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November 14, 2023

VIA EDGAR

Division of Corporation Finance
Office of Industrial Applications and Services
United States Securities and Exchange Commission
100 F Street, N.E.
Washington, D.C. 20549-3628
Attn: Tracey Houser
Terence O'Brien

Re: Fulgent Genetics, Inc.
Form 10-K for Fiscal Year Ended December 31, 2022
Filed February 28, 2023
File No. 001-37894

Dear Ms. Houser and Mr. O'Brien:

On behalf of Fulgent Genetics, Inc. (the "Company"), we are submitting this letter in response to the written comments of the staff (the "Staff") of the Securities and Exchange Commission (the "Commission"), dated November 1, 2023, with respect to the Company's Form 10-K filed with the Commission on February 28, 2023 for the fiscal year ended December 31, 2022 (the "2022 Form 10-K") (File No. 001-37894).

The proposed revised disclosures referenced in this letter are based on facts and circumstances as of the date of this letter and, accordingly, the Company notes that additional revisions may be required in future filings depending on the Company's strategy, operations, and financial performance at the time of such filing to ensure that the disclosures set forth in such future filings comply with applicable laws, including federal securities laws. The proposed revised and additional disclosures referenced in this response will be included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 (the "2023 Form 10-K") and all future applicable filings.

The Company understands that your review and comments are intended to assist them in compliance with applicable disclosure requirements and to enhance the overall quality of the disclosure in their filings. The Company shares these objectives and is responding to your comments with these goals in mind. Set forth below are the heading and text of each comment, followed by the Company's response.

Form 10-K for Fiscal Year Ended December 31, 2022

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations, page 54

1. **We note that the significant decline in COVID-19 testing revenues has significantly impacted your results of operations for fiscal year 2022. As these revenues are not anticipated to be a material part of your ongoing results of operations, please provide an analysis of the material factors that impact the revenues that are expected to be a material part of your results of operations going forward in comparison to the corresponding revenues for the prior period. Also provide a discussion and analysis of the material factors impacting the associated gross profit for these revenues to provide investors with a better understanding of your future expectations of your operating results with the remaining primary diagnostic testing revenues. When multiple factors are discussed, quantify the extent to which each factor impacted the related operating result line items. Refer to Item 303(b)(2) of Regulation S-K and Section 501.12 of the Financial Reporting Codification for guidance.**

Response:

The Company respectfully acknowledges the Staff's comment and confirms that it will, in future filings, beginning with the 2023 Form 10-K, provide a more comprehensive analysis of the material factors impacting (i) the revenues that are expected to be a material part of the Company's results of operations going forward in comparison to the corresponding revenues for the prior period and, (ii) to the extent applicable, the associated gross profit for these material revenues to provide investors with a better understanding of the Company's future expectations of its operating results.

* * *

2. **We note that you incur research and development expenses related to your diagnostics testing business and for your therapeutics development business. Please expand your discussion and analysis to quantify the costs for each of your research and development projects and to discuss the nature of the costs incurred for each project.**

Response:

The Company respectfully acknowledges the Staff's comment and confirms that it will, in future filings, beginning with the 2023 Form 10-K, expand its discussion and analysis to quantify the costs for each of its research and development projects and to discuss the nature of the costs incurred for each project. The Company advises the Staff that its total research and development expenses related to the therapeutic development business were not material for the Company for the fiscal year ended December 31, 2022.

* * *

Critical Accounting Policies and Use of Estimates
Valuation of Goodwill and Intangible Assets, page 59

3. **We note that you recognized $143 million of goodwill and $64.6 million of IPR&D, an indefinite-lived intangible asset, as of December 31, 2022. Please provide a more comprehensive discussion and analysis of the critical estimates associated with assessing goodwill and the indefinite-lived intangible asset for impairment. In this regard, we note that the fourth quarter of fiscal year 2022 is the first time you recognized operating and net losses since the second quarter of fiscal year 2020 due to the significant decline in revenues from COVID-19 testing. Expanded disclosures are to provide investors with sufficient information to assess any material uncertainty regarding the realizability of goodwill and the indefinite-lived intangible asset, including but not limited to the following.**

