



Fulgent Genetics and Helio Health Announce Strategic Partnership to Commercialize Early Cancer Detection Tests

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Partnership enables broad reach of cfDNA methylation blood tests for early cancer detection

TEMPLE CITY, Calif. & IRVINE, Calif.--(BUSINESS WIRE)--Aug. 9, 2021-- Fulgent Genetics, Inc. (NASDAQ: FLGT) ("Fulgent" or the "Company"), a technology-based genetic testing company focused on transforming patient care in oncology, infectious and rare diseases, and reproductive health, and Helio Health ("Helio"), an AI-biotechnology company developing blood-based early cancer detection tests, today announced the companies have entered into a strategic partnership to commercialize Helio's blood-based early cancer detection tests. In conjunction with the commercial strategic partnership whereby the company has secured exclusive commercial rights for laboratory develop tests ("LDTs") in the U.S. and Canada, Fulgent has made a strategic investment in Helio.

Under this partnership, the companies will initially commercialize and co-brand HelioLiver, a cell-free DNA (cfDNA) methylation blood test that incorporates protein markers and demographics for the detection of hepatocellular carcinoma (HCC) – or liver cancer. HelioLiver is currently undergoing clinical trials in the U.S. and China. Fulgent will be responsible for laboratory operations, supply chain operations, and marketing and sales leveraging its operational excellence and significant market reach, initially focused in the U.S. and Canada. Helio will provide intellectual property and continued support across research and development, publication development, market access and sales, as well as reimbursement operations. Fulgent and Helio will also work together on the development of additional liquid biopsy tests for different types of cancer in the future.

Liver cancer is the fastest growing and second deadliest cancer worldwide. According to the American Cancer Society, liver cancer incidence rates have more than tripled since 1980, while the death rates have more than doubled during this time. Studies show that early detection of liver cancer is critical to successful outcomes with a survival rate that is 12 times higher if caught in early versus late stages.

Helio's new approach to detecting cancer with cfDNA methylation technology has the potential to provide a paradigm shift in the way the disease is diagnosed and monitored. The companies expect to launch HelioLiver this calendar year.

"We are very excited to partner with Helio to offer Helio's liquid biopsy test for early cancer detection," said Dr. Larry Weiss, Chief Medical Officer at Fulgent. "Helio has demonstrated that its liquid biopsy test offers significantly better accuracy relative to other test methods for early cancer detection. Helio's methylation-based capabilities will supplement Fulgent's comprehensive test menu across oncology, infectious and rare diseases, and reproductive health."

"We are pleased to be working with Helio on the development and commercialization of its liquid biopsy testing capabilities," said Dr. Harry Gao, Chief Scientific Officer at Fulgent. "In addition to testing for liver cancer, Fulgent and Helio will work to develop early screening for other types of cancers using Helio's methylation-based technologies. This research and development opportunity will further expand Fulgent's capabilities in liquid biopsy and oncology testing."

"Partnering with Fulgent furthers our mission to save lives by dramatically improving the current standard of care methods of early cancer detection," said Justin Chen Li, CEO of Helio USA. "Fulgent's strong commercial capabilities will enable us to solidify quick adoption of the HelioLiver test in the U.S. and Canada, with the option to expand globally."

"Fulgent and Helio are very complementary in products, technology, operations, marketing and sales," said Albert Zhang, CEO of Helio China. "With the strategic partnership, I'm looking forward to further accelerating the commercial plan of both companies."

About Fulgent Genetics

Fulgent Genetics is a technology-based genetic testing company focused on transforming patient care in oncology, infectious and rare diseases, and reproductive health. Fulgent's proprietary technology platform has created a broad, flexible test menu and the ability to continually expand and improve its proprietary genetic reference library while maintaining accessible pricing, high accuracy, and competitive turnaround times. Combining next generation sequencing ("NGS") with its technology platform, the Company performs full-gene sequencing with deletion/duplication analysis in an array of panels that can be tailored to meet specific customer needs. A cornerstone of the Company's business is its ability to provide expansive options and flexibility for all clients' unique testing needs through a comprehensive technology offering including cloud computing, pipeline services, record management, web portal services, clinical workflow, sequencing as a service, and automated lab services.

