UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): May 9, 2023

GUARDANT HEALTH, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38683**	**45-4139254**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

3100 Hanover Street
Palo Alto, California 94304
(Address of principal executive offices) (Zip Code)

855-698-8887
(Registrant's telephone number, include area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.00001 par value per share	GH	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On May 9, 2023, Guardant Health, Inc. (the "Company") presented additional data from the ECLIPSE study at 2023 Digestive Disease Week (DDW) on the performance of the Company's Shield™ blood screening test for detecting colorectal cancer in average risk adults. The data presented at DDW elaborates on the top-line ECLIPSE study data the Company announced in December 2022. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release of Guardant Health, Inc., dated May 9, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GUARDANT HEALTH, INC.

Date: May 9, 2023

By: /s/ John G. Saia
John G. Saia
Chief Legal Officer

Exhibit 99.1

Guardant Health presents additional information from ECLIPSE study at 2023 Digestive Disease Week on the performance of Shield™ blood test

Shield™ blood test achieved overall 83% sensitivity and 90% specificity and demonstrated early-stage detection in range with other guideline-recommended non-invasive CRC screening modalities

PALO ALTO, Calif., May 9, 2023 — Guardant Health, Inc. (Nasdaq: GH), a leading precision oncology company, today presented additional data from the ECLIPSE study at 2023 Digestive Disease Week (DDW) titled, "Clinical Validation of a Cell-Free DNA Blood-Based Test for Colorectal Cancer in an Average Risk Population" (Abstract #913e) showcasing the performance of its blood-based technology to accurately detect early-stage colorectal cancer (CRC).

The ECLIPSE (Evaluation of ctDNA LUNAR Assay In an Average Patient Screening Episode) study is an over 20,000 patient registrational study evaluating the performance of the Shield blood test for detecting CRC in average-risk adults. The data presented at DDW elaborates on the top-line data the company announced in December 2022. Data presented today include:

- 83% sensitivity in detecting individuals with CRC;
- 81% sensitivity in detecting Stages I-III;
- 72% sensitivity in detecting localized disease (Stage I-II); and
- Sensitivity by stage of 55% for Stage I, 100% for Stage II, 100% for Stage III, and 100% for Stage IV.

These results are in range with other guideline recommended non-invasive screening modalities, where overall sensitivity ranges from 74-92%.

The ability to detect cancers in early stages is an important test parameter as the five-year survival rate is higher when caught early.[1] Shield's sensitivity of detecting stage I-III cases and localized cases (stage I-II) is in range with other guideline-recommended non-invasive screening modalities (FIT sensitivity in Stage I-III is 73%, and in localized cases is 70%).[2]

"There is a need for a more convenient and less invasive method to screen for colorectal cancer, and an accurate blood test has the potential to overcome many barriers patients face with traditional screening methods," said Daniel Chung, MD, gastroenterologist at Massachusetts General Hospital and Professor of Medicine at Harvard Medical School. "The data presented today at DDW highlight the promising results for blood-based CRC screening and the potential for blood tests to help close the gap in screening adherence."

Colorectal cancer is the third leading cause of cancer related death, but it is highly preventable and treatable if caught early.[3] Despite multiple screening modalities available for CRC, 49 million Americans remain unscreened.[4] Screening rates are even lower in minority and underserved populations.[5] This was a key consideration when conducting the ECLIPSE study, which reflects the diverse population of the U.S. Study data includes 13% Black, 15% Hispanic and 7% Asian American populations. Enrollment among Black Americans was above average for a clinical trial, which is important given the disproportionate impact of CRC on the black community.[6]

“Colorectal cancer screening saves lives, and yet, millions of people are still not getting it done. Blood tests have the potential to change that,” said Michael Sapienza, chief executive officer of the Colorectal Cancer Alliance. “Offering patients a convenient and minimally invasive option for getting screened that can reach them where they are is a great step forward in helping to close the screening gap.”

