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 29, 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:

☐ 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 February 29, 2024, MoonLake Immunotherapeutics (the "Company") issued a press release announcing its financial results for the quarter and fiscal year ended December 31, 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 and year ended December 31, 2023, are being furnished to the 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 February 29, 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 29, 2024**

By: /s/ Matthias Bodenstedt

Name: Matthias Bodenstedt

Title: Chief Financial Officer

MoonLake Immunotherapeutics Reports Full Year 2023 Financial Results, Recent Business Highlights and Announces an R&D Day on March 10

- *A successful year including the announcements of positive data from two Phase 2 trials of sonelokimab in hidradenitis suppurativa (HS), at 12 and 24 weeks, and active psoriatic arthritis (PsA), at 12 weeks, supporting a potential best-in-class profile across two key indications*
- *Phase 3 preparation for sonelokimab in HS nearing completion, following positive feedback from both FDA and EMA*
- *Year-end cash, cash equivalents and short-term marketable debt securities of $511.0 million, expected to support a roadmap rich in potential catalysts whilst providing a cash runway to the end of 2026*
- *R&D Day to be held on Sunday March 10 – alongside the American Academy of Dermatology (AAD) annual meeting – expected to include 24 week data from the ARGO PsA study and PsA program next steps, final plans for the HS Phase 3 VELA program, analysis of the size of the HS market, as well as catalyst updates including new pipeline indications*

ZUG, Switzerland, February 29, 2024 – MoonLake Immunotherapeutics (NASDAQ: MLTX) ("MoonLake"), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announced its financial results for the fourth quarter and year ended December 31, 2023, and provided recent business highlights.

Dr. Jorge Santos da Silva, Chief Executive Officer of MoonLake Immunotherapeutics, said: *"2023 was another momentous year for MoonLake in the inflammation and immunology field. We reported positive results from two global Phase 2 trials of our Nanobody® sonelokimab in hidradenitis suppurativa (HS) and active psoriatic arthritis. We were highly selective in our choice of endpoints for these trials in a deliberate plan to raise the bar for patients suffering from these diseases characterized by profound patient burden and significant unmet medical need. Following highly encouraging interactions with both the FDA and EMA regarding our data and forthcoming Phase 3 trial designs for HS, we are completing plans to initiate our Phase 3 trials for both indications. On top of this, support from world-renowned experts, clinicians, and patient organizations for our data, science and methodologies continues to mount. We look forward to sharing more information with everyone at our upcoming R&D Day on 10 March."*

Q4 highlights (including post-quarter end)

- Announced landmark top-line 12-week data from the global Phase 2 ARGO clinical trial of sonelokimab in patients with PsA in November, supporting a potential best-in-class profile
- Announced positive full 24-week data from the global Phase 2 MIRA clinical trial in October, achieving the primary endpoint, HiSCR75, with sonelokimab in patients with HS, in support of a highly promising and differentiated therapeutic solution
- Announced positive feedback from both FDA and EMA on the regulatory path for the Phase 3 VELA program of sonelokimab in HS, with the Phase 3 trial having a similar design to the validated Phase 2 trial and being in line with MoonLake's prior communications and expectations

Fourth quarter and year-end financial results

As of December 31, 2023, MoonLake held cash, cash equivalents and short-term marketable debt securities of $511.0 million, compared to $496.0 million as of September 30, 2023. The increase of $15.0 million was primarily attributable to the gross proceeds of at-the-market offerings, partially offset by cash used in the Company's operations.

Matthias Bodenstedt, Chief Financial Officer at MoonLake Immunotherapeutics, said: *"MoonLake has added considerable shareholder value over the past year, and we are driven to continue building on this. In December of last year, and in early 2024, we pursued at-the-market offerings, bringing in gross proceeds of $85 million at minimal dilution. The new funds allow us to double down on the clinical development of sonelokimab across multiple indications, whilst securing an additional expected cash runway to the end of 2026. We are looking forward to sharing updates on our roadmap rich in potential catalysts, together with the highly anticipated 24 week data from our ARGO study in active psoriatic arthritis, at our upcoming R&D Day."*

Research and development expenses for the fourth quarter ended December 31, 2023 were $8.1 million, compared to $7.6 million in the previous quarter. Research and development expenses for the year ended December 31, 2023 were $31.8 million, compared to $42.0 million in the previous year. The decrease was primarily driven by a decrease in milestone expense incurred under the in-licensing agreement of sonelokimab.

