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): August 31, 2023

23andMe Holding Co.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39587**	**87-1240344**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

349 Oyster Point Boulevard
South San Francisco, California 94080
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (650) 938-6300

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**
Class A Common Stock, $0.0001 par value per share	ME	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 August 31, 2023, 23andMe Holding Co. (the "Company") issued a press release announcing that that the U.S. Food and Drug Administration (FDA) granted 510(k) clearance to expand its existing BRCA1/BRCA2 (Selected Variants) Genetic Health Risk Report. In addition to the 510(k) clearance, the FDA also granted 23andMe the first-ever Predetermined Change Control Plan (PCCP), which allows the Company to report on additional BRCA variants without premarket review provided those variants meet the same rigorous analytical and clinical requirements demonstrated in this 510(k) clearance. The PCCP is pursuant to the FDA's "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning Enabled Device Software Functions" Guidance announced this spring. A copy of the press release is included as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information in this report furnished pursuant to Item 7.01, including Exhibit 99.1 attached hereto, shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference in any filing made by the Company pursuant to the Securities Act of 1933, as amended, other than to the extent that such filing incorporates by reference any or all of such information by express reference thereto.

The website address set forth in this report is included as an inactive textual reference only. The information contained on the website referenced herein is not incorporated into this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	23andMe Holding Co. Press Release, dated August 31, 2023
104	Cover Page Interactive Data File - the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are 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.

23ANDME HOLDING CO.

By: /s/ Kathy Hibbs
Name: Kathy Hibbs
Title: Chief Administrative Officer

Dated: August 31, 2023

EXHIBIT 99.1

23andMe Granted New FDA Clearance to Report Additional BRCA Variants

510(k) clearance will allow 23andMe to report an additional 41 genetic variants in the BRCA1 and BRCA2 genes that increase risk for breast, ovarian, prostate and pancreatic cancer

Many of these additional variants occur more often in people of African American and Hispanic/Latino descent

23andMe also granted an FDA Predetermined Change Control Plan, allowing the company to update its BRCA report with additional variants without a pre-market submission, provided those variants meet the same rigorous analytical and clinical requirements demonstrated in this 510(k) clearance

SOUTH SAN FRANCISCO, CALIF., August 31, 2023 – 23andMe Holding Co. (Nasdaq: ME) (23andMe), a leading human genetics and biopharmaceutical company, today announced the Company has received a U.S. Food and Drug Administration (FDA) 510(k) clearance to expand its existing BRCA1/BRCA2 (Selected Variants) Genetic Health Risk Report*. The clearance allows 23andMe to report an additional 41 variants in the BRCA1 and BRCA2 genes known to be associated with higher risk for breast, ovarian, prostate and pancreatic cancer. 23andMe received the first FDA authorization for a direct-to-consumer genetic test for cancer risk in 2018 to report 3 variants in the BRCA1 and BRCA2 genes, primarily found in people of Ashkenazi Jewish descent. Many of the 41 BRCA variants added through this clearance are known to have a higher rate of occurrence in populations traditionally underserved by genetic testing, including the African American and Hispanic/Latino communities. This marks the Company's fourth FDA clearance for genetic cancer risk.

In addition to the 510(k) clearance, the FDA also granted 23andMe the first-ever Predetermined Change Control Plan (PCCP), which allows the Company to add additional validated BRCA1 and BRCA2 variants and associated cancer risk information to its BRCA1/BRCA2 (Selected Variants) report without additional premarket review. The PCCP outlined the specific protocols and acceptance criteria that 23andMe intends to use to clinically and analytically validate eligible BRCA1/BRCA2 variants. The PCCP is pursuant to the FDA's "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning Enabled Device Software Functions" Guidance announced this spring.

"We continue to be the first and only company with FDA clearance to provide genetic information on cancer risk directly to consumers, without a prescription," said Anne Wojcicki, CEO and Co-Founder of 23andMe. "This clearance also allows us to increase the impact and reach of our results for traditionally underserved populations, a critical long-term goal of the Company. We are proud to continue pioneering a path for greater access to health information by becoming the first company to receive PCCP clearance from the FDA under this novel approach, which will enable us to increase the pace at which we improve and expand our BRCA report."

23andMe will now report on 44 variants in the BRCA1 and BRCA2 genes associated with a significantly higher risk of breast and ovarian cancer in females, and breast cancer in males. The variants may also be associated with an increased risk for prostate cancer, pancreatic cancer, and potentially other cancers. In addition to 3 BRCA variants common among people of Ashkenazi Jewish descent, the updated 23andMe BRCA report will now include variants accounting for about 30-40% of cancer-related BRCA variants among people of African American, non-Ashkenazi European and Hispanic/Latino descent; as well as variants found of people of East Asian and South Asian.

New and existing 23andMe Health + Ancestry Service customers who were genotyped on the Company's most recent platform will have access to the expanded BRCA1/BRCA2 (Selected Variants) report once it is updated. The Company plans/expects to release this report update by the end of fiscal year 2024. As with select other Genetic Health Risk reports, customers must specifically opt-in if they want to receive this information. The report also includes an education module to ensure customers are fully informed on what they can learn from this report and how to use the results.