About Helio Health

Helio Health is an AI-driven biotechnology company focused on commercializing early cancer detection tests from a simple blood draw. The company's mission is to saving lives by detecting cancer early. With Helio's AI-driven technology, both physicians and their patients gain powerful insights from accurate, accessible, and convenient blood tests, dramatically improving the current standard care cancer early detection methods.

Building on a robust research and development program, and with access to tens of thousands of patient samples, the company is currently in clinical trials in the U.S. and China with its lead liver cancer detection test. Helio's development program is focused on liver, colon, lung, breast, and other types of cancers.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Examples of forward-looking statements in this press release include statements about, among other things: management's and others' beliefs, judgments and estimates regarding the development and potential commercialization of Helio's products and product candidates, including the timing of this development and any related regulatory approval; the benefits and opportunities relating to or arising from Fulgent's investment and Fulgent and Helio's collaborations arrangements; Fulgent's testing solutions and services; the Company's identification and evaluation of opportunities and its ability to capitalize on opportunities to grow its business.

Forward-looking statements are statements other than historical facts and relate to future events or circumstances or the Company's future performance, and they are based on management's current assumptions, expectations and beliefs concerning future developments and their potential effect on the Company's business. These forward-looking statements are subject to a number of risks and uncertainties, which may cause the forward-looking events and circumstances described in this press release to not occur, and actual results to differ materially and adversely from those described in or implied by the forward-looking statements. These risks and uncertainties include, among others: risks that the tests developed by Helio will not be effective or achieve commercial success; the ongoing impacts of the COVID-19 pandemic, including the preventive public health measures that may continue to impact demand for its tests and the pandemic's effects on the global supply chain; the market potential for, and the rate and degree of market adoption of, the Company's tests, including its newly-developed tests for COVID-19 and genetic testing generally; the Company's ability to capture a sizable share of the developing market for genetic and COVID-19 testing and to compete successfully in these markets, including its ability to continue to develop new tests that are attractive to its various customer markets, its ability to maintain turnaround times and otherwise keep pace with rapidly changing technology; the Company's ability to successfully integrate acquired businesses and assets into its business strategy and to derive value from its investments; the Company's ability to maintain the low internal costs of its business model, particularly as the Company makes investments across its business; the Company's ability to maintain an acceptable margin on sales of its tests, particularly in light of increasing competitive pressures and other factors that may continue to reduce the Company's sale prices for and margins on its tests; risks related to volatility in the Company's results, which can fluctuate significantly from period to period; risks associated with the composition of the Company's customer base, which can fluctuate from period to period and can be comprised of a small number of customers that account for a significant portion of the Company's revenue; the Company's ability to grow and diversify its customer base and increase demand from existing and new customers; the Company's investments in its infrastructure, including its sales organization and operational capabilities, and the extent to which these investments impact the Company's business and performance and enable it to manage any growth it may experience in future periods; the Company's level of success in obtaining coverage and adequate reimbursement and collectability levels from third-party payors for its tests; the Company's level of success in establishing and obtaining the intended benefits from partnerships, joint ventures or other relationships; the Company's compliance with the various evolving and complex laws and regulations applicable to its business and its industry; risks associated with the Company's international operations; the Company's ability to protect its proprietary technology platform; and general industry, economic, political and market conditions. As a result of these risks and uncertainties, forward-looking statements should not be relied on or viewed as predictions of future events.

The forward-looking statements made in this press release speak only as of the date of this press release, and the Company assumes no obligation to update publicly any such forward-looking statements to reflect actual results or to changes in expectations, except as otherwise required by law.

The Company's reports filed with the U.S. Securities and Exchange Commission ("SEC"), including its annual report on Form 10-K for the year ended December 31, 2020 filed with the SEC on March 8, 2021 and the other reports it files from time to time, including subsequently filed quarterly and current reports, are made available on the Company's website upon their filing with the SEC. These reports contain more information about the Company, its business and the risks affecting its business.

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