General and administrative expenses for the fourth quarter ended December 31, 2023 were $6.9 million, compared to $5.4 million in the previous quarter. General and administrative expenses for the year ended December 31, 2023 were $22.3 million which was similar to the $23.0 million incurred in the prior year.

Other non-operating income increased from $0.6 million in the prior year to $10.1 million for the year ended December 31, 2023. The increase was primarily attributable to interest income achieved from investments in short-term marketable debt securities.

Net loss for the year ended December 31, 2023 was $44.1 million, compared to $64.5 million for the prior year ending December 31, 2022.

R&D Day, on Sunday, March 10

MoonLake will be hosting an R&D Day for investors and analysts in San Diego, USA on Sunday, March 10 alongside the American Academy of Dermatology (AAD) annual meeting. The event will take place from 09:00 – 11:30 PST/ 12:00 – 14:30 EST/18:00 – 20:30 CET at the Hotel Westin Bayview, San Diego and will be webcast for virtual attendees.

The R&D Day will provide important business updates from MoonLake's executive team including:

- Outcome of the end-of-Phase 2 (EoP2) interactions with the FDA and EMA, and plans for the Phase 3 VELA program for the Nanobody® sonelokimab in HS, expected to randomize the first patient in Q2 2024
- Analysis of the HS and PsA market opportunities and leadership potential for sonelokimab
- 24-week data from the ARGO trial in active PsA, plans related to EoP2 FDA meeting in Q2 2024, and expectation to randomize the first patient in Q4 2024
- Pipeline updates and details on the additional catalysts for 2024 and 2025, including new indications to be pursued
- Financials

The event will feature presentations from leading clinicians in dermatology and rheumatology. Professor Joesph F. Merola, Founding President of the Psoriasis and Psoriatic Arthritis Clinics Multicenter Advancement Network Consortium (PPACMAN) and Vice President of GRAPPA (Group for Research and Assessment of Psoriasis and Psoriatic Arthritis), and Professor Kenneth B. Gordon, Chair of Dermatology at the Medical College of Wisconsin, will share their perspectives on the potential of MoonLake's investigational Nanobody® sonelokimab in IL-17A and IL-17F driven inflammatory diseases.

A live Q&A session involving all presenters will follow the event. Register to attend either the in-person event or webcast at https://edge.media-server.com/mmc/p/2vvr2noc. A recording and additional details will be available on the Events & Presentations section of the Company's website at www.ir.moonlaketx.com.

Upcoming banking conferences

- Leerink Partners Global Biopharma Conference: March 11-13 (Miami)
- Jefferies Biotech on the Bay Summit: March 11-13 (Miami)
- Barclays 26th Annual Global Healthcare Conference: March 12-14 (Miami)
- H.C. Wainwright 2nd Annual Autoimmune & Inflammatory Disease Virtual Conference, March 28 (virtual)
- 23rd Annual Needham Virtual Healthcare Conference: April 8-11 (virtual)
- Van Lanschot Kempen Life Sciences Conference Amsterdam: April 16-17 (Amsterdam)

- Ends -

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.

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 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 (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). Sonelokimab is not yet approved for use in any indication.

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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 at: 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, expectations regarding future catalysts, 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 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.

