# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, D.C. 20549**

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# 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)**: **November 14, 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:

☐ 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 2.02. Results of Operations and Financial Condition.**

On November 14, 2023, MoonLake Immunotherapeutics (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2023. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

This Item 2.02 and the Press Release attached hereto as Exhibit 99.1, insofar as they disclose information regarding the Company's results of operation and financial condition for the quarter ended September 30, 2023, are being furnished to the U.S. Securities and Exchange Commission.

**Item 9.01. Financial Statements and Exhibits.**

(d) *Exhibits*. The following exhibit is being furnished herewith:

| Exhibit Number | Exhibit Title or Description |
|---|---|
| 99.1 | Press Release, dated November 14, 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: **November 14, 2023**

By: /s/ Matthias Bodenstedt

Name: Matthias Bodenstedt

Title: Chief Financial Officer

## MoonLake Immunotherapeutics Reports Third Quarter 2023 Financial Results and Provides a Business Update

- *Announced positive full 24-week data from the global Phase 2 MIRA clinical trial, establishing the Nanobody® sonelokimab as a highly promising and differentiated therapeutic solution for hidradenitis suppurativa*
- *Presented positive 12-week data from the global Phase 2 MIRA clinical trial for sonelokimab in hidradenitis suppurativa at a late-breaking session during the European Academy of Dermatology and Venereology Congress*
- *Announced landmark top-line 12-week data from the global Phase 2 ARGO clinical trial evaluating the efficacy and safety of sonelokimab in patients with active psoriatic arthritis, in support of a potential best-in-class profile*
- *Ended third quarter with $496.0 million in cash, cash equivalents and short-term marketable debt securities, which is expected to be sufficient for Phase 3 programs in hidradenitis suppurativa and psoriatic arthritis past data and into regulatory submission and initiation of work in additional indications*

**ZUG, Switzerland,** November 14, 2023 – MoonLake Immunotherapeutics (NASDAQ: MLTX) ("MoonLake" or the "Company"), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announced its financial results for the third quarter of 2023.

During the quarter and post period, MoonLake announced significant new positive clinical data from two global Phase 2 trials of sonelokimab: "MIRA", in moderate-to-severe hidradenitis suppurativa (HS) and "ARGO", in active psoriatic arthritis (PsA). Sonelokimab has already been successfully assessed in a randomized, placebo-controlled, Phase 2b trial in patients with moderate-to-severe plaque-type psoriasis, in which it demonstrated a rapid and durable skin clearance (Psoriasis Area Severity Index (PASI) 100 response).

Sonelokimab is an investigational Nanobody® designed to inhibit IL-17F in addition to IL-17A and, therefore, could represent a major improvement in treating inflammation in dermatological and rheumatological diseases, such as HS and PsA. The Nanobody's® smaller size versus traditional antibodies and its albumin-binding domain provide an opportunity for further efficacy.

**Third Quarter 2023 Business Highlights (including Post-Quarter End):**

- Completed patient randomization ahead of schedule in the global Phase 2 ARGO trial of the Nanobody® sonelokimab in active psoriatic arthritis (PsA)
- Hosted a Capital Markets Day for investors and analysts to discuss the evolving PsA market and expectations ahead of the top-line 12-week data from the global Phase 2 ARGO trial
- Presented landmark 12-week data from the global Phase 2 MIRA trial for the sonelokimab in hidradenitis suppurativa at a late-breaking session at the European Academy of Dermatology and Venereology Congress
- Announced landmark full 24-week data from the Phase 2 MIRA clinical trial, establishing sonelokimab as a highly promising and differentiated therapeutic solution for hidradenitis suppurativa
- Announced landmark topline 12-week data from the global Phase clinical 2 trial ARGO of sonelokimab in active psoriatic arthritis

**Dr. Jorge Santos da Silva, Chief Executive Officer of MoonLake Immunotherapeutics, said:** *"The third quarter and beginning of this quarter have been instrumental for MoonLake, with two sets of landmark data from the MIRA and ARGO clinical trials, reinforcing our confidence in sonelokimab as a differentiated product with a potentially best-in-class profile across two key indications in the immunology and inflammation space. The continued therapeutic effect observed at 24-weeks from the MIRA trial in hidradenitis suppurativa highlights the benefits of using a Nanobody® for added responses compared to larger therapeutic alternatives, a theme we believe will be replicated in our upcoming 24-week ARGO trial data for psoriatic arthritis. Looking ahead, we are in discussions with regulatory authorities for Phase 3 planning with a view to initiate these trials as soon as possible in 2024."*

**Third Quarter 2023 Financial Highlights:**

- As of September 30, 2023, MoonLake held cash and cash equivalents and short-term marketable debt securities of $496.0 million, compared to $501.8 million as of June 30, 2023.

