'll try to get them all out there upfront and then listen. So first, really a follow-up to the very first question, and I think it's the most important question tonight given the stock reaction in the aftermarket. So I want us to be airtight on this. Is the probability of FDA approval unchanged as a result of the NHS-Galleri readout? Because if the answer is, the probability is unchanged, it would mean the value associated with FDA approval and by extension, CMS reimbursement is also unchanged. So that's the first question. Yes or no, has the probability not changed?
>
> The second question is on NHS coverage in the U.K. I know, again, you just got a question on this, but I'm curious if there are any examples you can point to where a diagnostic has been reimbursed after missing a primary endpoint. And then my third question is, has your analysis of NHS-Galleri results led you to any explanation regarding why you came up short of the primary endpoint? Are there potential design issues or population SKUs, anything like that?
>
> <A: Robert P. Ragusa> Yes. Thanks, Doug. Maybe, Josh, I'll hand over to the FDA questions to you.
>
> <A: Joshua J. Ofman> Yes. Thanks for the question, Doug. Everything we've learned from the FDA, their history with us, our conversations has been, their focus is going to be on clinical performance and safety. And the data set that we are -- that we have submitted includes the full PATHFINDER 2 study of the first 25,000 participants and the first year, which is the performance period of the NHS Galleri trial.
>
> ***In their advisory board meetings and their public comments, they have been quite clear that their focus is on clinical validation and not clinical utility***. And what we've tried to demonstrate in the NHS trial is a population level effect well beyond clinical validation and clinical performance. And we were able to demonstrate a really important finding of a substantial reduction in Stage IV cancers and a fourfold improvement in the cancer detection rate. But those are things that are not part of our submission right now to the FDA. And based on their own comments, they're going to be focused on clinical validation.

. . .

<A: Harpal S. Kumar> So I think -- Doug, I think your second question was around endpoints on diagnostic studies. I think it's just worth pointing out that it's extremely rare for any diagnostic to go through a randomized controlled trial. It's very common for drugs to go through randomized controlled trials, but you actually very rarely see a diagnostic test evaluated in as rigorous a way as we have done through the NHS-Galleri trial. I just think it's really important to make that point.

Not only have we rigorously assessed it through an RCT, but it's enormously large trial, 142,000 people. So we have a data set the likes of which I am not aware any other diagnostic has been through other than sort of really significant interventional diagnostic type products. So I think that's the first thing to say.

The second thing to say is this is an enormously rich data set, and it has a large number of components to it, and we've shared those with you today. ***It's absolutely right to say we didn't hit the primary endpoint***. But what we did see was a very compelling clinical benefit here. And I think that story stands in terms of generating excitement out there in the clinical community around what's possible with a test like this. Being able to reduce Stage IV cancers gives clinicians the opportunity to use curative treatments that they otherwise wouldn't have the opportunity to use. So I think that's really very compelling.

And then your third question, I think, was about what are we learning looking at the data. And just a couple of comments on that. First of all, it's -- we've not had this data for very long. We're looking into it. ***There's a lot of data to work through. One of the things we've seen is that -- and if I break apart the primary endpoint, it's a combined Stage III and IV reduction. And so when you break that apart, we did see a Stage IV reduction. But as we've commented on, we saw an increase in Stage II cancers.***

And one of the things that looks to be the case when we look at the data is that we expect to see a stronger effect if we were to continue to follow up this cohort for a longer period of time. And that's why we're saying we want to extend the follow-up for a further 6 to 12 months, and that's why we'll be doing that. So that's one of the things that we've seen when we're looking at the data, but there's a lot more to learn.

. . .

<Q: Catherine Walden Ramsey Schulte – Robert W. Baird & Co. Inc. – Senior Research Analyst> I guess, first, just on that last point of extending the trial follow-up by 6 to 12 months. Is that something that you and NHS have already agreed on? And I guess, what is the goal of what you will see in that 6 to 12 months? Is it to push more on the Stage III reduction? Or is there something else that NHS is hoping to see?

. . .

<A: Harpal S. Kumar> Yes. Thanks, Catherine. We haven't discussed it in any detail with the NHS yet, but I think it's -- I really can't see any obstacles in being able to do that. What it requires is not going back to participants or clinicians. It would be a continuation of passive data collection, which is already being recorded. And so it's just about the passage of time and agreeing with the NHS team that we can get access to that data. I think that will -- I don't foresee any significant obstacles in that regard.

