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LATHAM & WATKINS LLP

March 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 February 26, 2024
Amendment No. 1 to
Draft Registration Statement Submitted on Form 10-12B
Submitted January 30, 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 of the U.S. Securities and Exchange Commission (the "***Staff***") by letter, dated February 26, 2024 (the "***Comment Letter***"), regarding the Company's Amendment No. 1 to Draft Registration Statement on Form 10-12B, as confidentially submitted to the Staff on January 30, 2024 ("***Amendment No. 1***").

The Company is concurrently confidentially submitting to the Staff Amendment No. 2 to the Draft Registration Statement ("***Amendment No. 2***"), which has been revised to reflect certain revisions to Amendment No. 1 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. 2 and all references to page numbers in such responses are to page numbers in Amendment No. 2.

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Amendment No. 1 to Draft Registration Statement on Form 10-12B Submitted January 30, 2024

Summary, page 2

1. **We note your revised disclosure in response to previous comment 2 and re-issue the comment in part. If true, please clarify that Galleri's clinical validation is the view or belief of management based on the results of your clinical studies completed to date or otherwise revise your statement so that it is clear that the Galleri test has not been approved by the FDA or an equivalent foreign regulator.**

   Response: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on pages 2, 6, 115, 118 and 176 of Amendment No. 2 accordingly.

2. **We note your revised disclosure in response to comment 3. Please address the following:**

   - **You disclose that, based on data from your CCGA and PATHFINDER studies, Galleri "can predict with high accuracy (88%) the specific organ or tissue type where the cancer signal originated." Please revise your disclosure to disclose the data underlying your "88%" high accuracy rate, and briefly explain, as you do on page 127, how this measure relates to the PPVs of 43% and 44% noted on page 4 related to the same studies.**

     Response: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on pages 2, 3, 115, 116, 128 and 176 of Amendment No. 2 accordingly. The Company respectfully advises the Staff that it determined to remove the phrase "high accuracy (88%)" from pages 2, 115 and 176 because it believes including detailed information, such as underlying data, patient counts and percentages, would result in a long and dense initial paragraph for investors to navigate. In response to the Staff's comment, the Company revised the disclosure on pages 3, 116 and 128 to refer to the underlying study and disclose the data underlying the "88%" high accuracy rate.

   - **You disclose that "[a]pproximately 67% of cancer deaths result from cancers that have no recommended screening guidelines, based on our own estimates using 2022 American Cancer Society Facts and Figures." Please disclose the relevant "facts and figures" supporting your estimate. Make conforming changes throughout your filing where you cite to your estimates based on these facts and figures, including the description of your business on page 122 where you disclose that "we estimate that asymptomatic individuals undertaking a standard of care screening test are many times (2-24x depending on cancer type) more likely to have a different type of cancer than the cancer type for which they are being screened," and "single-cancer screening tests are also unlikely to be developed for detecting less common cancers."**

Response: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on pages 2, 3, 115, 122 and 123 of Amendment No. 2 accordingly.

- **We note your disclosure that "we estimate that adding Galleri to these five standard of care single-cancer screening tests (breast, cervical, colorectal, lung cancer, and prostate) could detect many more cancers at an earlier stage and potentially avert approximately 100,000 deaths per year in the United States as measured by five-year survival." Please provide the basis for your statement.**

  Response: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on pages 3, 115 and 131 of Amendment No. 2 accordingly. The Company respectfully advises the Staff that the potential to avert 100,000 deaths per year is based on a model published in Cancer Epidemiology, Biomarkers & Prevention in 2021 (Modeled Reductions in Late-stage Cancer with a Multi-Cancer Early Detection Test, *Cancer Epidemiol Biomarkers Prev.* 2021; 30:460–8).