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MOONLAKE IMMUNOTHERAPEUTICS
CONSOLIDATED BALANCE SHEETS

(Amounts in USD, except share data)

	December 31, 2023	September 30, 2023 (Unaudited)
Current assets		
Cash and cash equivalents	$ 451,169,337	$ 318,165,809
Short-term marketable debt securities	59,838,900	177,812,899
Other receivables	1,056,862	720,755
Prepaid expenses - current	2,102,203	3,310,281
Total current assets	**514,167,302**	**500,009,744**
Non-current assets		
Operating lease right-of-use assets	3,628,480	169,422
Property and equipment, net	320,865	39,520
Prepaid expenses - non-current	8,423,468	—
Total non-current assets	**12,372,813**	**208,942**
Total assets	**$ 526,540,115**	**$ 500,218,686**
Current liabilities		
Trade and other payables	$ 1,837,684	$ 3,404,728
Short-term portion of operating lease liabilities	1,197,876	156,338
Accrued expenses and other current liabilities	6,930,120	6,746,951
Total current liabilities	**9,965,680**	**10,308,017**
Non-current liabilities		
Long-term portion of operating lease liabilities	2,499,990	13,084
Pension liability	583,426	255,399
Total non-current liabilities	**3,083,416**	**268,483**
Total liabilities	**13,049,096**	**10,576,500**
Commitments and contingencies		
Equity (deficit)		
Class A Ordinary Shares: $0.0001 par value; 500,000,000 shares authorized; 60,466,453 shares issued and outstanding as of December 31, 2023; 53,561,488 shares issued and outstanding as of September 30, 2023	6,047	5,356
Class C Ordinary Shares: $0.0001 par value; 100,000,000 shares authorized; 2,505,476 shares issued and outstanding as of December 31, 2023; 8,884,517 shares issued and outstanding as of September 30, 2023	251	889
Additional paid-in capital	609,969,236	531,271,953
Accumulated deficit	(116,657,472)	(109,220,396)
Accumulated other comprehensive income	2,357,621	2,875,198
Total shareholders' equity (deficit)	**495,675,683**	**424,933,000**
Noncontrolling interests	17,815,336	64,709,186
Total equity	**513,491,019**	**489,642,186**
Total liabilities and equity	**$ 526,540,115**	**$ 500,218,686**

MOONLAKE IMMUNOTHERAPEUTICS
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

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

	For the Three Months Period Ended		For the Year Ended	
	December 31, 2023	September 30, 2023	December 31, 2023	December 31, 2022
Operating expenses				
Research and development	$ (8,097,794)	$ (7,585,136)	$ (31,801,880)	$ (42,048,954)
General and administrative	(6,931,096)	(5,391,607)	(22,321,216)	(23,012,463)
Total operating expenses	**(15,028,890)**	**(12,976,743)**	**(54,123,096)**	**(65,061,417)**
Operating loss	**(15,028,890)**	**(12,976,743)**	**(54,123,096)**	**(65,061,417)**
Other income, net	7,185,810	1,386,313	10,138,367	591,732
Loss before income tax	**(7,843,080)**	**(11,590,430)**	**(43,984,729)**	**(64,469,685)**
Income tax expense	(44,309)	(28,923)	(94,388)	(36,366)
Net loss	**$ (7,887,389)**	**$ (11,619,353)**	**$ (44,079,117)**	**$ (64,506,051)**
Of which: net loss attributable to controlling interests shareholders	*(7,437,074)*	*(9,426,049)*	*(36,007,260)*	*(49,973,249)*
Of which: net loss attributable to noncontrolling interests shareholders	*(450,315)*	*(2,193,304)*	*(8,071,857)*	*(14,532,802)*
Net unrealized gain on marketable securities and short-term investments	(716,437)	3,437,291	2,330,101	390,753
Actuarial income (loss) on employee benefit plans	(317,256)	39,157	(336,579)	269,893
Other comprehensive income	(1,033,693)	3,476,448	1,993,522	660,646
Comprehensive loss	**$ (8,921,082)**	**$ (8,142,905)**	**$ (42,085,595)**	**$ (63,845,405)**
Comprehensive loss attributable to controlling interests shareholders	*(8,415,796)*	*(6,590,259)*	*(34,511,723)*	*(49,437,461)*
Comprehensive loss attributable to noncontrolling interests	*(505,286)*	*(1,552,646)*	*(7,573,872)*	*(14,407,944)*
Weighted-average number of Class A Ordinary Shares, basic and diluted	59,914,592	53,517,655	49,122,534	29,361,353
Basic and diluted net loss per share attributable to controlling interests shareholders	**$ (0.12)**	**$ (0.18)**	**$ (0.73)**	**$ (1.70)**