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): February 26, 2024

MOONLAKE IMMUNOTHERAPEUTICS
(Exact Name of Registrant as Specified in Its Charter)

Cayman Islands	**001-39630**	**98-1711963**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Dorfstrasse 29
6300 Zug
Switzerland
(Address of principal executive offices and Zip Code)

41 415108022
(Registrant's Telephone Number, Including Area Code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

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 (see General Instruction A.2 below):

☐ 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 ordinary share, par value $0.0001 per share	MLTX	The Nasdaq Capital 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 February 26, 2024, MoonLake Immunotherapeutics (the "Company") issued a press release announcing the successful outcome of its end-of-Phase 2 interactions with the U.S. Food and Drug Administration, as well as positive feedback from its interactions with the E.U. European Medicines Agency, with both regulatory bodies unanimously supporting the Company's proposed approach for advancing its Phase 3 program of the Nanobody® sonelokimab in hidradenitis suppurativa.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein. The exhibit furnished under Item 7.01 of this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits*. The following exhibits are being furnished herewith:

Exhibit Number	Exhibit Title or Description
99.1	Press Release, dated February 26, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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

MOONLAKE IMMUNOTHERAPEUTICS

Date: **February 26, 2024**

By: /s/ Matthias Bodenstedt
Name: Matthias Bodenstedt
Title: Chief Financial Officer

Exhibit 99.1

MoonLake Immunotherapeutics Announces Positive Feedback from both FDA and EMA on Regulatory Path for the Phase 3 Program of the Nanobody® sonelokimab (SLK) in Hidradenitis Suppurativa (HS)

- *Clarified path for HS Phase 3 program with study design, patient population and endpoints agreed*
- *One dose of SLK (120mg) to be tested with a similar protocol as in Phase 2*
- *Total Phase 3 population of 800 patients to be complemented by Phase 2 population for registration*
- *Phase 3 trial has similar design to validated Phase 2 trial and in line with the Company's communications and expectations*
- *First patient expected to be randomized in Q2 2024, primary endpoint readout expected mid-2025*
- *Further details to be provided in upcoming R&D Day*

ZUG, Switzerland, February 26, 2024 – MoonLake Immunotherapeutics (NASDAQ:MLTX) ("MoonLake"), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announced the successful outcome of its end-of-Phase 2 interactions with the U.S. Food and Drug Administration (FDA), as well as positive feedback from its interactions with the E.U. European Medicines Agency (EMA), with both regulatory bodies unanimously supporting MoonLake's proposed approach for advancing its Phase 3 program of the Nanobody® sonelokimab (SLK) in hidradenitis suppurativa (HS).

The Phase 3 program, named VELA, is expected to enroll 800 patients and in combination with the data from Phase 2 MIRA trial will support both a Biologics License Application (BLA) and E.U. Marketing Authorization Application. The Phase 3 trial design will compare a single SLK dose (120mg) to placebo over a 16-week period, with the placebo group subsequently transitioning to SLK 120mg. The primary endpoint (HiSCR75) and key secondary endpoints read out at week 16. The VELA trial program is designed to run for 52 weeks followed by an open-label extension (OLE). The number of patients, the straightforward trial design, the similarity of protocol to the Phase 2 trial, and the identification of the HS dose, collectively, enhance the clarity of SLK's clinical development and displays promise for the HS franchise. The readout of the primary endpoint is anticipated in mid-2025.

Dr. Jorge Santos da Silva, Chief Executive Officer of MoonLake Immunotherapeutics, said: *"The favorable response from both the FDA and EMA aligns with the strengths we have consistently highlighted in our trial programs and outlines a clear regulatory path for sonelokimab in hidradenitis suppurativa. We deeply appreciate the support from both agencies and continue to work swiftly to ramp up the Phase 3 program in HS, named VELA. This represents a crucial step in offering a potential innovative treatment option to patients and their dedicated physicians, addressing a condition that is often under-recognized, under-treated and significantly impacts patients' lives."*

Additionally, MoonLake plans to have an end-of-Phase 2 meeting with the FDA regarding its psoriatic arthritis (PsA) program in Q2 2024 and begin the Phase 3 program in Q4 2024.

Moonlake will provide more information relating to the plans for both the HS and PsA programs during an upcoming R&D Day.

- Ends -

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About MoonLake Immunotherapeutics

MoonLake Immunotherapeutics is a clinical-stage biopharmaceutical company unlocking the potential of sonelokimab, a novel investigational Nanobody® for the treatment of inflammatory disease, to revolutionize outcomes for patients. Sonelokimab inhibits IL-17A and IL-17F by inhibiting the IL-17A/A, IL-17A/F, and IL-17F/F dimers that drive inflammation. The company's focus is on inflammatory diseases with a major unmet need, including hidradenitis suppurativa and psoriatic arthritis – conditions affecting millions of people worldwide with a large need for improved treatment options. MoonLake was founded in 2021 and is headquartered in Zug, Switzerland. Further information is available on www.moonlaketx.com.

