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): **May 7, 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 May 7, 2024, MoonLake Immunotherapeutics (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2024. 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 March 31, 2024, 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 May 7, 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: **May 7, 2024**

By: /s/ Matthias Bodenstedt

Name: Matthias Bodenstedt

Title: Chief Financial Officer

MoonLake Immunotherapeutics Reports First Quarter 2024 Financial Results and Provides a Business Update

- *Announced positive feedback from both FDA and EMA on the regulatory path for the Phase 3 program of the Nanobody® sonelokimab in hidradenitis suppurativa (HS) and outlined the development plan with topline results anticipated in mid-2025*
- *Reported significant improvements observed across all key outcomes with sonelokimab over 24 weeks in the ARGO Phase 2 trial in active psoriatic arthritis (PsA) including unprecedented multi-domain responses across joints, skin and other domains, supporting potential best-in-class profile of sonelokimab*
- *Announced the imminent commencement of four additional clinical trials of sonelokimab across dermatology, and rheumatology, including innovative trials in palmo-plantar pustulosis (PPP), juvenile HS and seronegative spondyloarthritis*
- *Ended the first quarter with $547.1 million in cash, cash equivalents and short-term marketable debt securities, expected to support a roadmap rich in potential catalysts and a cash runway to the end of 2026*

ZUG, Switzerland, May 7, 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 first quarter of 2024.

Dr. Jorge Santos da Silva, Chief Executive Officer of MoonLake Immunotherapeutics, said: *"2024 is shaping up to be a strong year for MoonLake. We announced more positive data for our Nanobody® sonelokimab in PsA at our recent R&D Day and are looking forward to initiating the Phase 3 program in HS imminently, and the Phase 3 program in PsA later this year. We also expect to initiate a further Phase 3 program in juvenile HS, as well as three Phase 2 trials across dermatology, and rheumatology, broadening our pipeline to address some of the fastest growing markets in inflammatory diseases. These new trials ensure that we continue to evaluate the full potential of our Nanobody® sonelokimab for indications in which IL-17A and IL-17F are implicated and where there is a need for deep tissue penetration."*

Q1 highlights (including post-period end)

- Provided an update on the development of sonelokimab in HS including details on Phase 3 trial design and timelines for this program, named VELA, which is set to enroll 800 patients and which follows positive feedback from both FDA and EMA
- Presented MIRA trial data of sonelokimab in HS as a late breaker at the American Academy of Dermatology (AAD) Annual Meeting 2024, including unprecedented primary endpoint Hidradenitis Suppurativa Clinical Response (HiSCR)75 treatment effects at week 12 (~43% HISCR75) and week 24 (~57% HiSCR75) and International Hidradenitis Suppurativa Severity Score System (IHS4)100 responses (~1/4 of patients reaching this level of inflammatory remission)
- Hosted an R&D Day alongside the AAD Annual Meeting, featuring presentations from eminent key opinion leaders in dermatology and rheumatology
- Announced significant improvements with sonelokimab over 24 weeks in the ARGO Phase 2 trial of sonelokimab in active PsA including unprecedented multi-domain responses, such as up to 52% of patients achieving ACR50 + Psoriasis Area and Severity Index (PASI)100 and up to 61% of patients achieving Minimal Disease Activity (MDA)
- Announced the planned commencement of four additional clinical trials of sonelokimab across dermatology and rheumatology, including innovative trials in palmo-plantar pustulosis, juvenile HS and seronegative spondyloarthritis
- Signed a three-year technology partnership with Komodo Health to advance research on inflammatory skin and joint conditions and presented initial data from this partnership, indicating that at least two million Americans have been diagnosed with HS as of 2023, highlighting a significant unmet need and impact on healthcare systems and a potential market opportunity exceeding $10bn by 2035

First quarter 2024 financial results

As of March 31, 2024, MoonLake held cash, cash equivalents and short-term marketable debt securities of $547.1 million.