And in answer to your second question, yes, what we want to see is particularly the control arm data maturing more than we've been able to see. And perhaps if I just elaborate a little bit on that, what you tend to see in a screening trial -- in any screening trial is that you're finding cancers that would have been detected later. And so if you think about what that means in practice, you're pulling forward into your intervention arm cancers from the future.

For a control arm of the study, those cancers may not yet have manifested. So when you're comparing 2 arms of the study, what you'd like to have is long enough follow-up that you can compare the 2 arms really, really well together. And what ***we've concluded looking at the data is we probably need a longer follow-up time to be able to do that adequately***.

. . .

<Q: Daniel Gregory Brennan – TD Cowen – MD and Senior Tools & Diagnostics Analyst> And I mean if I can sneak in one final one. So the trial was set up for 3 years. Obviously, it was going to be a surrogate for mortality because mortality would just take too long. So I think that was pretty well established. Was there a decision when you set it up for 3 years as opposed to maybe setting it up with a longer follow-up period, kind of how that decision was made? Obviously, it sounds like now you're hoping, obviously, the longer follow-up will still prove out the study. But I'm just wondering when you went into it, how was that decision made?

<A: Harpal S. Kumar> Yes. I mean, look, as with any study, it's designed and sized and powered with the best information you have at the time. And at the time, we felt that 3 rounds of screening followed by a year of follow-up would be sufficient. ***I think with the benefit of hindsight, we probably should have allowed for a longer follow-up period***.

There have interestingly been a number of publications over the last couple of years about screening studies in general, not just about NHS-Galleri, which make this exact point that the trial should be followed up for longer than 12 months post the last appointment. ***As I say, this trial was designed 6 years ago, and that was the best information we had at the time.*** But as I've already touched on, on this call, we have the ability to continue follow-up. So that's what we're going to be doing.

<A: Joshua J. Ofman> And it's probably just worth noting that most screening trials have gone on for decades, at least 1 decade, if not 2. And so this was a very -- in

> the context of screening trials, ***this was actually a very short trial with a very ambitious endpoint***. And that's part of the story here. But it is the first time that an MCED test has shown the ability to shift the stage diagnosis for the population in a randomized clinical trial. And I don't think we should let that kind of go by.

(Emphasis added).

44. The aforementioned press releases and statements made by the Individual Defendants are in direct contrast to statements they made during the May 13, September 9, October 20, November 12, and November 13, 2025, earnings calls, releases, and shareholder presentations. In those publications, Defendants withheld or otherwise failed to disclose to investors the true probability of success the NHS-Galleri study had in achieving its primary endpoint, while repeatedly promoting alternative metrics that gave investors a false sense of security and minimizing risks associated with study design and patient variability.

45. Investors and analysts reacted immediately to Grail's revelation. The price of Grail's common stock declined dramatically. From a closing market price of $101.53 per share on February 19, 2026, Grail's stock price fell to $50.21 per share on February 20, 2026, a decline of about 50.55% in the span of just a single day.

46. A number of well-known analysts who had been following Grail lowered their price targets in response to Grail's disclosures. For example, Baird, who had only initiated coverage in the days leading up to the drop on February 17, 2026, promptly slashed their price target by more than 27% to $31. When they initiated, Baird indicated they "believe results from the NHS-Galleri trial could represent a meaningful catalyst for broader international uptake of MCED testing (particularly in Europe)." Following the disappointing results, the Analyst highlighted the study's failure to achieve its endpoint, stating: "GRAL released initial top-line results from its NHS-Galleri study, missing its primary endpoint of demonstrating a statistically significant reduction for stage III-IV cancer." The Analyst further noted that "this likely decreases (but does not necessarily eliminate) the likelihood of broader NHS adoption in the near-term," justifying the swift price cut.

47. Similarly, Canaccord Genuity while maintaining a buy rating only after lowering its price target more than 20% from $105 to $80, highlighted investors' disappointment on the top-line results for the NHS-Galleri trial, stating, in pertinent part:

> Critically, GRAIL also announced (top-line) results from its 142,000-patient NHS-Galleri trial did not achieve statistical significance with respect to the study's primary endpoint (reduction in Stage III-IV cancer diagnoses). Although FDA approval of Galleri does not appear to be at material risk, it remains to be seen if CMS will consider the NHS data as it decides to establish an MCED coverage policy.