- Research and development expenses for the quarter ended September 30, 2023, were $7.6 million, compared to $8.7 million in the previous quarter. General and administrative expenses for the quarter ended September 30, 2023, were $5.4 million, compared to $4.5 million in the previous quarter.

**Matthias Bodenstedt, Chief Financial Officer of MoonLake Immunotherapeutics, said:** *"MoonLake has very healthy capital reserves at the end of Q3, which we expect to fully fund the Phase 3 programs in both HS and PsA and bring sonelokimab to regulatory filing. Building on the successful readouts in now three indications, we have also reserved a meaningful budget to initiate work in additional indications. We expect to announce more details on those plans in the next quarter. Our cash burn continues to be materially lower than that of peers, highlighting our cost efficient setup and allowing us to focus on long-term value creation for shareholders, patients, and clinicians."*

**Important upcoming anticipated events and clinical data for MoonLake:**

December:

- End of Phase 2 meeting with the FDA to discuss Phase 2 HS data and Phase 3 development plan

Q1 2024:

- R&D Day to share the final Phase 3 plans and other clinical and business catalysts in 2024 and beyond
- 24-week data from the global Phase 2 ARGO clinical trial evaluating the efficacy and safety of the Nanobody® sonelokimab in patients with active psoriatic arthritis

**Calendar of upcoming investor conferences:**

- Jefferies Healthcare Conference 2023, London, UK: November 14-16, 2023
- JP Morgan 42nd annual healthcare conference 2024, San Francisco, US: January 8-11, 2024
- Leerink Partners Global Biopharma Conference, Miami, US: March 11-14, 2024
- Barclays Global Healthcare Conference, Miami, US: March 12-14, 2024

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

**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 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 (trial ongoing) 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. Clinical response (considering the Investigator's Global Assessment Score 0 or 1, and the Psoriasis Area and Severity Index 90/100) was 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 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 the ARGO trial**

The ARGO trial (M1095-PSA-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 PsA. The trial is designed to evaluate different doses of sonelokimab, with placebo control and adalimumab as an active reference arm. The primary endpoint of the trial is the percentage of participants achieving ≥50% improvement in signs and symptoms of disease from baseline, compared to placebo, as measured by the American College of Rheumatology (ACR) 50 response. The trial also evaluates a number of secondary endpoints, including improvement compared to placebo in ACR20, complete skin clearance as measured by at least a 100% improvement in the Psoriasis Area and Severity Index (PASI), physical function as measured by the Health Assessment Questionnaire-Disability Index, enthesitis as measured by the Leeds Enthesitis Index and pain as measured by the Patients Assessment of Arthritis Pain. Further details are available on: https://clinicaltrials.gov/ct2/show/NCT05640245

**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 expectations regarding the timing of the Phase 3 programs in HS and 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, the initiation of work in and the timing of future announcements regarding additional indications for sonelokimab, the timing for meeting with regulatory authorities and our anticipated cash usage and the period of time we anticipate such cash to be available. 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; expectations regarding the timing of the Phase 3 programs in HS and PsA; positive results from a clinical trial may not necessarily be predictive of the results of future or ongoing clinical studies; MoonLake's substantial dependence on the success of its Nanobody® sonelokimab; 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.

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.

**CONTACT**

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**MOONLAKE IMMUNOTHERAPEUTICS**
**CONDENSED CONSOLIDATED BALANCE SHEETS**

