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

DIVISION OF
CORPORATION FINANCE

March 28, 2024

Robert Ragusa
Chief Executive Officer
GRAIL, LLC
1525 O'Brien Drive
Menlo Park, California 94025

Re: GRAIL, LLC
Amendment No. 2 to
Draft Registration Statement on Form 10-12B
Submitted March 11, 2024
CIK No. 0001699031

Dear Robert Ragusa:

We have reviewed your amended draft registration statement and have the following comment(s).

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe a comment applies to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to this letter and your amended draft registration statement or filed registration statement, we may have additional comments. Unless we note otherwise, any references to prior comments are to comments in our February 26, 2024 letter.

Amendment No. 2 to Draft Registration Statement on Form 10-12B

Summary
Our mission is to detect cancer early, when it can be cured., page 2

1. We note your responses to comments 1 and 2, and reissue these comments in part. In this regard, please revise your summary so that it is clear and prominent to investors that you do not produce or market a diagnostic test, but rather, a cancer screening test, and that this test has not been approved by the FDA. Please also make it clear and prominent that your future business and commercialization plans include FDA approval. In your revised disclosure, please address the following comments:

- At first instance, where you disclose that you believe Galleri is clinically validated, please revise your disclosure to make it clear that the Galleri test has not been approved by the FDA or an equivalent foreign regulator, and that the Galleri test has been validated as a screening test rather than a diagnostic test. In this regard, where you discuss "detection" by Galleri, please ensure that it is clear that this detection required additional diagnostic testing.

- Where you make claims about the accuracy of your Galleri test, including at first instance, please provide data to support your claims, or include a cross reference to the data elsewhere in your filing. Please also clarify that "accuracy" in this context does not mean that the Galleri test itself was used to provide a cancer diagnosis. In addition, please provide additional context for your statement that "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," including that there is no guarantee Galleri will be added to the current standard of care screening.

2. We note your response to comment 3 and your revised disclosure that your DAC test is a "medium- to longer-term objective." Please revise your disclosure to provide an estimated timeframe for "medium- to longer-term."

Risks Relating to Our Business and Industry
We may be unable to develop and commercialize new products, including enhanced versions of current products., page 41

3. We note your revised disclosure in response to previous comment 6 regarding bridging studies for new or enhanced versions of your current products and re-issue the comment in part. Your response to comment 11 from our January 8, 2024 comment letter, included in your January 29, 2024 response letter:

- noted that "in the near term, enhancements are focused on improvements to Galleri and, in particular, on automation, panel size, and other scaling improvements and updates to the machine-learning classifier" and that "[f]uture enhancements may also include a reduction in panel size to enable additional scaling, as well as further training of the classifier on additional data for potential future improvement;"

- in addition to bridging studies, discussed the need to conduct "a non-inferiority study compared to the relevant current version of Galleri using clinical study and real world evidence data (obtained through Galleri’s current commercial use as an LDT);"

- explained that because of the bridging study, "the Company does not believe the

changes will impact the Company's ability to rely on previously-collected data generated from earlier versions of the Company's products;" and

- also noted that "[a]s a contingency plan, if non-inferiority or non-concordance cannot be established, the Company can revert to the prior classifier and version of the test used in the existing version of Galleri."

Please include similar disclosure in the Information Statement when discussing potential enhanced versions of your products, or otherwise briefly explain what changes or improvements you expect to make to the enhanced versions of your current products, and if you believe these changes will impact your ability to rely on previously-collected data on earlier versions of your products in connection with your submission for marketing authorization (or certification) of your products.