    - **The percentage by which the estimated fair value exceeds the carrying value of your reporting unit(s) or indefinite-lived intangible asset to the extent that the fair value does not substantially exceed the carrying value.**
    - **The methodologies used to estimate the fair value of the reporting unit(s) and the indefinite-lived intangible asset for the most recent quantitative assessment, including the material judgements, assumptions and estimates made.**
    - **A discussion of the degree of uncertainty associated with the key assumptions and estimates along with the potential impact reasonably possible changes in the key assumptions would have on your impairment analysis.**
    - **A discussion of the potential events and/or changes in circumstances that could reasonably be expected to occur and negatively affect the key assumptions and result in a material impairment charge.**

    Refer to Item 303(b)(3) of Regulation S-K and Section 501.14 of the Financial Reporting Codification for guidance.

Response:

The Company respectfully acknowledges the Staff's comment and confirms that it will, in future filings, beginning with the 2023 Form 10-K, provide a more comprehensive analysis of the critical estimates associated with assessing goodwill and the indefinite-lived intangible asset for impairment.

* * *

Note 2. Summary of Significant Accounting Policies
Goodwill, page F-13

4. **Please expand your accounting policy to disclose the level at which you are testing goodwill for impairment (i.e., the identification of your reporting unit(s)). Also disclose**

when you perform your annual impairment test, the circumstances in which you would perform an interim impairment test, and the method(s) used to estimate the fair value of your reporting unit(s) to the extent that you prepare a quantitative assessment.

Response:

The Company respectfully acknowledges the Staff's comment and proposes to add in its future filings, beginning with the 2023 Form 10-K, disclosure of the level at which the Company is testing goodwill for impairment, the circumstances in which the Company would perform an interim impairment test in connection with the annual impairment test, and, to the extent the Company prepares a quantitative assessment, the methods used to estimate the fair value of the Company's reporting units.

* * *

Reporting Segment and Geographic Information, page F-15

5. **We note your disclosure that you view your operations and manage your business in one "reporting segment". We further note that you acquired Fulgent Pharma, a clinical-stage, therapeutics development company, which differs from your historical clinical diagnostic business. As such, please tell us your consideration of the guidance in ASC 280-10-50-1 through 50-5 for the identification of your operating segments and/or reportable segments.**

Response:

The Company respectfully informs the Staff that the following facts outlined below were taken into consideration when the Company was identifying operating segments in accordance with ASC 280-10-50-1, which states that an operating segment is a component of a public entity that has all of the following characteristics:

a. It engages in business activities from which it may recognize revenues and incur expenses (including revenues and expenses relating to transactions with other components of the same public entity).

   Characteristic a. was considered, and the Company determined it WAS MET at the component level.

   The Company evaluated and identified its clinical diagnostic business and its therapeutic development business as its two components and both components satisfied this characteristic.

   The clinical diagnostics component offered molecular diagnostic testing services, comprehensive genetic testing, and anatomic pathology testing. The clinical diagnostics component engaged in business activities from which it recognized revenues and incurred expenses.

As noted in the Staff's comment, the Company acquired a clinical-stage, therapeutics development company ("Fulgent Pharma"). Fulgent Pharma is early in its development efforts, with only one therapeutic candidate having entered clinical trials ("FID-007"). The therapeutic development component engaged in business activities from which it incurred expenses related to research and development activities; however, it is pre-revenue and did not recognize any revenue as of December 31, 2022.

b. Its operating results are regularly reviewed by the public entity's chief operating decision maker to make decisions about resources to be allocated to the segment and assess its performance.

Characteristic b. was considered, and the Company determined it was NOT MET at the component level but WAS MET at the consolidated level.

In accordance with ASC 280-10-50-5, the Company identified the Chief Executive Officer ("CEO") of the Company as its chief operating decision maker ("CODM"). The CEO made decisions as to funding, structuring, and allocation of resources for the Company as a whole.

It was the Company's practice to hold regular meetings to review financial performance. The financial package (the "CODM Package"), was prepared at a consolidated level. The consolidated CODM Package was reviewed by the CODM to make operating decisions, allocate resources, and assess the performance of the Company. In these meetings, the CEO reviewed the following:

- a consolidated income statement that included revenue, cost of sales, gross profit (loss), operating expenses, and net income (loss);
- a consolidated balance sheet; and
- a consolidated budget and expenditure report.

