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): June 10, 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 June 10, 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 (the "FDA"), as well as positive feedback from its interactions with the E.U. European Medicines Agency (the "EMA"), with both regulatory bodies unanimously supporting the Company's proposed approach for advancing its Phase 3 program of the Nanobody® sonelokimab ("SLK") in psoriatic arthritis ("PsA").

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 of 1934 (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 of 1933, regardless of any general incorporation language in such filing.

Item 8.01. Other Events.

On June 10, 2024, the Company announced the successful outcome of its end-of-Phase 2 interactions with the FDA, as well as positive feedback from its interactions with the EMA, with both regulatory bodies unanimously supporting the Company's proposed approach for advancing its Phase 3 program of SLK in PsA. The Phase 3 program, named IZAR, is expected to enroll around 1,500 patients and, in combination with data from the Phase 2 ARGO trial, is designed to support a Biologics License Application and E.U. Marketing Authorization Application.

Forward-Looking Statements

This Current Report on Form 8-K and the press release furnished as Exhibit 99.1 contain 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 the Company's expectations, hopes, beliefs, intentions or strategies regarding the future including, without limitation, statements regarding: plans for and timing of clinical trials, including the topline primary endpoint readout for the Phase 3 IZAR program, the trial design and patient enrollment across the IZAR-1 and IZAR-2 trials, the initiation of the Phase 3 program in PsA, the efficacy and safety of SLK for the treatment of hidradenitis suppurativa and PsA, including in comparison to existing standards or care or other competing therapies, clinical trials and research and development programs and the anticipated timing of the results from those studies and trials. 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. These statements reflect our plans, estimates, and expectations, as of the date of this Current Report on Form 8-K. These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in this Current Report on Form 8-K. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties. Additional risks and factors are identified under "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 and subsequent filings with the Securities and Exchange Commission.

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 June 10, 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: **June 10, 2024**

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

Exhibit 99.1

MoonLake Immunotherapeutics Announces Positive Regulatory Feedback from both FDA and EMA on Path for the Phase 3 Program for the Nanobody® sonelokimab in Psoriatic Arthritis

- *Builds upon the positive regulatory feedback received from FDA and EMA on Phase 3 VELA program for sonelokimab in hidradenitis suppurativa (HS), which has started recruitment*
- *Clarified path for PsA Phase 3 program with study design, patient population and endpoints agreed – program is called IZAR and two trials are planned with one focusing on bio-naïve patients and radiographic progression (IZAR-1) and another on TNF-IR patients (IZAR-2)*
- *The main dose to be tested will be 60mg, and the 120mg dose will also be tested, with risankizumab as a reference arm (in IZAR-2)*
- *Total Phase 3 population of approximately 1,500 patients to be complemented by Phase 2 population for registration*
- *Phase 3 trial design in line with the Company's communications and guidance*
- *First patient expected to be randomized in Q4 2024; primary endpoint readout expected end-2026*

ZUG, Switzerland, June 10, 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 in psoriatic arthritis (PsA).

The Phase 3 program, named IZAR, is expected to enroll around 1,500 patients and in combination with data from the Phase 2 ARGO trial is designed to support both a Biologics License Application (BLA) and E.U. Marketing Authorization Application. Two global, randomized, double blind, placebo-controlled trials are planned (IZAR-1 and IZAR-2) to evaluate the efficacy and safety of the Nanobody® sonelokimab over one year. IZAR-1 will enroll a biologic naïve population and include an evaluation of radiographic progression, while IZAR-2 will enroll a TNF-IR population and will be the first trial to include a risankizumab active reference arm. The IZAR program will assess a 60mg sonelokimab dose as well as a 120mg sonelokimab dose. The primary endpoint (ACR50) compared to placebo and key secondary endpoints for both trials will read out at week 16. The readout of the primary endpoint is anticipated at the end of 2026.

Dr. Jorge Santos da Silva, Chief Executive Officer of MoonLake Immunotherapeutics, said: *"The recent regulatory milestones for PsA mark the second such significant achievement for MoonLake building on the positive FDA and EMA feedback for HS earlier this year. These regulatory outcomes provide a clear roadmap for PsA and, by the end of 2024, we will have independently commenced three Phase 3 programs addressing two inflammatory indications that are under diagnosed and underserved. This progress is a testament to our specialized expertise and steadfast commitment to advancing the field of inflammation and immunology."*

- Ends –

About Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic and progressive inflammatory arthritis associated with psoriasis primarily affecting the peripheral joints. The clinical features of PsA are diverse, involving pain, swelling, and stiffness of the joints, which can result in restricted mobility and fatigue. PsA occurs in up to 30% of patients with psoriasis, most commonly those aged between 30 and 60 years. The symptom burden of PsA can have a substantial negative impact on patient quality of life. Although the exact mechanism of disease is not fully understood, evidence suggests that activation of the IL-17 pathway plays an important role in the disease pathophysiology.