Risks Relating to Regulation and Legal Compliance
Our multi-cancer detection tests are a new approach to cancer screening, which present a number of novel and complex issues..., page 61

4. We note your revised disclosure in response to previous comment 7 and re-issue the comment in part. In your January 29, 2024 response letter, you noted that "following several pre-submissions to the FDA regarding the Company's proposed clinical studies, and a meeting with the FDA in June 2023, the Company received feedback on several aspects of the clinical validation pathway for Galleri PMA. First, the FDA will permit the number of cancer-type specific clinical samples required for the Company's proposed cancer type claims to be based on the prevalence of each particular cancer type in the intended use population. Second, the FDA will not require the Company to perform a head-to-head comparison of Galleri and standard of care screening methods as a prerequisite for PMA approval, and will instead address such comparative data as part of labelling or at a later date. Third, the FDA will permit GRAIL to return results to ordering providers on any cancer signal of origin detected by Galleri, regardless of whether GRAIL has sufficient clinical evidence for an affirmative claim for that cancer type." Please include this information in your disclosure as it provides important context to the risk that it is difficult to predict what information you will need to submit to obtain approval of a PMA from the FDA. Alternatively, please advise us why you do not believe this information is material or should be disclosed in the Information Statement.

Reasons for the Spin-Off, page 100

5. We note the removal of references to outside advisors from the Information Statement in response to previous comment 8 and re-issue the comment in part. With respect to any information and analyses from outside advisors that the Illumina board has already received and that have aided the board in its consideration of strategic alternatives, please provide a more detailed legal analysis describing why the reports and recommendations provided by these outside advisors are not material to the board's decision. If the board is

still evaluating potential divestment transactions and has not made a final determination to move forward with the Spin-Off, please note this in your next response letter and provide any materiality analysis in the context of the board's ultimate decision once known. To the extent that the board receives additional information and analyses from outside advisors in connection with its evaluation of the Spin-Off, including with respect to any final determination to move forward with the Spin-Off rather than any of the other potential divestment transactions, please include disclosure regarding the third party advisors and their recommendations in a subsequent amendment or provide us with a legal analysis describing why this information is not material.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Research and Development and Research and Development—Related Parties, page 181

6. We note your revised disclosure that you expect your research and development expenses to plateau over the coming years as your existing clinical studies and development of your automated platform conclude. Please revise your disclosure to provide an estimated timeframe for "the coming years."

Goodwill Impairment, page 182

7. We note your disclosure that "[i]n the third quarter of 2023, we concluded the sustained decrease in Illumina’s stock price and overall market capitalization during the quarter was a triggering event indicating the fair value of GRAIL might be less than its carrying amount that led us to test goodwill for impairment," and "[w]e recognized an additional goodwill impairment of $608.5 million in 2023 primarily due to changes to expected timing of revenue and a higher discount rate." Please revise your filing to provide a risk factor discussing the risks associated with this impairment and possible future impairments or explain why you do not believe a risk factor is warranted.

Results of Operations, Comparison of Fiscal Year 2023 to Fiscal Year 2022
Screening Revenue and Screening Revenue—Related Parties, page 184

8. We reference the 90% increase in revenue from fiscal year 2022 to fiscal year 2023. Please revise to provide greater insight into the contributors to the significant increase in revenue, including the underlying reasons for the increase in Galleri sales volume. Reference Item 303(a)-(b) of Regulation S-K and the three principal objectives of MD&A, as noted in SEC Release No. 33-8350.

Development Services Revenue, page 184

9. We note your disclosure that "[t]he increase in development services revenue of $2.4 million was primarily due to new pilots initiated with biopharmaceutical partners in fiscal year 2023." In an appropriate place in your filing, please describe the terms of these pilots with biopharmaceutical partners, if material.

Non-GAAP Financial Measures, page 190

10. We note your response to comment 14. You state that the bonuses were allocated amongst all employees in good standing below the executive leadership team level and that no additional services were required to be provided by the employees above and beyond their normal employment compared to other similar roles and responsibilities. Therefore, it appears that these costs represent cash compensation, which is a normal, recurring operating expense. As such, we request that you discontinue including this adjustment in your non-GAAP measures for any period presented in accordance with Rule 100(b) of Regulation G as interpreted by Question 100.01 of the Non-GAAP Financial Measures Compliance & Disclosure Interpretations, as updated December 13, 2022.

Please contact Kristin Lochhead at 202-551-3664 or Terence O'Brien at 202-551-3355 if you have questions regarding comments on the financial statements and related matters. Please contact Conlon Danberg at 202-551-4466 or Katherine Bagley at 202-551-2545 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Industrial Applications and Services

cc: Ross McAloon, Esq.