During these meetings, the executive officers and other members of management, including members of senior management who oversee business development, sales and marketing, compliance, and research and development (including Dr. Ray Yin in connection with his research and development role at Fulgent Pharma) functions, provided an overview of their respective areas of expertise and responsibility, to provide the CEO additional color and insights as needed relating to the financial performance of the Company.

In these meetings, the CEO reviewed the CODM Package to assess the overall consolidated business performance. The CEO also reviewed the budget at a consolidated level. Compensation was determined at the consolidated level and managed by a centralized human resources team. The consolidated budget along with compensation and resource allocation were presented to the Board of Directors of the Company (the "Board"). The Board received the same information that the CEO received and reviewed as the same CODM Package was utilized for the Board meetings. The CEO reviewed and made

operating decisions to allocate resources and assess the Company's performance based upon consolidated financials.

Given the Company's sales outside of the United States, and material revenues since 2020 from COVID-19 testing, the Company also considered whether its operating segments identification might exist on a geographic basis or at the service line or revenue stream level. The CODM did not make resource allocation decisions based upon foreign locations outside of the United States or specifically for COVID-19 testing. The Company concluded that COVID-19 testing is merely another type of diagnostic test that the Company offers. The resources, workflow, and reporting system for its COVID-19 tests are generally the same as the resources, workflow, and reporting system for its regular genetics testing. Therefore, the Company concluded that it did not have any geographic operating segments at this time (although it did comply with the entity wide geographic disclosures in accordance with ASC 280-10-50-41). The Company also concluded that COVID-19 testing was not a separate operating segment.

c. Its discrete financial information is available.

Characteristic c. was considered, and the Company determined it WAS MET at the component level.

Discrete financial information is available at the component level for both its clinical diagnostic business and its therapeutic development business.

Based on the Company's evaluation of the operating segment characteristics, the Company determined its operating segment identification at the consolidated level and not at the component level. Characteristic b. was NOT MET at the component level, therefore operating segment identification was NOT MET at the component level.

* * *

Note 15. Business Combinations
Fulgent Pharma Holdings, Inc., page F-33

6. We note that you acquired Fulgent Pharma with one drug candidate for which IPR&D of $64.6 million was recognized compared to the purchase price of $68 million. Please address each of the following:

- **Provide us with your analysis of the guidance in ASC 805-10-55-5A through 55-5C, including the calculation of the screen test.**
- **To the extent that you are able to demonstrate the screen test is not met, provide us with your analysis of Fulgent Pharma meeting the definition of a business based on the guidance in ASC 805-10-55.**

Response:

The Company respectfully informs the Staff that the following facts outlined below were taken into consideration when determining whether the acquisition of Fulgent Pharma met the requirements to be treated as a business combination under ASC 805.

ASC 805-10 55-5A provides that if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the set is not considered a business.

The Company considered the assets identified on the November 7, 2022 Fulgent Pharma closing balance sheet, excluding cash and cash equivalents and restricted cash, and the combined identifiable assets were as follows: Identified in-process research and development ("IPR&D") intangible assets consisted of $64.6 million or 89.9%, fixed assets, net, of $1.3 million or 1.8% and goodwill excluding the effects of deferred taxes of $5.9 million or 8.2% of gross assets acquired.

The Company then followed the following steps outlined in ASC 805-10-55-5B & C. The single identified IPR&D asset valued related to FID-007's use with Fulgent Pharma's platform and primary drug candidate, FID-007. Assuming prompt Food and Drug Administration ("FDA") approval and commercialization, the FID-007 potential cash flows included cash flows for the sale of FID-007 for the treatment of (i) head and neck cancer indications within the approximate three-year period following the date of the completion of the Fulgent Pharma acquisition, and (ii) pancreas, lung and breast cancer indications in the approximate three-year period following prompt FDA approval of FID-007 for the treatment of head and neck cancer indications. In applying the screen test, the Company evaluated whether substantially all of the fair value of the gross assets acquired was concentrated in a single asset or group of similar assets. While the standard does not define what constitutes "substantially all," this term is used in other areas of Generally Accepted Accounting Principles (e.g., revenue, leases). There is no bright line, but it is typically interpreted to mean at least 90%. Here, the IPR&D assets valued by a third-party valuation company approached the 90% threshold at approximately 89.9% of the gross assets acquired. When there is uncertainty around whether the quantitative threshold of the screen test is met and because the ratio is close to 90%, additional factors should be considered. As such, the Company further considered the following qualitative factors before it ultimately concluded that the Fulgent Pharma screen test was not met and that a full assessment must be performed:

- The scientific team and management of Fulgent Pharma had the necessary skills, knowledge, and experience to continue the clinical trials or expand upon its existing research and development of the pipeline of drugs. The experienced management and scientists represented an organized workforce that, when applied to the acquired inputs (IPR&D), significantly contributed to the ability to create outputs. In recent years, this workforce had advanced the process of its drug candidates through early clinical development. The Company believed this demonstrated an ability for the business to operate independently to continue to advance the pipeline of Fulgent Pharma's drug candidates, which contributed to the goodwill recognized as part of the transaction.

- Fulgent Pharma had the rights to a significant number of patents on various drug candidates and had other drug candidates in the preclinical development.

As such, the Company qualitatively concluded that substantially all the fair value of the gross assets acquired was not concentrated in a single identifiable asset or a group of similar identifiable assets, and thus, the transaction would proceed past the screen test. The Company next considered whether Fulgent Pharma was a business.

ASC 805-10-55-3A provides that a business is an integrated set of activities and assets that is capable of being conducted and managed for the purpose of providing a return in the form of dividends, lower costs, or other economic benefits directly to investors or other owners, members, or participants. The Company assessed the three elements of a business defined (ASC 805-10-55-4) as follows:

a. Input – Any economic resource that creates or has the ability to contribute to the creation of, outputs when one or more processes are applied to it.

Fulgent Pharma had the necessary equipment, intellectual property, and the ability to obtain access to necessary materials or intellectual property rights for the continued research and development of their drug candidates and technology.

b. Process – Any system, standard, protocol, convention, or rule that, when applied to an input or inputs, creates or has the ability to contribute to the creation of outputs.

The Company determined the employees made up an organized workforce, and that this workforce had the necessary skills, knowledge, or experience to perform a process that was critical to the ability to develop the drug candidates into commercialized products. Fulgent Pharma had employees, which the Company acquired as part of the transaction, with their existing employment agreements (i.e., there was no re-hire or renegotiation process required). These employees, which included doctoral backgrounds, fulfilled notably non-administrative roles, were critical to the development of Fulgent Pharma's in process research, and were supplemented with contractor support.

c. Output – The result of inputs and processes applied to those inputs that provide goods or services to customers, investment income (such as dividends or interest), or other revenues.

Outputs are not required for a set to be a business. Being a pre-revenue company, Fulgent Pharma did not yet have any output, and its drug candidates are still currently under research and development. ASC 805-10-55-5D states that, "[w]hen a set does not have outputs (for example, an early-stage company that has not generated revenues), the set will have both an input and a substantive process that together significantly contribute to the ability to create outputs only if it includes employees that form an organized workforce and an input that the workforce could develop or convert into output. The organized workforce must have the necessary skills, knowledge, or experience to perform an acquired process (or group of processes) that when applied to another acquired input or inputs is critical to the ability to develop or convert that acquired input or inputs into outputs."

The processes performed by the Fulgent Pharma workforce in developing its pipeline were in process, were not ancillary, and resulted in intellectual property that could be used to develop a good. These processes were independently underway prior to the transaction. These conclusions are consistent with *Case C: Acquisition of Biotech* referenced within ASC 805-10-55-70 through 72.

Based on the above analysis, the Company concluded that Fulgent Pharma had the necessary inputs and substantive processes, had the ability to operate independently on a stand-alone basis, and was therefore a business. The transaction was accounted for as a business combination.

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We hope that the foregoing has been responsive to the Staff's comments. If you have any additional questions or comments related to this letter, please feel free to contact me directly at MRLevy@mintz.com or 858-314-1873.

Very truly yours,

/s/ Melanie Ruthrauff Levy
Melanie Ruthrauff Levy

cc: Scott Stanton, Mintz. Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
Paul Kim, Fulgent Genetics, Inc.