

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): January 6, 2022

23andMe Holding Co.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39587
(Commission
File Number)

87-1240344
(IRS Employer
Identification No.)

223 N. Mathilda Avenue
Sunnyvale, California 94086
(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 January 6, 2022, 23andMe Holding Co. (the “Company”) issued a press release announcing that the Company initiated a Phase 1 clinical trial for its first wholly-owned immuno-oncology antibody for patients with solid tumors. In addition, the Company announced that it will be hosting a virtual R&D Day on January 18, 2022. 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 “filed” for the 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. It may only be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended, if such subsequent filing specifically references the information furnished pursuant to Item 7.01 of this report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
99.1	23andMe Holding Co. Press Release, dated January 6, 2022
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 Legal and Regulatory Officer

Dated: January 6, 2022

23andMe Initiates Phase 1 Clinical Trial for First Wholly-Owned Immuno-oncology Antibody for Patients with Solid Tumors

23ME-00610 targets CD200R1, an important regulator of T cells and myeloid cells

CD200R1 was identified as a promising immuno-oncology target through 23andMe's proprietary genetic and health survey database

Company will host a virtual R&D Day event on January 18, 2022

SUNNYVALE, CA - JANUARY 6, 2022 - 23andMe Holding Co. (Nasdaq: ME) ("23andMe"), a leading consumer genetics and research company, today announced the first participant has been dosed in a Phase 1 clinical trial evaluating 23ME-00610 for the treatment of advanced solid tumors. 23ME-00610 is 23andMe's first wholly-owned immuno-oncology (I/O) antibody to enter the clinic. The target for the new investigational antibody, CD200R1, was identified as a promising immuno-oncology target through 23andMe's proprietary genetic and health survey database.

"This is an important milestone for 23andMe in our mission to help people access, understand and benefit from the human genome," said Anne Wojcicki, CEO and co-founder, 23andMe. "When we started our Therapeutics group, our goal was to find new medicines validated by human genetics for people with serious unmet medical needs. That's why we're excited to move 23ME-00610 into the clinic to potentially help people with cancer who are in need of new treatment options."

The Phase 1 clinical trial is designed to evaluate the safety, tolerability and pharmacokinetics of 23ME-00610 in patients with locally advanced or metastatic solid tumors whose disease has progressed after standard of care treatment. 23ME-00610 is part of 23andMe's larger drug discovery program of targets validated by human genetics across a spectrum of disease areas, including oncology, immunology, respiratory, and cardiometabolic diseases.

"Our approach to drug discovery is driven by human genetics, and we have an incredibly large database from which to select and advance genetically validated targets more efficiently, and with a potentially higher probability of success, than traditional drug discovery methods currently allow," said Kenneth Hillan, Head of Therapeutics at 23andMe. "23ME-00610 is an exciting example of how we are translating our data into investigational therapeutics."

23andMe has approximately 12 million customers, approximately 80% of whom consent to participate in research. 23andMe scientists study aggregate, de-identified genetics of these participants, alongside more than 4 billion health survey answers. Using its large database of genetically linked health traits and machine learning applied to its proprietary I/O genetic signature, 23andMe is able to pinpoint areas of the genome that contain targets for cancer therapeutics based on human genetics, including the 23ME-00610 target.

23andMe's Immuno-oncology genetic signature

Using its genetic data, 23andMe can identify immune-related genes that are expected to have an impact on cancer biology. Specifically, germline genetics can reveal which of the immune-related genes harbor genetic variants that also alter an individual's predisposition for developing cancer. 23andMe has developed an analytical approach, termed the immuno-oncology (I/O) genetic signature, to identify evidence for genetic variants that increase immune function while decreasing cancer risk. Using this approach, 23andMe scientists discovered that three components of the CD200R1 pathway exhibit an I/O genetic signature, including the CD200R1 receptor, the CD200 ligand, and DOK2, a mediator of downstream signaling from CD200R1. Following this genetic insight, 23andMe subsequently generated data consistent with CD200R1's role in inhibiting anti-tumor responses in immune cells.

About CD200R1 and 23-ME-00610

The CD200–CD200R1 axis is an immunological checkpoint that plays a pivotal role in maintenance of immune tolerance. CD200R1 is an inhibitory receptor expressed on T cells and myeloid cells while CD200, the ligand for CD200R1, is highly expressed on certain tumors. Binding of tumor associated CD200 to CD200R1 leads to immune suppression and decreased immune cell killing of cancer cells.

23ME-00610 is a high-affinity humanized monoclonal antibody that is designed to bind to the CD200R1 receptor and prevent the interaction of CD200 and CD200R1. Preclinical data indicate that this mechanism has the potential to reinvigorate tumor-exhausted T-cells and myeloid cells to restore their ability to kill cancer cells.

About the Phase 1 23ME-00610 Study

The first-in-human, multi-center, open-label clinical trial will determine the safety and tolerability of 23ME-00610 in people with locally advanced or metastatic solid malignancies that have progressed after standard therapy. This study will also evaluate preliminary anticancer activity, and the pharmacokinetic and pharmacodynamic profile of 23ME-00610 to identify the optimal dose and schedule for further clinical studies. After the Phase I dose escalation phase is completed, 23andMe will seek to enroll people with specific tumor types to evaluate the potential for anticancer efficacy and changes in pharmacodynamic endpoints in the expansion phase.

Participants with ECOG performance status 0-1, and with histologically diagnosed locally advanced or metastatic solid malignancy that has progressed after standard therapy for the specific tumor type are eligible. Additionally, adolescents 12 years and older with histologically diagnosed locally advanced, or metastatic solid malignancy are eligible for enrolment in the expansion phase.

R&D Day Event Information

To discuss 23ME-00610 and other developments from its Therapeutics group in more detail, the company will host a virtual R&D Day event from 8:00 a.m. to 11:30 am Pacific Time on Tuesday, January 18, 2022. The webcast event can be accessed on the day of the event at <https://investors.23andme.com/news-events/events-presentations>. A webcast replay will be available at the same address for a limited time within 24 hours after the event.

About 23andMe

23andMe, headquartered in Sunnyvale, CA, is a leading consumer genetics and research company. Founded in 2006, the company's mission is to help people access, understand, and benefit from the human genome. 23andMe has pioneered direct access to genetic information as the only company with multiple FDA authorizations for genetic health risk reports. The company has created the world's largest crowdsourced platform for genetic research, with ~ 80 percent of its customers electing to participate. The 23andMe research platform has generated more than 180 publications on the genetic underpinnings of a wide range of diseases, conditions, and traits. The platform also powers the 23andMe Therapeutics group, currently pursuing drug discovery programs rooted in human genetics across a spectrum of disease areas, including oncology, respiratory, and cardiovascular diseases, in addition to other therapeutic areas. More information is available at www.23andMe.com.

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. 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 and objectives of management, clinical trials and the potential outcomes and timing thereof, the identification and advancement of genetically validated targets, and the potential or success of any such genetically validated targets, 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 to other risks and uncertainties that are described in 23andMe's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 filed with the Securities and Exchange Commission ("SEC") on November 10, 2021 and in the reports subsequently filed by 23andMe with the SEC. 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.

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