

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): August 10, 2023

MOONLAKE IMMUNOTHERAPEUTICS  
(Exact Name of Registrant as Specified in Its Charter)

Cayman Islands

(State or Other Jurisdiction  
of Incorporation)

001-39630

(Commission File Number)

98-1711963

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

On August 10, 2023, Moonlake Immunotherapeutics (the “Company”) issued a press release announcing its financial results for the quarter ended June 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 June 30, 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:

<b>Exhibit Number</b>	<b>Exhibit Title or Description</b>
99.1	<a href="#">Press release, dated August 10, 2023</a>
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: **August 10, 2023**

By: /s/ Matthias Bodenstedt

Name: Matthias Bodenstedt

Title: Chief Financial Officer

**MoonLake Immunotherapeutics Reports Second Quarter 2023 Financial Results and Provides a Business Update**

- *Achieved landmark milestone with positive results from Phase 2 MIRA trial in hidradenitis suppurativa (HS), suggesting that, as early as week 12, the Nanobody<sup>®</sup> sonelokimab, relative to placebo, reaches the highest clinical activity among all other therapies tested in similarly stringent pivotal-like trials; top-line 24-week data readout is expected in mid-October 2023*
- *Successfully completed randomization of the target 200 patients several weeks ahead of schedule in its global Phase 2 ARGO trial in active psoriatic arthritis (PsA); top-line 12-week data readout is expected in the first half of November 2023*
- *Raised gross proceeds of approximately \$460 million in an upsized public follow-on offering, providing significant new funds to advance the development of sonelokimab and for general corporate purposes*

**ZUG, Switzerland**, August 10, 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 second quarter of 2023.

MoonLake continues to make significant progress with the clinical development of sonelokimab, which is currently being investigated in two Phase 2 clinical trials: the first, “MIRA”, in moderate-to-severe hidradenitis suppurativa (HS) and the second, “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<sup>®</sup> designed to inhibit IL-17F in addition to IL-17A and therefore could represent a major improvement in treating inflammation in these dermatological and rheumatological diseases. The Nanobody’s<sup>®</sup> smaller size versus traditional antibodies and its albumin-binding domain provide an opportunity for further efficacy. The MIRA and the ARGO trials both achieved their target patient enrollment and randomization faster than anticipated, reflecting the Company’s strong execution and interest from physicians and patients in MoonLake’s clinical development programs.

**Dr. Jorge Santos da Silva, Chief Executive Officer of MoonLake Immunotherapeutics, said:** *“This quarter has been transformational for MoonLake. The positive Phase 2 results from our MIRA trial were a landmark milestone. We look ahead with confidence to a number of key catalysts for sonelokimab this year, including the final 24-week data in HS, expected in mid-October, and the topline 12-week data in active PsA, expected in the first half of November, and to creating long-term value for both patients and shareholders.”*

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

- On April 19, MoonLake held a Capital Markets Day, which featured a series of presentations from its executive team, who provided a look to the year ahead at near-term catalysts and a financial update. External speaker, Professor Kenneth B. Gordon, Chair of Dermatology at the Medical College of Wisconsin, provided an update on the treatment landscape for HS, reflecting on data and key takeaways from the American Academy of Dermatology Annual Meeting.
  - On May 3, MoonLake announced a collaboration agreement with SHL Medical to develop an autoinjector for clinical and potential subsequent commercial supply of MoonLake’s Nanobody<sup>®</sup> sonelokimab.
  - On June 25, MoonLake announced it achieved a landmark milestone with positive top-line 12-week data readout from its global Phase 2 MIRA trial evaluating the efficacy and safety of the Nanobody<sup>®</sup> sonelokimab in patients with moderate-to-severe HS. The trial met its primary endpoint with a significantly greater proportion of patients treated with both sonelokimab 120mg and 240mg achieving Hidradenitis Suppurativa Clinical Response (HiSCR) 75 compared to those on placebo at week 12. The results suggest that, as early as week 12, the Nanobody<sup>®</sup> sonelokimab, relative to placebo, reaches the highest clinical activity among all other therapies tested in similarly stringent pivotal-like trials.
  - On July 25 (post period-end), MoonLake announced that:
    - it successfully completed randomization of the target 200 patients ahead of schedule in its global Phase 2 ARGO trial in active PsA; and
    - a Capital Markets Day will be held on September 11, 2023 to discuss the PsA market and to share expectations on the ARGO 12-week data readout in PsA (results expected in the first half of November 2023) and the MIRA 24-week data readout in HS (results expected in mid-October 2023).
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## Second Quarter 2023 Financial Highlights:

- On June 30, 2023, MoonLake closed a public offering of 8,000,000 Class A Ordinary Shares at a public offering price of \$50.00 per Share. MoonLake also granted the underwriters of this offering the option to purchase up to an additional 1,200,000 Class A Ordinary Shares at the public offering price less the underwriting discounts and commissions, and this option was exercised in full, bringing total gross proceeds of this offering to \$460 million.
- In addition, during the three months ended June 30, 2023, MoonLake sold 544,894 Class A Ordinary Shares through an At-the-Market facility, yielding gross proceeds of \$15.2 million.
- As of June 30, 2023, MoonLake held cash and cash equivalents and short-term marketable debt securities of \$501.8 million, compared to \$63.1 million as of March 31, 2023.
- Research and development expenses for the quarter ended June 30, 2023, were \$8.7 million, compared to \$7.4 million in the previous quarter. The increase was primarily driven by expenses for the conduct of the MIRA and ARGO studies.
- General and administrative expenses for the quarter ended June 30, 2023, were \$4.5 million, compared to \$5.5 million in the previous quarter. The decrease was primarily driven by lower expenses for professional services and share-based compensation.

**Matthias Bodenstedt, Chief Financial Officer of MoonLake Immunotherapeutics, said:** *“The past quarter has seen MoonLake raise significant new funds, enabling us to fund the advancement of sonelokimab into multiple Phase 3 programs and putting us in a very strong position for the next phase of growth. We welcome our new shareholders who recognize the value of our Nanobody<sup>®</sup> and are as excited as we are by our continued advancement of sonelokimab’s clinical development to address some of the fastest growing markets in inflammatory diseases.”*

## Important upcoming anticipated events and next expected data readouts for MoonLake:

### September:

- Capital Markets Day to discuss PsA market and provide guidance for upcoming 12-week ARGO PsA and 24-week MIRA HS readouts

### October:

- MIRA trial top-line 12-week data to be presented at a scientific meeting
- R&D Day virtual webcast to share top-line 24-week MIRA HS trial data and Phase 3 plans in HS

### November:

- R&D Day virtual webcast to share top-line 12-week ARGO PsA trial data

### December:

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

### Early 2024:

- R&D Day to share the final Phase 3 plans and other clinical and business catalysts in 2024 and beyond

## Calendar of upcoming investor conferences in the second half of 2023:

- Wedbush 2023 PacGrow Healthcare Conference: August 8-9
- Wells Fargo Healthcare Conference 2023: September 6-8
- Stifel 2023 Immunology & Inflammation Virtual Summit: September 19
- Cantor Fitzgerald Global Healthcare Conference 2023: September 26-28
- Guggenheim Securities 5th Annual Inflammation & Immunology Conference: November 6-7
- UBS Biopharma Conference 2023: November 8-9
- Jefferies London Healthcare Conference 2023: November 14-16

## About MoonLake Immunotherapeutics

MoonLake Immunotherapeutics is a clinical-stage biopharmaceutical company unlocking the potential of sonelokimab, a novel investigational Nanobody<sup>®</sup> 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](http://www.moonlaketx.com).

## About Nanobodies<sup>®</sup>

Nanobodies<sup>®</sup> 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<sup>®</sup> have a number of potential advantages over traditional antibodies, including their small size, enhanced tissue penetration, resistance to temperature changes, ease of manufacturing, and the ability to design multivalent therapeutic molecules with bespoke target combinations.

## About Sonelokimab

Sonelokimab (M1095) is an investigational ~40 kDa humanized Nanobody<sup>®</sup> 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. 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. A significantly greater proportion of patients treated with both sonelokimab 120mg and 240mg achieved HiSCR75 compared to those on placebo at week 12. The positive results suggest that, as early as week 12, sonelokimab, relative to placebo, reaches the highest clinical activity among all other therapies tested in similarly stringent pivotal-like trials. The trial proceeds to week 24, with a 4-week safety follow-up.