Research and development expenses for the quarter ended March 31, 2024, were $13.0 million, compared to $8.1 million in the previous quarter. The increase was primarily due to expenses incurred to initiate the new clinical trials. General and administrative expenses for the quarter ended March 31, 2024 were $6.8 million, similar to the $6.9 million incurred in the previous quarter.

Matthias Bodenstedt, Chief Financial Officer at MoonLake Immunotherapeutics, said: *"MoonLake harbors big ambitions for the future and ended the first quarter of 2024 in a strong financial position with a very healthy cash balance that we expect to fund our catalyst-rich roadmap to the end of 2026, including the anticipated primary readout of the Phase 3 HS VELA program from mid-2025 and the filing for regulatory approval. We are also encouraged by the data coming from recent U.S. launches, including the uptake of secukinumab in HS and of bimekizumab in psoriasis, that further validate our view on the significant market opportunity and the demand for new treatment options. With sonelokimab, we have the unique combination of a small, albumin-binding Nanobody® with high affinity and the proven IL-17A and IL-17F mechanism of action, which positions us well to succeed in our focus indications. Going into the second quarter, we look forward to building on the momentum generated so far this year as we broaden our pipeline into other inflammatory diseases with significant unmet need."*

Important upcoming anticipated events for MoonLake:

- Q2-2024: Initiation of the Phase 3 VELA program in HS
- Q2-2024: End-of-Phase 2 meetings with the FDA and EMA for PsA
- 2H-2024: Initiation of the Phase 3 program in PsA
- 2H-2024: Initiation of additional studies as announced for dermatology and rheumatology indications

Upcoming banking conferences

- Jefferies Healthcare Conference, June 5 – 6, New York, US
- Goldman Sachs 45th Annual Global Healthcare Conference, June 10 – 12, Miami, US
- Stifel European Healthcare Summit, 25 – 27 June, Lyon, France

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

For HS, sonelokimab is being assessed in two Phase 3 trials, VELA I and VELA II 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 October 2023, the full dataset from the Phase 2 MIRA trial at 24 weeks (NCT05322473) showed that maintenance treatment with sonelokimab led to further improvements in 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 and other clinically relevant outcomes. Prior to this, in June 2023, topline results of the MIRA trial at 12 weeks showed that the trial met its primary endpoint, HiSCR75.

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 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 ACR50 response 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 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.

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

Sonelokimab will also be assessed for seronegative spondyloarthritis with a Phase 2 trial in radiographic and non-radiographic axial spondyloarthritis (axSpA) expected to start in 2024. The trials will feature an innovative design complementing traditional clinical outcomes with modern 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.

About the VELA program

The VELA program is expected to enroll 800 patients across two similarly designed Phase 3 trials (VELA I and VELA II) with the aim to evaluate the efficacy and safety of the Nanobody® sonelokimab, administered subcutaneously, in adult patients with active moderate-to-severe hidradenitis suppurativa. Similar to the design of the landmark Phase 2 MIRA trial, the primary endpoint of the program 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 will also evaluate a number of secondary endpoints, including the proportion of patients achieving Hidradenitis Suppurative Clinical Response (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).

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 will comprise over 200 patients, and will evaluate two different doses of sonelokimab, with placebo control and adalimumab as an active control 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 will also evaluate 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 on: 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 sonelokimab, administered subcutaneously, in the treatment of adult patients with active PsA. The trial is expected to comprise of approximately 200 patients, and 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 will also evaluate a number of secondary endpoints, including improvement compared to placebo in ACR70, complete skin clearance as measured by at least a 100% improvement in the Psoriasis Area and Severity Index, 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

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 indicates that at least 2 million Americans have been diagnosed with HS as of 2023, 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-17F-mediated inflammation as a key driver of the pathogenesis of HS, with other identified risk factors including genetics, cigarette smoking, and obesity.

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.