- **You disclose that "a recent analysis published in *Data* in September 2017 estimated that diagnosing cancer early could result in an estimated $26 billion in annual cost- savings in the United States." Please identify the article or analysis. In addition, given your characterization of this statistic as "recent," please revise your disclosure to provide a more current source or tell us why you are unable to do so.**

  Response: In response to the Staff's comment regarding the analysis published in Data in September 2017, the Company has revised the disclosure on pages 3, 115 and 122 to identify the article and remove the characterization of this statistic as "recent". The Company respectfully advises the Staff that such article is the most reputable and recent analysis estimating estimated cost-savings in the United States for early cancer detection of which the Company is aware, and that such analysis continues to be cited in recent reputable publications. For example, this analysis was cited in recent articles appearing in BMC Health Services Research (The aggregate value of cancer screenings in the United States: full potential value and value considering adherence. *BMC Health Serv Res 23*, 829 in August 2023); Journal of Managed Care – Specialty Pharmacy (Time duration and health care resource use during cancer diagnoses in the United States: A large claims database analysis. *J. Manage Care Spec Pharm*. 2023; 29(6) in June 2023); and Applied Health Economics Health Policy (Productivity Loss and Indirect Costs for Patients Newly Diagnosed with Early- versus Late-Stage Cancer in the USA: A Large-Scale Observational Research Study. *Appl Health Econ Health Policy* in November 2022), among others.

- **Your revised disclosure on page 5 includes a statement that "Data published in *The Lancet Oncology* showed that, in a symptomatic patient population, our methylation technology was able to detect many cancer types and identify where the cancer signal origin was located in the body with high accuracy (91%)." Please disclose the source of the data published in the *Lancet* and describe the data supporting the 91% accuracy rate.**

  Response: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on pages 5, 118 and 136 of Amendment No. 2 accordingly. The Company respectfully notes that the data published in *The Lancet Oncology* was from the Company's SYMPLIFY study.

Generally, where you reference an article or analyses in a publication, please identify the specific article or analyses. For example, we note your disclosures on page 121 referencing "an article" in JAMA Oncology and "an article" in the Journal of the National Comprehensive Cancer Network.

Response: The Company respectfully acknowledges the Staff's comment and has revised the references in Amendment No. 2 accordingly.

3. **We note your response and revised disclosure in response to previous comment 8 and re-issue the comment in part. In addition to providing your anticipated timeline for launching the DAC test, please also describe the status of your development efforts. To the extent you believe your other products in development are not currently material to your business, please include a statement to this effect in your disclosure or revise to remove statements that such future products present significant market opportunities.**

   Response: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on pages 6, 118 and 136 of Amendment No. 2 accordingly.

4. **Please briefly describe the difference between "PPV" and "modeled PPV," as it relates to your PATHFINDER and CCGA studies.**

   Response: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on pages 4 and 117 of Amendment No. 2 accordingly.

Risk Factors, page 30

5. We note the statements in your response to previous comment 10 that "risks related to the regulatory proceedings are fundamentally borne by Illumina" and that "The Company expects that future costs associated with regulatory proceedings will be limited because the Separation and Distribution is anticipated to expedite resolution of these regulatory proceedings and the Company does not anticipate being a separate party to ongoing regulatory proceedings after the spin-off transaction." To provide investors with context about the potential regulatory risks to GRAIL, please include substantially similar statements in the Information Statement when discussing the regulatory proceedings.

Response: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on pages 98 and 99 of Amendment No. 2 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

6. We note the statements including in your response letter in response to previous comment 11. Please include similar disclosure in the Information Statement when discussing potential enhanced versions of your products.

Response: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on pages 121 and 133 of Amendment No. 2 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

7. We note the statements included in your response to previous comment 12. Please include similar disclosure in the Information Statement when discussing your FDA submissions and FDA approval of your products. In this regard, we note that a portion of the risk factor addresses the risk that "it is difficult to predict what information [you] will need to submit to obtain approval of a PMA from the FDA for a proposed intended use." The additional details in your response letter provide helpful context in evaluating this risk. Given the potential importance of FDA approval of your products, this additional information should be included in your disclosure.

Response: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on pages 4, 8, 61, 62, 116, 120, 152 and 179 of Amendment No. 2 accordingly.

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Reasons for the Spin-Off, page 99

8. We note your response to comment 16, including that "outside advisors provided information and analyses to assist the Illumina Board, and the committee thereof, understand the range of potential divestment transactions, including regarding their respective structures, timing and process and legal considerations." Given that the information and analyses of the outside advisors appears to have aided the Illumina board in its consideration of strategic alternatives and ultimate determination to effect the spin-off, please provide a more detailed legal analysis describing why the reports and recommendations provided by these outside advisors were not material to the board's decision. Alternatively, please revise your disclosure to identify the outside advisors and discuss the nature of the reports and recommendations provided by them to the Illumina board.

