
**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): January 29, 2024

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.)

**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 January 31, 2024, 23andMe Holding Co. (the “Company”) issued a press release announcing that the U.S. Food and Drug Administration (FDA) has cleared the investigational new drug application for 23ME-01473 (‘1473), a novel Natural Killer (NK) cell activator for the treatment of cancer. ‘1473 will be evaluated in patients with advanced solid tumors in a Phase 1 clinical study beginning in the first half of 2024. 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 January 31, 2024
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.

Date: January 31, 2024

By: /s/ Joseph Selsavage

Name: Joseph Selsavage

Title: Interim Chief Financial and Accounting Officer

23andMe Announces FDA Clearance of IND Application for its Dual Mechanism Antibody, 23ME-01473, Targeting ULBP6

- *23ME-01473 ('1473) seeks to treat cancer by restoring anti-tumor immunity through NK and T cells*
- *'1473 has dual mechanisms of blocking the immunosuppressive effects of soluble ULBP6, and inducing Fc receptor-mediated killing of ULBP6-expressing cancer cells through enhanced effector function*
- *Phase 1 clinical study in patients with solid tumors to commence in H1 2024*
- *The target for '1473 was discovered through 23andMe's proprietary research platform, the world's largest recontactable database of de-identified human genetic and phenotypic information*

SOUTH SAN FRANCISCO, CALIF., January 31, 2024 - 23andMe Holding Co. (Nasdaq: ME) (23andMe), a leading human genetics and biopharmaceutical company, announced the U.S. Food and Drug Administration (FDA) has cleared the investigational new drug application for 23ME-01473 ('1473), a natural killer (NK) cell activator intended to treat cancer. 23andMe plans to evaluate '1473 in participants with advanced solid tumors in a Phase 1 clinical study beginning in the first half of 2024.

'1473 targets ULBP6 to restore anti-tumor immunity through NK and T cells. ULBPs are stress-induced ligands found on the surface of cancer cells that bind to their receptor, NKG2D, on NK and T cells. Cancers escape immune cell recognition by shedding ULBP ligands from their cell surface, which act as immunosuppressive molecular decoys.

Blocking the binding of soluble ULBP6 to NKG2D may restore immune cell recognition and killing of cancers. Further, '1473 is Fc-effector enhanced, which provides an additional mechanism for NK cells to induce cell death of ULBP6-expressing cancer cells.

'1473 also has the potential to address a major unmet need in cancer treatment: patients who may have or may develop tumor resistance to checkpoint inhibitors. By combining NK and T cell activation, '1473 may initiate a broader and deeper response of the immune system to kill cancer cells, and delay tumor resistance seen in treatment with traditional checkpoint inhibitors.

"This program further validates the 23andMe database as a proven resource for identifying novel therapeutic targets," said Jennifer Low, Head of Therapeutics Development, 23andMe. "The team is excited to initiate our next immuno-oncology program, '1473, which is particularly

interesting given its two mechanisms of action, which may synergize to enhance NK and T cell immunity against certain tumors.”

About 23andMe

23andMe is a genetics-led consumer healthcare and biopharmaceutical company empowering a healthier future. For more information, please visit 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, including, without limitation, statements regarding the future plans of 23andMe's therapeutics business. All statements, other than statements of historical fact, included or incorporated in this press release, including statements regarding 23andMe's strategy, the plans for and results of its clinical trials 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.

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