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): October 15, 2023

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 October 15, 2023, MoonLake Immunotherapeutics (the "Company") issued a press release announcing positive 24-week top-line results from its global Phase 2 MIRA trial (M1095-HS-201) evaluating the efficacy and safety of the Nanobody® sonelokimab in patients with moderate-to-severe hidradenitis suppurativa. The Company will host a webcast today, Monday, October 16, 2023 at 8:00 am, Eastern Time, to discuss the data results.

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 October 15, 2023
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: **October 16, 2023**

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

Exhibit 99.1

MoonLake Immunotherapeutics announces the full dataset from its 24-week MIRA clinical trial, establishing the Nanobody® sonelokimab as a highly promising and differentiated therapeutic solution for Hidradenitis Suppurativa (HS)

- Maintenance treatment with sonelokimab dosed every 4 weeks (Q4W), demonstrated that 57% of patients achieved HiSCR75 at week 24, increasing the landmark week 12 responses (primary endpoint) by over 10 ppt (percentage points)
- The depth of responses continued to increase from week 12 to week 24 across several scores, including over 14 ppt increases in HiSCR90 and IHS4-90 (to approximately 40% of patients) – 1 in every 4 patients reached inflammatory remission with IHS4-100, reflecting 100% reduction in abscesses, nodules and draining tunnels
- Rates of complete resolution of inflammatory nodules and abscesses (AN 100) and draining tunnels (DT 100) increased between week 12 and 24
- Clinical responses translated to robust improvements in health related quality of life (DLQI), skin pain (NRS30), and self-reported absent or minimal disease (PGI-S)
- Maintenance dosing, placebo cross-overs to sonelokimab 120mg or 240mg, as well as pharmacokinetic data, confirm 120mg as the dose with optimal benefit-risk profile
- For non-responders to adalimumab at week 12 switching to sonelokimab resulted in HiSCR75 response rates similar to those randomized to sonelokimab at baseline
- Safety results of sonelokimab were consistent with previously reported studies with no new observed safety signals
- Topline data will be discussed on **16 October, at 2pm CEST/ 8am EDT**, via webcast (registration link below)

ZUG, Switzerland, October 15 2023 – MoonLake Immunotherapeutics ("MoonLake"; Nasdaq: MLTX), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announced positive 24-week top-line results from its global Phase 2 MIRA trial showing that maintenance treatment with its Nanobody® sonelokimab led to further improvements in HiSCR75 response rates and other clinically relevant outcomes in patients with moderate-to-severe hidradenitis suppurativa (HS).

Jorge Santos da Silva, PhD, Founder and Chief Executive Officer at MoonLake, said: *"The overall data package created with the MIRA trial establishes MoonLake's position as a leading innovator in the Immunology and Inflammation (I&I) and IL-17 space. We have consistently observed best-in-class clinical activity with our Nanobody® sonelokimab for hidradenitis suppurativa and these results demonstrate its effect on a number of clinically meaningful endpoints. In June we elevated the bar for clinical response to HiSCR75 as the primary endpoint. We have now advanced to demonstrating even deeper responses (such as HiSCR90, AN 100 and DT 100) and on scores that are important for patients, such as complete inflammatory remission with IHS4-100 and absent or minimal disease activity as reported by patients (PGI-S). Importantly, the results have confirmed our view that 120mg is the optimal dose and we are on track to discuss our Phase 3 development plans with the FDA by the end of this year."*

The 24-week results follow the positive 12-week results, announced in June 2023 and subsequently presented at the European Academy of Dermatology and Venereology Congress in October 2023, in which the primary endpoint was met with 29 percentage points delta versus placebo (p=0.0002) at week 12. The MIRA trial set a landmark milestone as the first placebo-controlled randomized trial in HS to use Hidradenitis Suppurative Clinical Response 75 (HiSCR75) as the primary endpoint.

The 24-week results show that ongoing treatment with sonelokimab 120mg and 240mg dosed Q4W, further increased HiSCR75 response rates compared to week 12. 57% of patients continuously treated with 120mg achieved a HiSCR75 response (more than 10 ppt improvement from Week 12) and 38% achieved HiSCR90 (more than 14ppt improvement versus week 12). The IHS4 score, which encompasses changes in all active HS lesions (nodules, abscesses, draining tunnels), decreased by 65% in patients treated with the 120mg maintenance dose.

Rates of complete resolution of inflammatory nodules and abscesses (AN 100) together with complete resolution of draining tunnels (DT 100) also increased between week 12 and 24 (31% and 49% of patients achieving this high level of response at week 24 with 120mg respectively, an increase of up to 15 ppt). Complete inflammatory remission (IHS4-100) was achieved in 1 in 4 patients (24%) treated with 120mg at week 24. Clinical responses translated to profound improvements in patient-reported outcomes at 24 weeks including quality of life (DLQI), pain (NRS30), and patient global impression of severity. 43% of patients reached self-reported absent or minimal disease activity on the PGI-S scale.