About IZAR

IZAR-1 and IZAR-2 are planned global, randomized, double-blind, placebo-controlled Phase 3 trials that will be designed to evaluate the efficacy and safety of sonelokimab compared with placebo in a total of approximately 1,500 adults with active PsA, with a primary endpoint of superiority to placebo in ACR 50 response at Week 16. IZAR-1 will enroll a biologic-naïve population and include an evaluation of radiographic progression, while IZAR-2 will enroll a TNF-experienced population — reflecting patients commonly seen in clinical practice — and will be the first PsA trial to include a risankizumab active reference arm. Both trials will also include a range of secondary endpoints reflecting the multiple disease manifestations characteristic of PsA, including skin and nail outcomes, multidomain endpoints, and patient-reported outcome measures such as pain and quality of life assessments.

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 lead indications, HS and psoriatic arthritis (PSA), and the Company is pursuing other indications in dermatology and rheumatology.

For HS, sonelokimab is being assessed in the Phase 3 trials, VELA-1 and VELA-2, following the successful outcome of MoonLake's end-of-Phase 2 interactions with the FDA and as well as positive feedback from its interactions with the EMA announced in February 2024. 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 high threshold clinical and patient relevant outcomes. The safety profile of sonelokimab in the MIRA trial was consistent with previous trials with no new safety signals detected.

For PsA, Phase 3 initiation is anticipated in Q4 2024 following the announcement in March 2024 of the full dataset from the global Phase 2 ARGO trial (M1095-PSA-201) evaluating the efficacy and safety of the Nanobody® sonelokimab over 24 weeks in patients with active PsA. Significant improvements were observed across all key outcomes, including approximately 60% of patients treated with sonelokimab achieving an American College of Rheumatology (ACR) 50 response and Minimal Disease Activity (MDA) at week 24. This followed the positive top-line results in November 2023, where the trial met its primary endpoint with a statistically significant greater proportion of patients treated with either sonelokimab 60mg or 120mg (with induction) achieving ACR50 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. The safety profile of sonelokimab in the ARGO trial was consistent with previous trials with no new safety signals detected.

A Phase 2 trial is expected to be initiated in 2024 for palmo-plantar pustulosis (PPP), a debilitating inflammatory skin condition affecting a significant number of patients. In addition, a Phase 3 trial is expected to initiate in juvenile HS, a condition that typically manifests at this early stage of a patient's life, and the period in which irreversible damage and inflammatory remission is most critical.

Sonelokimab will also be assessed in seronegative spondyloarthritis with Phase 2 trials in radiographic and non-radiographic axial spondyloarthritis (axSpA) and PsA expected to start in 2024. The trials are set to incorporate innovative designs that enhance traditional clinical outcomes with contemporary tissue and cellular imaging techniques.

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 (Investigator's Global Assessment Score 0 or 1, and 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).

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).

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 their ability to be designed into multivalent therapeutic molecules with bespoke target combinations.

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

About Hidradenitis Suppurativa

Hidradenitis suppurativa is a severely debilitating chronic skin condition resulting in irreversible tissue destruction. HS manifests as painful inflammatory skin lesions, typically around the armpits, groin, and buttocks. Over time, uncontrolled and inadequately treated inflammation can result in irreversible tissue destruction and scarring. The disease affects 0.05–4.1% of the global population, with three times more females affected than males. Real-world data in the US indicates that at least 2 million unique patients have been diagnosed with and treated for HS between 2016 and 2023 alone, highlighting a significant unmet need and impact on healthcare systems, and a market opportunity exceeding $10bn by 2035. Onset typically occurs in early adulthood and HS has a profound negative impact on quality of life, with a higher morbidity than other dermatologic conditions. There is increasing scientific evidence to support IL-17A- and IL-17-mediated inflammation as a key driver of the pathogenesis of HS, with other identified risk factors including genetics, cigarette smoking, and obesity.

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 IL17F/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 at www.moonlaketx.com.

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: plans for and timing of clinical trials, including the topline primary endpoint readout for the Phase 3 IZAR program, the trial design and patient enrollment across the IZAR-1 and IZAR-2 trials, the initiation of the Phase 3 program in PsA, 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, clinical trials and research and development programs and the anticipated timing of the results from those studies and trials. 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, state and federal healthcare reform measures that could result in reduced demand for MoonLake's product candidates and reliance on third parties to conduct and support its preclinical studies and clinical trials and the other risks described in or incorporated by reference into MoonLake's Annual Report on Form 10-K for the year ended December 31, 2023 and subsequent filings with the Securities and Exchange Commission.

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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