The 23andMe BRCA1/BRCA2 (Selected Variants) Genetic Health Risk Report utilizes the same informational concepts previously demonstrated in studies submitted to the FDA for its Genetic Health Risk reports, which were shown to have 90% or greater overall user comprehension in a demographically diverse population study. 23andMe also underwent robust analytical validation in order to meet FDA requirements to add variants to the BRCA1/BRCA2 (Selected Variants) report. Each variant tested demonstrated >99% concordance with Sanger sequencing, and each variant tested also showed >99% reproducibility when tested under different laboratory conditions.

With this clearance, 23andMe continues to lead consumer access to genetic information, and remains the only company that is able to offer carrier, genetic health risk, cancer risk and drug metabolism and response reports, without a prescription. This clearance is the eighth pre-market authorization granted by the FDA to 23andMe covering its multiplexed Personal Genome Service.

BRCA variants indicated in the 510(k) clearance:

The 23andMe Personal Genome Service (PGS) Genetic Health Risk Report for BRCA1/BRCA2 (Selected Variants) is indicated for the reporting of the following 44 variants in the BRCA1 and BRCA2 genes.

BRCA1: c.68_69del, c.213-11T>G, c.427G>T, c.815_824dup, c.1556del, c.1687C>T, c.1960A>T, c.1961del, c.2681_2682del, c.2864C>A, c.3481_3491del, c.3598C>T, c.3627dup, c.3756_3759del, c.3770_3771del, c.4035del, c.4065_4068del, c.4327C>T, c.4357+1G>A, c.4964_4982del, c.4986+6T>G, c.5123C>A, c.5177_5180del, c.5266dup.

BRCA2: c.658_659del, c.771_775del, c.1929del, c.2808_2811del, c.2957_2958insG, c.3170_3174del, c.3264dup, c.3545_3546del, c.3847_3848del, c.4471_4474del, c.5542del, c.5576_5579del, c.5682C>G, c.5946del, c.6037A>T, c.6275_6276del, c.7024C>T, c.7480C>T, c.7934del, c.8904del.

Warnings and Limitations:

The 23andMe PGS test uses qualitative genotyping to detect select clinically relevant variants in the genomic DNA of adults from saliva for the purpose of reporting and interpreting genetic health risks, including the 23andMe PGS Genetic Health Risk Report for BRCA1/BRCA2 (Selected Variants). Your ethnicity may affect the relevance of each report and how your genetic health risk results are interpreted. The test is not intended to diagnose any disease and does not describe a person's overall risk of developing any type of cancer. It is not intended to tell you anything about your current state of health, or to be used to make medical decisions, including whether or not you should take a medication, how much of a medication you should take, or determine any treatments. **Warnings & Limitations:** The 23andMe PGS Genetic Health Risk Report for BRCA1/BRCA2 (Selected Variants) is indicated for reporting of 44 variants in the BRCA1 and BRCA2 genes. The report describes if a person's genetic result is associated with an increased risk of developing breast cancer and ovarian cancer and may be associated with an increased risk for prostate cancer, pancreatic cancer, and potentially other cancers. The variants included in this report do not represent the majority of the BRCA1/BRCA2 variants in people of most ethnicities. This report does not include variants in other genes linked to hereditary cancers and the absence of variants included in this report does not rule out the presence of other genetic variants that may impact cancer risk. This report is for over-the-counter use by adults over the age of 18, and provides genetic information to inform discussions with a healthcare professional. The PGS test is not a substitute for visits to a healthcare professional for recommended screenings or appropriate follow-up. Results should be confirmed by an independent genetic test prescribed by your own healthcare provider before taking any medical action.

About 23andMe

23andMe is a genetics-led consumer healthcare and therapeutics company empowering a healthier future. For more information, please visit investors.23andme.com.

Additional Information

This press release shall not constitute an offer to sell or a solicitation of an offer to buy any of the securities, nor shall there be any sale of these securities, in any state or jurisdiction in which such an offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including, without limitation, statements regarding the future performance of 23andMe's businesses in consumer genetics and therapeutics and the growth and potential of its proprietary research platform. All statements, other than statements of historical fact, included or incorporated in this press release, including statements regarding 23andMe's strategy, financial position, funding for continued operations, cash reserves, projected costs, plans, potential future collaborations, product development and launches, the successful commercialization and market acceptance of new products and objectives of management, are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," "predicts," "continue," "will," "schedule," and "would" or, in each case, their negative or other variations or comparable terminology, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are predictions based on 23andMe's current expectations and projections about future events and various assumptions. 23andMe cannot guarantee that it will actually achieve the plans, intentions, or expectations disclosed in its forward-looking statements and you should not place undue reliance on 23andMe's forward-looking statements. These forward-looking statements involve a number of risks, uncertainties (many of which are beyond the control of 23andMe), or other assumptions that may cause actual results or performance to differ materially from those expressed or implied by these forward-looking statements. The forward-looking statements contained herein are also subject generally to other risks and uncertainties that are described from time to time in the Company's filings with the Securities and Exchange Commission, including under Item 1A, "Risk Factors" in the Company's most recent Annual Report on Form 10-K, as filed with the Securities and Exchange Commission, and as revised and updated by our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. The statements made herein are made as of the date of this press release and, except as may be required by law, 23andMe undertakes no obligation to update them, whether as a result of new information, developments, or otherwise.

Contacts:

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