Results obtained with placebo patients re-randomized to sonelokimab 120mg or 240mg in Part B, after the primary analysis, replicated the dose responses observed in Part A. Difficult-to-treat subgroup analysis (e.g., in Hurley stage III patients or those previously exposed to biologics) confirms the advantage of the 120mg dose. Similarly, pharmacokinetics (PK) analysis support the use of the monthly maintenance 120mg dose. For patients who were inadequate responders to adalimumab at week 12 switching to sonelokimab resulted in HiSCR75 response rates similar to responses in those randomized to sonelokimab at baseline. Sonelokimab provided better durability of response compared to that observed with adalimumab in other studies.

The safety profile of sonelokimab was consistent with previously reported studies with no new safety signals observed. Overall, sonelokimab continues to show a favorable safety profile, in line with the known profile of IL-17 inhibitors.

Based on the efficacy and safety results, Q4W maintenance dosing of sonelokimab 120mg has been confirmed in the Company's view as the optimal dose, in terms of speed and depth of response, and overall benefit-risk profile, for progression into Phase 3 development.

Kristian Reich, MD, PhD, Founder and Chief Scientific Officer at MoonLake, commented: "*These positive results at 24 weeks, which build upon the initial 12-week results, show that the clinical activity and responses with longer exposure of sonelokimab deepen over time in patients with hidradenitis suppurativa as we saw in psoriasis. It underscores the advantage of treating patients with a smaller biologic with albumin-binding capacity to inhibit IL-17A and IL-17F for the treatment of inflammatory diseases and highlights the impact our Nanobody® sonelokimab has on a breadth of outcomes that matter for patients with HS, beyond HiSCR75. MIRA creates, in my opinion, a unique Phase 2 data package, for a disease that has proven to be extremely challenging to treat.*"

Joslyn Kirby, MD, MEd, MS, Professor and Vice Chair for Education, Department of Dermatology at Penn State, and President of the Hidradenitis Suppurativa Foundation added: *"Hidradenitis suppurativa is a chronic, inflammatory condition that has profound impacts on a patients' lives. As a clinician who works with people with HS, there is an urgent need for new treatment options that give patients high levels of response and meaningful improvements in their condition. The high clinical response rates observed with sonelokimab in the Phase 2 MIRA trial, which are accompanied by critical improvements in patient reported outcomes, are exciting, demonstrating its promise as a potential future treatment option."*

These topline data will be discussed on **16 October 2023 at 2pm CEST/ 8am EDT before the Nasdaq market opens, via webcast** at:

Registration Link:
https://onlinexperiences.com/Launch/QReg/ShowUUID=172DFCAF-36D9-4C44-BF2C-982C999BE61F&LangLocaleID=1033&GroupID=Onyx

Login Link: (for those already registered)
https://onlinexperiences.com/Launch/Event/ShowKey=241209

A replay of the webcast and the presentation document will be made available at https://ir.moonlaketx.com.

Full results from the MIRA trial will be submitted for publication in a peer-reviewed medical journal and for presentation at an upcoming scientific meeting.

Sonelokimab has already been successfully assessed in a randomized, placebo-controlled, Phase 2b trial (NCT03384745) in 313 patients with moderate-to-severe plaque-type psoriasis in which it demonstrated a rapid and durable skin clearance (PASI100) with no unexpected safety findings.

Sonelokimab is currently also being evaluated in a Phase 2 trial (NCT05640245), 'ARGO', in patients with active psoriatic arthritis with the primary end-point readout expected in early November this year.

Sonelokimab is not yet approved for use in any indication.

- Ends –

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. 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-17F-mediated inflammation as a key driver of the pathogenesis of HS, with other identified risk factors including genetics, cigarette smoking, and obesity.

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.

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 currently being assessed in two ongoing trials, the Phase 2 MIRA trial in HS and the Phase 2 ARGO trial in PsA. In June 2023, the MIRA 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. Following the positive 12-week results, positive results at 24 weeks have now been announced in October 2023.

Sonelokimab has been assessed in a randomized, placebo-controlled Phase 2b study in 313 patients with moderate-to-severe plaque-type psoriasis. Sonelokimab demonstrated a rapid and durable clinical response (Investigator's Global Assessment Score 0 or 1, Psoriasis Area and Severity Index 90/100) 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 study 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). Currently, a global phase 2 trial in psoriatic arthritis (NCT05640245, M1095-PSA-201, "ARGO") including multiple arms and over 200 patients is ongoing (announced on Dec 14, 2022).

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 at 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 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.

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 clinical trials and research and development programs; and the anticipated timing of the results from those trials, including completing the MIRA trial and commencing a phase 3 trial; and the efficacy of our products, if approved, including in relation to other products. 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 such 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, and reliance on third parties to conduct and support its 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, 2022 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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