Response: The Company respectfully acknowledges the Staff's comment and respectfully advises the Staff that it has determined to remove any references to outside advisors from the Information Statement. The Company has revised the disclosure on pages 13, 16 and 100 of Amendment No. 2 accordingly.

Reasons for Illumina's Retention of up to 14.5% of GRAIL Common Stock, page 101

9. We note your revised disclosure and response to comment 17. We are considering your response and may have further comment. We will advise you once we have completed our consideration of this issue.

Response: The Company respectfully acknowledges the Staff's comment and will await the Staff's further consideration and comment.

Galleri Standard of Care Performance, page 127

10. We note your response to comment 23 and your revised disclosure in the footnotes to the graphic on page 127. Given your disclosure that your graphic presents the PPVs and number of false positives associated with the "current" standard of care screening tests, please provide more current sources for your disclosure about the relevant data in the table, or tell us why you are unable to do so. In this regard, we note that some of the sources in your footnotes are greater than five years old, and were published as early as 2009.

Response: The Company respectfully acknowledges the Staff's comment and advises the Staff that it has sought to provide current and reputable sourcing for its disclosure of the data in the table in the Information Statement. The Company notes to the Staff that the standard of care for cancer screening does not change frequently, due in part to the fact that studies can take significant resources and many years to complete, and that the technology underlying the standard of care screening is relatively slow to update. The Company believes that the sources cited are generally considered seminal or highly reputable articles, analyses and sources in their respective fields, and notes that these sources continue to be cited as authority and information sources in other, more recent reputable publications. The Company advises the Staff that it does not believe there are more current sources that would be more appropriate than those selected for inclusion in the table in the Information Statement.

For example, while the sources for prostate PPV and false positive rate data were published in 2010 and 2009, respectively, each of these sources continue to be cited by recent publications. In particular, the 2009 source presents information from the Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial, which was designed and sponsored by the National Cancer Institute and is generally considered by medical professionals and industry participants as a seminal trial and data source despite enrollment originally occurring between 1993 and 2001. The PLCO Trial was one of the primary sources of evidence evaluated by the U.S. Preventative Services Task Force (USPSTF) to determine its recommendations for prostate-specific antigen (PSA) prostate cancer screening, and as such represents a highly validated and widely accepted data set and source. The false positive rate reported for prostate cancer screening in the PLCO Trial was 10.4%, which is reflected in the data in the table in the table in the Information Statement. The USPSTF also evaluated the results from the European Randomized Study of Screening for Prostate Cancer (ERSPC) Trial, which reported a false positive rate for prostate cancer screening of 17.8%.

Further, the 2010 source was created following an initiative by the American Cancer Society (ACS) Prostate Cancer Advisory Committee to develop guidelines and recommendations for prostate cancer screening. While there are certain more recent sources that analyze prostate screening PPV, the data in these sources is generally in line with the data in the original 2010 source and is specific to patient subgroups or demographics. For example, an analysis of 2,606 Chinese men published in 2017 in the Asian Journal of Andrology (The performance characteristics of prostate-specific antigen and prostate-specific antigen density in Chinese men. *Asian J Androl*. 2017 Jan-Feb;19(1):113-116) recommended prostate screening parameters for Chinese men that would be expected to generate a PPV of 29.5%, in line with the 30% reflected in the data in the table in the Information Statement. Similar other studies involving men in Indian and Korea reported PPVs of 15-24% and 16%, respectively. Further, a recent analysis published in 2024 in European Urology Oncology (Comparing the Performance of Digital Rectal Examination and Prostate-specific Antigen as a Screening Test for Prostate Cancer: A Systematic Review and Meta-analysis. *European Urology Oncology*, 2024) calculated a pooled prostate cancer screening PPV of 22% based on data from eight studies involving over 85,000 patients.

The Company respectfully advises the Staff that similar analysis and rationale applies for the use of sources with publication dates ranging from May 2013 to May 2019 for the breast, cervical, colorectal and lung cancer data in the table in the Information Statement. In addition, the Company has supplemented the disclosure of the data in the table in the Information Statement to include additional colorectal cancer data regarding Cologuard's sDNA FIT screen, which is noted specifically in USPSTF guidelines. The source for such data is Cologuard's PMA summary of safety and effectiveness. The Company determined that including this testing method is appropriate given that it is cited by the USPSTF as a testing method for colorectal cancer.