Since the commercial launch of the laboratory developed version of the Shield test in May 2022, it has shown an adherence rate greater than 90% in the real-world clinical setting.[7] Shield’s performance in detecting CRCs, combined with this real-world adherence, suggests that Shield has the potential to detect more CRCs at a curable stage than traditional modalities.[8,9,10]

“There is an unmet need in CRC screening for a high-performance screening test that gets completed. The Shield test is spearheading a new patient-preferred category in CRC screening and has the potential to significantly increase overall screening rates,” said AmirAli Talasaz, Guardant Health co-CEO. “We believe that as a longitudinal screening test, taken every three years, Shield would detect nearly all CRCs at a curable stage and will save many lives.”

To view the full presentation, please visit the “*Clinical Studies - Key Publications*” page of our website at https://guardanthealth.com/clinical-studies/key-publications/**.**

About the Shield™ Test

The Shield test detects colorectal cancer signals in the bloodstream from DNA that is shed by tumors, called circulating tumor DNA (ctDNA). Specifically, the test identifies specific characteristics of the DNA that may indicate the presence of cancer.

Shield is commercially available for eligible individuals by prescription only through healthcare professionals. This LDT (Laboratory Developed Test) is intended to be complementary to, and not a replacement for, current recommended CRC screening methods. A negative result does not rule out the presence of cancer. Patients with an abnormal blood-based screening result should be referred for a diagnostic colonoscopic evaluation.

More information about the Shield test is available at bloodbasedscreening.com.

About Digestive Disease Week®

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA), the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW is an in-person and online meeting from May 6-9, 2023. The meeting showcases more than 3,100 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

About Guardant Health

Guardant Health is a leading precision oncology company focused on helping conquer cancer globally through use of its proprietary tests, vast data sets and advanced analytics. The Guardant Health oncology platform leverages capabilities to drive commercial adoption, improve patient clinical outcomes and lower healthcare costs across all stages of the cancer care continuum. Guardant Health has commercially launched Guardant360®, Guardant360 CDx, Guardant360 TissueNext™, Guardant360 Response™, and GuardantINFINITY™ tests for advanced-stage cancer patients, and Guardant Reveal™ for early-stage cancer patients. The Guardant Health screening portfolio, including the commercially launched Shield™ test, aims to address the needs of individuals eligible for cancer screening. For more information, visit guardanthealth.com and follow the company on LinkedIn and Twitter.

Guardant Health Forward-Looking Statement

This press release contains forward-looking statements within the meaning of federal securities laws, including statements regarding the potential utilities, values, benefits and advantages of Guardant Health's liquid biopsy tests or assays, which involve risks and uncertainties that could cause the actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are based on current expectations, forecasts and assumptions, and actual outcomes and results could differ materially from these statements due to a number of factors. These and additional risks and uncertainties that could affect Guardant Health's financial and operating results and cause actual results to differ materially from those indicated by the forward-looking statements made in this press release include those discussed under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operation" and elsewhere in its Annual Report on Form 10-K for the year ended December 31, 2022, and any current and periodic reports filed with or furnished to the Securities and Exchange Commission thereafter. The forward-looking statements in this press release are based on information available to Guardant Health as of the date hereof, and Guardant Health disclaims any obligation to update any forward-looking statements provided to reflect any change in its expectations or any change in events, conditions, or circumstances on which any such statement is based, except as required by law. These forward-looking statements should not be relied upon as representing Guardant Health's views as of any date subsequent to the date of this press release.

References

1. Cancer.net. Colorectal Cancer: Statistics. Accessed online May 8. 2023. https://www.cancer.net/cancer-types/colorectal-cancer/statistics
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6. U.S. Food & Drug Administration. 2020 Drug Trials Snapshots Summary Report. FDA.gov website. Accessed online May 8, 2023. https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots

7. Shield LDT internal data.

8. Bretthauer M, Løberg M, Wieszczy P, et al.; NordICC Study Group. Effect of colonoscopy screening on risks of colorectal cancer and related death. N Engl J Med. 2022;387:1547-1556.

9. Knudsen AB, Rutter CM, Peterse EFP, et al. Colorectal cancer screening: An updated decision analysis for the U.S. Preventive Services Task Force. Rockville (MD): Agency for Healthcare Research and Quality; 2021a. Report No.: 202s.

10. Imperiale TF, Ransohoff DF, Itzkowitz SH, et al. Multitarget stool DNA testing for colorectal-cancer screening. NEJM. 2014.

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