*(Amounts in USD, except share data)*

| | September 30, 2023 (Unaudited) | June 30, 2023 (Unaudited) |
|---|---|---|
| **Current assets** | | |
| Cash and cash equivalents | $ 318,165,809 | $ 501,786,997 |
| Short-term marketable debt securities | 177,812,899 | — |
| Other receivables | 720,755 | 619,767 |
| Prepaid expenses | 3,310,281 | 3,960,383 |
| **Total current assets** | **500,009,744** | **506,367,147** |
| | | |
| **Non-current assets** | | |
| Operating lease right-of-use assets | 169,422 | 211,238 |
| Property and equipment, net | 39,520 | 42,810 |
| **Total non-current assets** | **208,942** | **254,048** |
| **Total assets** | **$ 500,218,686** | **$ 506,621,195** |
| | | |
| **Current liabilities** | | |
| Trade and other payables | $ 3,404,728 | $ 4,359,923 |
| Short-term portion of operating lease liabilities | 156,338 | 158,221 |
| Accrued expenses and other current liabilities | 6,746,951 | 2,616,482 |
| **Total current liabilities** | **10,308,017** | **7,134,626** |
| | | |
| **Non-current liabilities** | | |
| Long-term portion of operating lease liabilities | 13,084 | 53,017 |
| Pension liability | 255,399 | 323,597 |
| **Total non-current liabilities** | **268,483** | **376,614** |
| **Total liabilities** | **10,576,500** | **7,511,240** |
| Commitments and contingencies (Note 15) | | |
| | | |
| **Equity (deficit)** | | |
| Class A Ordinary Shares: $0.0001 par value; 500,000,000 shares authorized; 53,561,488 shares issued and outstanding as of September 30, 2023; 53,486,810 shares issued and outstanding as of June 30, 2023 | 5,349 | 5,349 |
| Class C Ordinary Shares: $0.0001 par value; 100,000,000 shares authorized; 8,884,517 shares issued and outstanding as of September 30, 2023; 8,959,195 shares issued and outstanding as of June 30, 2023 | 889 | 896 |
| Additional paid-in capital | 531,271,953 | 589,549,979 |
| Accumulated deficit | (109,220,396) | (99,794,347) |
| Accumulated other comprehensive income | 2,875,198 | 35,124 |
| **Total shareholders' equity (deficit)** | **424,933,000** | **489,797,001** |
| Noncontrolling interests | 64,709,186 | 9,312,954 |
| **Total equity** | **489,642,188** | **499,109,955** |
| **Total liabilities and equity** | **$ 500,218,686** | **$ 506,621,195** |

**MOONLAKE IMMUNOTHERAPEUTICS**
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**
**(Unaudited)**

*(Amounts in USD, except share and per share data)*

| | For the Three Months Period Ended | | For the Nine Months Period Ended |
|---|---|---|---|
| | **September 30, 2023** | **June 30, 2023** | **September 30, 2023** |
| **Operating expenses** | | | |
| Research and development | $ (7,585,136) | $ (8,703,849) | $ (23,704,087) |
| General and administrative | (5,391,607) | (4,482,041) | (15,390,117) |
| **Total operating expenses** | **(12,976,743)** | **(13,185,890)** | **(39,094,204)** |
| **Operating loss** | **(12,976,743)** | **(13,185,890)** | **(39,094,204)** |
| | | | |
| Other income, net | 1,386,313 | 842,652 | 2,952,557 |
| **Loss before income tax** | **(11,590,430)** | **(12,343,238)** | **(36,141,647)** |
| | | | |
| Income tax expense | (28,923) | (10,149) | (50,080) |
| **Net loss** | **$ (11,619,353)** | **$ (12,353,387)** | **$ (36,191,727)** |
| *Of which: net loss attributable to controlling interests shareholders* | *(9,426,049)* | *(10,139,279)* | *(28,570,184)* |
| *Of which: net loss attributable to noncontrolling interests shareholders* | *(2,193,304)* | *(2,214,108)* | *(7,621,543)* |
| | | | |
| Net unrealized gain (loss) on marketable securities and short term investments | 3,437,291 | (415,225) | 3,046,538 |
| Actuarial gain (loss) on employee benefit plans | 39,157 | (16,336) | (19,323) |
| **Other comprehensive income (loss)** | 3,476,448 | (431,561) | 3,027,215 |
| **Comprehensive loss** | **$ (8,142,905)** | **$ (12,784,948)** | **$ (33,164,512)** |
| *Comprehensive loss attributable to controlling interests shareholders* | *(6,590,259)* | *(10,488,185)* | *(26,095,926)* |
| *Comprehensive loss attributable to noncontrolling interests* | *(1,552,646)* | *(2,296,763)* | *(7,068,586)* |
| | | | |
| Weighted-average number of Class A Ordinary Shares, basic and diluted | 53,517,655 | 43,718,464 | 45,485,650 |
| **Basic and diluted net loss per share attributable to controlling interests shareholders** | **$ (0.18)** | **$ (0.23)** | **$ (0.63)** |