About Nanobodies®

Nanobodies® represent a new generation of antibody-derived targeted therapies. They consist of one or more domains based on the small antigen-binding variable regions of heavy-chain-only antibodies (VHH). Nanobodies® have a number of potential advantages over traditional antibodies, including their small size, enhanced tissue penetration, resistance to temperature changes, ease of manufacturing, and the ability to design multivalent therapeutic molecules with bespoke target combinations.

The terms Nanobody® and Nanobodies® are trademarks of Ablynx, a Sanofi company.

About Sonelokimab

Sonelokimab (M1095) is an investigational ~40 kDa humanized Nanobody® consisting of three VHH domains covalently linked by flexible glycine-serine spacers. With two domains, sonelokimab selectively binds with high affinity to IL-17A and IL-17F, thereby inhibiting the IL-17A/A, IL-17A/F, and IL-17F/F dimers. A third central domain binds to human albumin, facilitating further enrichment of sonelokimab at sites of inflammatory edema.

Sonelokimab is being assessed in two trials, the Phase 2 ARGO trial in PsA and the Phase 2 MIRA trial in HS. In June 2023, topline results of the MIRA trial (NCT05322473) at 12 weeks showed that the trial met its primary endpoint, the Hidradenitis Suppurativa Clinical Response (HiSCR)75, which is a higher measure of clinical response versus the HiSCR50 measure used in other clinical trials, setting a landmark milestone. In October 2023, the full dataset from the MIRA trial at 24 weeks showed that maintenance treatment with sonelokimab led to further improvements in HiSCR75 response rates and other clinically relevant outcomes. In November 2023, MoonLake announced positive top-line results from its global Phase 2 ARGO trial evaluating the efficacy and safety of the Nanobody® sonelokimab in patients with active psoriatic arthritis (PsA). The trial met its primary endpoint with a statistically significant greater proportion of patients treated with either sonelokimab 60mg or 120mg (with induction) achieving an American College of Rheumatology (ACR) 50 response compared to those on placebo at week 12. All key secondary endpoints in the trial were met for the 60mg and 120mg doses with induction.

Sonelokimab has also been assessed in a randomized, placebo-controlled Phase 2b trial (NCT03384745) in 313 patients with moderate-to-severe plaque-type psoriasis. High threshold clinical responses (the Investigator's Global Assessment Score 0 or 1, and the Psoriasis Area and Severity Index 90/100) were observed in patients with moderate-to-severe plaque-type psoriasis. Sonelokimab was generally well tolerated, with a safety profile similar to the active control, secukinumab (Papp KA, et al. Lancet. 2021; 397:1564-1575).

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In an earlier Phase 1 trial in patients with moderate-to-severe plaque-type psoriasis, sonelokimab has been shown to decrease (to normal skin levels) the cutaneous gene expression of pro-inflammatory cytokines and chemokines (Svecova D. J Am Acad Dermatol. 2019;81:196–203).

Sonelokimab is not yet approved for use in any indication.

About the MIRA trial

The MIRA trial (M1095-HS-201) is a global, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of the Nanobody® sonelokimab, administered subcutaneously, in the treatment of adult patients with active moderate-to-severe hidradenitis suppurativa. The trial recruited 234 patients, with the aim to evaluate two different doses of sonelokimab (120mg and 240mg) with placebo control and adalimumab as an active reference arm. The primary endpoint of the trial is the percentage of participants achieving Hidradenitis Suppurativa Clinical Response 75 (HiSCR75), defined as a ≥75% reduction in total abscess and inflammatory nodule (AN) count with no increase in abscess or draining tunnel count relative to baseline. The trial also evaluated a number of secondary endpoints, including the proportion of patients achieving HiSCR50, the change from baseline in International Hidradenitis Suppurativa Severity Score System (IHS4), the proportion of patients achieving a Dermatology Life Quality Index (DLQI) total score of ≤5, and the proportion of patients achieving at least 30% reduction from baseline in Numerical Rating Scale (NRS30) in the Patient's Global Assessment of Skin Pain (PGA Skin Pain). Further details are available at: https://www.clinicaltrials.gov/ct2/show/NCT05322473.

Cautionary Statement Regarding Forward Looking Statements

This press release contains certain "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements regarding MoonLake's expectations, hopes, beliefs, intentions or strategies regarding the future including, without limitation, statements regarding: anticipated support from regulatory agencies with respect to the Company's development plans, anticipated size and timing of enrollment for the VELA trial, the sufficiency of data from the VELA trial to support regulatory filings in the US and EU, the anticipated trial design for the VELA trial and the timing of expected readouts, the efficacy and safety of sonelokimab for the treatment of HS and PsA, including in comparison to existing standards or care or other competing therapies, and the Company's plans with respect to FDA meetings for its PsA program and the commencement of a Phase 3 trial in PsA. In addition, any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward- looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that statement is not forward looking.

Forward-looking statements are based on current expectations and assumptions that, while considered reasonable by MoonLake and its management, as the case may be, are inherently uncertain. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with MoonLake's business in general and limited operating history, difficulty enrolling patients in clinical trials, unknown future interactions with regulatory agencies, and reliance on third parties to conduct and support its preclinical studies and clinical trials.

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Nothing in this press release should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements in this press release, which speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein. MoonLake does not undertake or accept any duty to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or in the events, conditions or circumstances on which any such statement is based.

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