United States securities and exchange commission logo

February 26, 2024

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

Re: GRAIL, LLC
Amendment No. 1 to
Draft Registration Statement on Form 10-12B
Submitted January 30, 2024
CIK No. 0001699031

Dear Robert Ragusa:

We have reviewed your amended draft registration statement and have the following comments.

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 January 8, 2024 letter.

Amendment No. 1 to Draft Registration Statement on Form 10-12B

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.
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.

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."

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.

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.

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.

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.

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

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.

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.

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.

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.

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.

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.

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.

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