48. The analyst continued, noting the reason for Canaccord's price cut was due to the combination of "increased risk" and a reduced revenue potential.

49. The fact that these analysts, and others, discussed the failure of the NHS-Galleri study to achieve its primary endpoint suggests the public placed significant weight on Grail's prior statements of confidence and omitted concerns. The frequent, in-depth discussion of Grail's sharp fall in valuation confirms that Defendants' statements during the Class Period were material.

D. Additional Scienter Allegations

50. During the Class Period, Defendants acted with scienter in that they knew, should have known, or otherwise were deliberately reckless in not knowing that the public statements disseminated on behalf of Grail were materially false and misleading at the time they were made. Defendants had actual knowledge of, or access to, non-public information concerning the probability of the NHS-Galleri trial achieving its primary endpoint, including evidence suggesting the three-year timeline was less likely than previously though to be sufficient to demonstrate its achievability.

51. Notwithstanding such, Defendants repeatedly and affirmatively represented to investors that the NHS-Galleri study was likely to have a positive outcome, that the duration of the study was sufficient to demonstrate the achievability of its primary endpoint, and that ongoing study results, including the NHS-Galleri trial's Screening Round and the Pathfinder 2 results, only increased Defendants' confidence.

52. Yet, Defendants made selective and misleading disclosures in repeated positive statements regarding the ultimate readout. Defendants notably claimed to "expect that the

results … will provide [Grail] with the data to really turn those conversations into meaningful opportunities" in the future.

53. Defendants' scienter is also evidenced by their efforts to routinely point to differentiated metrics from ongoing and existing study results when discussing the potential for NHS-Galleri to achieve its primary endpoint. When debuting NHS-Galleri's first round results and repeatedly thereafter, Defendants' proudly pointed to the early PPV metric the study had achieved, announcing it was "substantially higher" than the Pathfinder 1 study, and even referring to it as a "key metric" for the study.

54. Notably, the NHS itself had declined to accelerate implementation despite seeing the same 1-year PPV result Galleri was praising. The NHS remained cautious and determined the results were not "exceptional enough to accelerate" and "wanted to wait for the final study results" and the primary endpoint readout.

55. Additionally, while they fell short of claiming a positive endpoint readout could be directly inferred from the Pathfinder 2 readout, Defendants, while discussing the NHS-Galleri trial, nevertheless suggested that they were "encourage[d]" by the results and now had "more confidence in the overall performance of Galleri."

56. Defendants' scienter was further evidenced by their refusal to publicize or otherwise share pertinent information regarding early-round reductions in Stage III and IV cancers. Defendants instead argued that publicizing the effectiveness as to a reduction in Stage III-IV cancers after one year of screening would "risk the integrity of the trial as a whole," as such data was more likely to culminate in later rounds. Yet, by doing so, Defendants placed themselves in the sole position of having access to particular data which could have altered the assessed probability of NHS-Grail achieving its primary endpoint, either in the time allotted for the study or altogether on effectiveness grounds.

57. Defendants further claimed that the study was specifically tailored in both size and length "to be able to deliver a statistically significant result" in its primary endpoint. Defendants indicated primary endpoint results "ha[d] to come with 3 years of data," implying less could not be revealed and more would be unnecessary.

58. Moreover, considering Defendant Ofman's eventual concession that NHS-Galleri was "actually a very short trial with a very ambitious endpoint," Defendants repeated assurances and statements of confidence were, at best, deliberately reckless.

E. Loss Causation and Economic Loss

59. During the Class Period, as detailed herein, Defendants made materially false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Grail's common stock and operated as a fraud or deceit on Class Period purchasers of Grail's common stock by materially misleading the investing public. Later, Defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of Grail's common stock materially declined, as the prior artificial inflation came out of the price over time. As a result of their purchases of Grail's common stock during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages under federal securities laws.

60. Grail's stock price fell in response to the corrective event on February 19, 2026, as alleged *supra*. On February 19, 2026, Defendants disclosed information that was directly related to their prior misrepresentations and material omissions concerning Grail's NHS-Galleri study.

61. In particular, on February 19, 2026, Grail announced significantly that the study had failed to achieve its primary endpoint of demonstrating that the screening test resulted in a reduction of stage III and IV cancers.