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 initiation of Phase 3 VELA program of the sonelokimab in HS and Phase 3 program in PsA, commencement of clinical trials of sonelokimab in PPP, juvenile HS and seronegative spondyloarthritis,

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, anticipated meetings with regulatory authorities, including the FDA and EMA 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, 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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MOONLAKE IMMUNOTHERAPEUTICS
CONDENSED CONSOLIDATED BALANCE SHEETS

(Amounts in USD, except share data)

	March 31, 2024 (Unaudited)	December 31.2023
Current assets		
Cash and cash equivalents	$ 458,441,051	$ 451,169,337
Short-term marketable debt securities	88,613,700	59,838,900
Other receivables	1,495,876	1,056,862
Prepaid expenses - current	5,039,343	2,102,203
Total current assets	**553,589,970**	**514,167,302**
Non-current assets		
Operating lease right-of-use assets	3,698,514	3,628,480
Property and equipment, net	509,816	320,865
Prepaid expenses - non-current	6,318,838	8,423,468
Total non-current assets	**10,527,168**	**12,372,813**
Total assets	**$ 564,117,138**	**$ 526,540,115**
Current liabilities		
Trade and other payables	$ 3,482,790	$ 1,837,684
Short-term portion of operating lease liabilities	1,304,426	1,197,876
Accrued expenses and other current liabilities	4,123,304	6,930,120
Total current liabilities	**8,910,520**	**9,965,680**
Non-current liabilities		
Long-term portion of operating lease liabilities	2,357,495	2,499,990
Pension liability	462,735	583,426
Total non-current liabilities	**2,820,230**	**3,083,416**
Total liabilities	**11,730,750**	**13,049,096**
Commitments and contingencies (Note 15)		
Equity		
Class A Ordinary Shares: $0.0001 par value; 500,000,000 shares authorized; 62,874,637 shares issued and outstanding as of March 31, 2024; 60,466,453 shares issued and outstanding as of December 31, 2023	6,287	6,047
Class C Ordinary Shares: $0.0001 par value; 100,000,000 shares authorized; 995,267 shares issued and outstanding as of March 31, 2024; 2,505,476 shares issued and outstanding as of December 31, 2023	100	251
Additional paid-in capital	670,185,376	609,969,236
Accumulated deficit	(130,331,128)	(116,657,472)
Accumulated other comprehensive income	2,693,096	2,357,621
Total shareholders' equity	**542,553,731**	**495,675,683**
Noncontrolling interests	9,832,657	17,815,336
Total equity	**552,386,388**	**513,491,019**
Total liabilities and equity	**$ 564,117,138**	**$ 526,540,115**

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	
	March 31, 2024	**December 31 2023**
Operating expenses		
Research and development	$ (13,014,049)	$ (8,097,794)
General and administrative	(6,806,440)	(6,931,096)
Total operating expenses	**(19,820,489)**	**(15,028,890)**
Operating loss	**(19,820,489)**	**(15,028,890)**
Other income, net	5,915,220	7,185,810
Loss before income tax	**(13,905,269)**	**(7,843,080)**
Income tax expense	(70,252)	(44,309)
Net loss	**$ (13,975,521)**	**$ (7,887,389)**
Of which: net loss attributable to controlling interests shareholders	*(13,673,656)*	*(7,437,074)*
Of which: net loss attributable to noncontrolling interests shareholders	*(301,865)*	*(450,315)*
Net unrealized gain on marketable securities and short term investments	182,273	(716,437)
Actuarial gain (loss) on employee benefit plans	81,230	(317,256)
Other comprehensive income (loss)	263,503	(1,033,693)
Comprehensive loss	**$ (13,712,018)**	**$ (8,921,082)**
Comprehensive loss attributable to controlling interests shareholders	*(13,415,707)*	*(8,415,796)*
Comprehensive loss attributable to noncontrolling interests	*(296,311)*	*(505,286)*
Weighted-average number of Class A Ordinary Shares, basic and diluted	62,637,212	59,914,592
Basic and diluted net loss per share attributable to controlling interests shareholders	**$ (0.22)**	**$ (0.12)**