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April 8, 2024

VIA EDGAR

U.S. Securities and Exchange Commission
Division of Corporation Finance
100 F Street, N.E.
Washington, D.C. 20549-6010

Attention: Kristin Lochhead
Terence O'Brien
Conlon Danberg
Katherine Bagley

Re: GRAIL, Inc.
Response to Letter dated March 28, 2024
Amendment No. 2 to
Draft Registration Statement Submitted on Form 10-12B
Submitted March 11, 2024
CIK No. 0001699031

To the addressee set forth above:

On behalf of our client, GRAIL, LLC (to be converted into a corporation named GRAIL, Inc.) (the "***Company***"), we are submitting this letter in response to the comments received from the staff (the "***Staff***") of the U.S. Securities and Exchange Commission (the "***SEC***") by letter, dated March 28, 2024 (the "***Comment Letter***"), regarding the Company's Amendment No. 2 to Draft Registration Statement on Form 10-12B, as confidentially submitted to the Staff on March 11, 2024 ("***Amendment No. 2***").

The Company is concurrently confidentially submitting to the Staff Amendment No. 3 to the Draft Registration Statement on Form 10-12B ("***Amendment No. 3***") together with this letter, via EDGAR with the SEC, which has been revised to reflect certain revisions to Amendment No. 2 in response to the Comment Letter as well as certain other changes.

For ease of review, we have set forth below each of the numbered comments of the Staff contained in the Comment Letter in bold type followed by the Company's responses thereto. Unless otherwise indicated, capitalized terms used herein have the meanings assigned to them in Amendment No. 3 and all references to page numbers in such responses are to page numbers in Amendment No. 3.

LATHAM & WATKINS LLP

Amendment No. 2 to Draft Registration Statement on Form 10-12B Submitted March 11, 2024

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.**

     Response: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on pages 2, 3, 6, 124, 132, 133, 135 and 182 of Amendment No. 3 accordingly.

   - **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.**

     Response: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on pages 3, 121, 122, 124, 133 and 137 of Amendment No. 3 accordingly.

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."

Response: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on pages 6, 124 and 142 of Amendment No. 3 accordingly.

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.

Response: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on pages 9, 11, 33, 34, 43, 127, 128, 139 and 140 of Amendment No. 3 accordingly.

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.**

   Response: The Company acknowledges the Staff's comment and respectfully advises the Staff that it does not believe this information is material or should be disclosed in the Information Statement. While the Company believes the statements in the January 29, 2024 response letter are helpful and responsive to give the Staff the requested additional context in response to its comment, the Company respectfully submits that the details noted are not material and do not provide significant additional context beyond the current statements on the same page in the Information Statement, which assert that (i) the FDA has never granted marketing authorization for a multi-cancer detection test and is working to inform its thinking on how to assess these types of tests, (ii) the FDA requirements that will govern multi-cancer detection tests, as well as the breadth and nature of data the Company must provide the FDA, to support the proposed intended use, may be subject to change, (iii) the Company has been engaged and will continue to engage the FDA, but the FDA may raise additional questions or request additional information, and (iv) "we cannot be certain whether we will receive FDA approval for Galleri and whether the studies we have conducted, are currently conducting, or plan to conduct, will be sufficient to provide the data that the FDA requires to support a proposed intended use." The Company respectfully submits that the material risks regarding the information needed to obtain approval of a PMA, including the fact that the full scope of

such information is subject to change due to the novel nature of MCED, are appropriately addressed in the Information Statement. In response to the Staff's comment, however, the Company revised the disclosure on page 63 of Amendment No. 3 to note that discussions with the FDA and any feedback from the FDA regarding the PMA process are preliminary and non-binding in nature.

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.

Response: The Company respectfully acknowledges the Staff's comment and additional disclosure has been added to the Information Statement with respect to the Illumina Board's ongoing evaluation of potential divestment transactions, including the identity and role of Illumina's outside advisors, on page 102. GRAIL respectfully informs the Staff that it has been informed by Illumina that as of the date hereof the Illumina Board has not made a final determination as to which divestment alternative it will pursue and that the draft disclosure will be revised as necessary when the Illumina Board makes a final determination. GRAIL further informs the Staff that it has been advised by Illumina that none of Illumina's outside advisors have made a recommendation to Illumina as to which divestment option to elect and that it will update the relevant disclosure if a recommendation is made, although it is not currently anticipated that any such recommendation will be made.

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."

Response: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on page 188 of Amendment No. 3 accordingly.

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.

Response: The Company respectfully acknowledges the Staff's comment and has added a risk factor on page 40 of Amendment No. 3 accordingly.

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.

Response: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on page 190 of Amendment No. 3 accordingly.

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.

Response: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on page 190 of Amendment No. 3 accordingly. The Company respectfully advises the Staff that the terms of these pilots are not 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.

Response: The Company respectfully acknowledges the Staff's comment and submits it believes that excluding the amounts subject to bonuses is consistent with the guidance in Question 100.01 of the Non-GAAP Financial Measures Compliance and Disclosure Interpretation, as updated December 13, 2022, because such payments will not repeat on a regular or irregular basis, and are not otherwise related to the Company's operations, revenue generating activities, business strategy, industry or regulatory environment. As these bonuses were tied specifically to the one-time event of the Company's acquisition by Illumina, so long as the respective employees remained a Company employee, these payments are not related to the core aspects of the Company's underlying business and are instead specifically tied to the acquisition. For example, the expenses impacted one historical period and do not carry across multiple periods. In addition, the Company notes that expenses relating to the recurring bonus plans are included in the non-GAAP measures as these are considered normal, recurring operating expenses and the payments are made in connection with the Company's execution of business operations and strategy.

As a result, the Company believes that excluding expenses for the acquisition bonuses paid to employees related to acquisitions from the non-GAAP financial measures is useful to both management and investors because it facilitates comparability of period to period results. Additionally, management does not consider acquisition-related bonuses in evaluating post-acquisition performance, as such charges are not representative of any underlying, ongoing business. The Company believes that excluding these expenses from the non-GAAP measures is useful to investors because it provides meaningful supplemental information regarding the Company's core operating performance. The Company further believes that excluding such expenses does not result in the non-GAAP financial measures being misleading. In response to the Staff's comment, the Company revised the disclosure on page 198 of Amendment No. 3 to note the non-recurring nature of the expense.

* * *

LATHAM & WATKINS LLP

We hope the foregoing answers are responsive to your comments. Please do not hesitate to contact me by telephone at (714) 755-8051 with any questions or comments regarding this correspondence.

Very truly yours,

/s/ Ross McAloon
Ross McAloon
of LATHAM & WATKINS LLP

cc: Robert Ragusa, GRAIL, LLC
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