Our Clinical Studies, page 138

11. We note your response to comment 26, and your revised disclosure throughout this section listing "the name of certain larger partners involved in each of [y]our studies." Please expand your disclosure to include a brief description of the material terms of such collaborations, including whether you have funded or are funding any studies and research and if any compensation was involved.

Response: The Company respectfully acknowledges the Staff's comment and advises the Staff that its partnerships and collaborations involving clinical trials were subject to terms generally consistent with sponsored studies and that no such terms or arrangements are material to the Company. In response to the Staff's comment, the Company has revised the disclosure on pages 142, 143, 144, 145, 147, 148 and 149 of Amendment No. 2 to note the standard nature of the terms and disclose that the Company funded the clinical trials.

Intellectual Property, page 151

12. **We note your revised disclosure in response to comment 30. To the extent any individual patents in the patent families discussed are material to your business, please expand your disclosure to discuss the type of patent protection that the relevant issued patent(s) provide, the jurisdictions where the patent(s) have been issued, and the relevant expiration dates. In addition, given the extent of the disclosure related to your patent families, please consider providing the disclosure in tabular form by patent family.**

    Response: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on pages 154, 155 and 156 of Amendment No. 2 accordingly.

License Agreements with the Chinese University of Hong Kong, page 153

13. **We note your response to previous comment 31 noting that the Company is currently paying royalties to CUHK on net sales across your Galleri, precision oncology and DAC products. Please reference the royalty payable to CUHK where you discuss the payment of other royalties in the Summary and Risk Factor sections or explain to us why you do not view this payment obligation as material.**

    Response: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on pages 10, 37 and 38 of Amendment No. 2 accordingly. The Company notes that while such royalty payments may grow to be significant in value, the royalty payments to CUHK are not material as compared to the royalty payments payable under the agreement with Illumina, which is in the high-single-digits and is payable in perpetuity. Moreover, the Company notes that certain provisions in its agreement with Illumina permit a reduction in the royalty payable to Illumina by up to a low single-digit percentage in respect of third party royalties actually paid, such as our royalty payment to Chinese University of Hong Kong.

Management's Discussion and Analysis of Financial Condition and Results of Operations Non-GAAP Financial Measures

Adjusted EBITDA, page 184

14. **We reference prior comment 32 in our letter dated January 8, 2024. Please further elaborate on the nature and terms of the retention bonuses provided in connection with the acquisition by Illumina, including a discussion of the term of the retention commitment, any additional services required to be provided by the employees above and beyond their normal employment and compared to employees in similar roles and responsibilities, and how the retention bonuses were calculated. Please note that under *Question 100.01 of the Non-GAAP Financial Measures Compliance & Disclosure Interpretations*, it is generally not appropriate to adjust GAAP measures for costs that relate to revenue generating activities.**

Response: The Company respectfully acknowledges the Staff's comment and advises the Staff that the Company Disclosure Letter, dated as of September 20, 2020, entered into in connection with the Company's acquisition by Illumina, contains language permitting a special retention pool of up to a specified amount related to the acquisition. The special retention pool was allocated amongst all employees in good standing below the executive leadership team level in the fourth quarter of 2020, such that any new hires subsequent to that date were not eligible for a cash retention award. The amount allocated to each employee was determined after consideration multiple factors, including but not limited to such employee's performance, and the awards, including the amounts, were communicated in letter to eligible employees in the fourth quarter of 2020. The terms and conditions of such letters provided that the one-time cash award was only payable upon the closing of the acquisition, subject to such employee being active and in good standing on the payment date. No additional services were required to be provided by the employees above and beyond their normal employment compared to other similar roles and responsibilities. If an employee terminated prior to the payment date, such employee was no longer entitled to or received the cash retention incentive. The Company did not reallocate the cancelled award to other employees, resulting in the amount actually issued to be below the limit in the retention pool.

The Company respectfully notes to the Staff that the Company does not believe these non-recurring, one-time payments only payable at the closing of the acquisition are related to revenue generating activities.

Management, page 193

15. **Please revise to provide all of the information required by Item 401(e) of Regulation S-K. For example, revise to describe the business experience, principal occupations and employment of your officers over the last five years, including the dates and duration of employment.**

Response: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on page 200 of Amendment No. 2 accordingly.

* * *

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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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