F. Presumption of Reliance; Fraud-On-The-Market

62. At all relevant times, the market for Grail's common stock was an efficient market for the following reasons, among others:

(a) Grail's common stock met the requirements for listing and was listed and actively traded on the NASDAQ during the Class Period, a highly efficient and automated market;

(b) Grail communicated with public investors via established market communication mechanisms, including disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

(c) Grail was followed by several securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms during the Class Period. Each of these reports was publicly available and entered the public marketplace; and

(d) Unexpected material news about Grail was reflected in and incorporated into the Company's stock price during the Class Period.

63. As a result of the foregoing, the market for Grail's common stock promptly digested current information regarding the Company from all publicly available sources and reflected such information in Grail's stock price. Under these circumstances, all purchasers of Grail's common stock during the Class Period suffered similar injury through their purchase of Grail's common stock at artificially inflated prices, and a presumption of reliance applies.

64. Alternatively, reliance need not be proven in this action because the action involves omissions and deficient disclosures. Positive proof of reliance is not a prerequisite to recovery pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security.

G. No Safe Harbor; Inapplicability of Bespeaks Caution Doctrine

65. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the material misrepresentations and omissions alleged in this Complaint. As alleged above, Defendants' liability stems from the fact that they provided investors with a confident presentation of a trial set up for success to likely achieve its primary endpoint, while at the same time concealing pertinent risk information to investors related to the trial's chances of success. Defendants provided the public with statements that omitted or otherwise diminished such risks and/or failed to adequately disclose the fact that the Company had not sufficiently articulated the likelihood of achievability of the primary endpoint.

66. To the extent certain of the statements alleged to be misleading or inaccurate may be characterized as forward looking, they were not identified as "forward-looking statements"

when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

67. Defendants are also liable for any false or misleading "forward-looking statements" pleaded because, at the time each "forward-looking statement" was made, the speaker knew the "forward-looking statement" was false or misleading and the "forward-looking statement" was authorized and/or approved by an executive officer of Grail who knew that the "forward-looking statement" was false. Alternatively, none of the historic or present-tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by the defendants expressly related to or stated to be dependent on those historic or present-tense statements when made.

CLASS ACTION ALLEGATIONS

68. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Grail's common stock during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosure. Excluded from the Class are defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

69. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Grail's common stock were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Grail or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in

securities class actions. As of March 6, 2026, there were 41 million shares of the Company's common stock outstanding. Upon information and belief, these shares are held by thousands, if not millions, of individuals located throughout the country and possibly the world. Joinder would be highly impracticable.

70. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

71. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

72. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Grail;

(c) whether the Individual Defendants caused Grail to issue false and misleading financial statements during the Class Period;

(d) whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

(e) whether the prices of Grail's common stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

(f) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

73. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden

of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

Against All Defendants for Violations of

Section 10(b) and Rule 10b-5 Promulgated Thereunder

74. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

75. This Count is asserted against defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

76. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon. Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Grail common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Grail's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

77. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Grail's securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company.

78. By virtue of their positions at the Company, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

79. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within defendants' knowledge and control. As the senior managers and/or directors of the Company, the Individual Defendants had knowledge of the details of Grail's internal affairs.

80. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of the Company. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Grail's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Grail's common stock was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning the Company which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Grail's common stock at artificially inflated prices and relied upon the price of the common stock, the integrity of the market for the common stock and/or upon statements disseminated by Defendants, and were damaged thereby.

81. During the Class Period, Grail's common stock was traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the defendants made, issued or caused to be

disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Grail's common stock at prices artificially inflated by defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said common stock, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Grail's common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Grail's common stock declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

82. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

83. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's common stock during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

Against the Individual Defendants

for Violations of Section 20(a) of the Exchange Act

84. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

85. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information about Grail's misstatements.

86. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information, and to correct promptly any public statements issued by Grail which had become materially false or misleading.

87. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Grail disseminated in the marketplace during the Class Period concerning the misrepresentations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Grail to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Grail's common stock.

88. Each of the Individual Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause Grail to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

89. By reason of the above conduct, the Individual Defendants and/or Grail are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representatives;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class pre-judgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: June 5, 2026

Respectfully submitted,

LEVI & KORSINSKY, LLP

/s/ Adam M. Apton

Adam M. Apton (SBN 316506)
1160 Battery Street East, Suite 100
San Francisco, CA 94111
Tel: (415) 373-1671
Email: aapton@zlk.com

Attorneys for Plaintiff