Sonelokimab has also been assessed in a randomized, placebo-controlled Phase 2b trial 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 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). Recently, a global phase 2 trial in psoriatic arthritis (NCT05640245, M1095-PSA-201, "ARGO") including multiple arms and over 200 patients has been initiated.

Sonelokimab is not yet approved for use in any indication.

## 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<sup>®</sup> sonelokimab, administered subcutaneously, in the treatment of adult patients with active moderate to severe HS. The trial recruited 234 patients, with the aim to evaluate two 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 Hidradenitis Suppurativa Clinical Response 75 (HiSCR75), defined as a  $\geq 75\%$  reduction in total abscess and inflammatory nodule (AN) count with no increase in abscess or draining tunnel count relative to baseline. The trial also evaluates 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  $\leq 5$ , 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 Nanobody<sup>®</sup> 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  $\geq 50\%$  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 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>

## **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 and outcome of the MIRA and ARGO trials, 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 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 and outcome of the MIRA and ARGO trials; 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<sup>®</sup> 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)*

	<b>June 30, 2023 (Unaudited)</b>	<b>March 31, 2023 (Unaudited)</b>
<b>Current assets</b>		
Cash and cash equivalents	\$ 501,786,997	\$ 50,129,197
Short-term marketable debt securities	—	12,920,960
Other receivables	619,767	378,445
Prepaid expenses	3,960,383	3,075,862
<b>Total current assets</b>	<b>506,367,147</b>	<b>66,504,464</b>
<b>Non-current assets</b>		
Operating lease right-of-use assets	211,238	246,256
Property and equipment, net	42,810	46,099
<b>Total non-current assets</b>	<b>254,048</b>	<b>292,355</b>
<b>Total assets</b>	<b>\$ 506,621,195</b>	<b>\$ 66,796,819</b>
<b>Current liabilities</b>		
Trade and other payables	\$ 4,359,923	\$ 3,827,403
Short-term portion of operating lease liabilities	158,221	155,173
Accrued expenses and other current liabilities	2,616,482	3,296,839
<b>Total current liabilities</b>	<b>7,134,626</b>	<b>7,279,415</b>
<b>Non-current liabilities</b>		
Long-term portion of operating lease liabilities	53,017	91,081
Pension liability	323,597	314,174
<b>Total non-current liabilities</b>	<b>376,614</b>	<b>405,255</b>
<b>Total liabilities</b>	<b>7,511,240</b>	<b>7,684,670</b>
Commitments and contingencies (Note 15)		
<b>Equity (deficit)</b>		
Class A Ordinary Shares: \$0.0001 par value; 500,000,000 shares authorized; 53,486,810 shares issued and outstanding as of June 30, 2023; 39,154,203 shares issued and outstanding as of March 31, 2023	5,349	3,916
Class C Ordinary Shares: \$0.0001 par value; 100,000,000 shares authorized; 8,959,195 shares issued and outstanding as of June 30, 2023; 13,546,908 shares issued and outstanding as of March 31, 2023	896	1,355
Additional paid-in capital	589,549,979	131,308,849
Accumulated deficit	(99,794,347)	(89,655,068)
Accumulated other comprehensive income	35,124	340,108
<b>Total shareholders' equity (deficit)</b>	<b>489,797,001</b>	<b>41,999,160</b>
Noncontrolling interests	9,312,954	17,112,989
<b>Total equity</b>	<b>499,109,955</b>	<b>59,112,149</b>
<b>Total liabilities and equity</b>	<b>\$ 506,621,195</b>	<b>\$ 66,796,819</b>



**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 Six Months Period Ended
	June 30, 2023	March 31, 2023	June 30, 2023
<b>Operating expenses</b>			
Research and development	\$ (8,703,849)	\$ (7,415,097)	\$ (16,118,949)
General and administrative	(4,482,041)	(5,516,469)	(9,998,510)
<b>Total operating expenses</b>	<b>(13,185,890)</b>	<b>(12,931,566)</b>	<b>(26,117,459)</b>
<b>Operating loss</b>	<b>(13,185,890)</b>	<b>(12,931,566)</b>	<b>(26,117,459)</b>
Other income, net	842,652	723,589	1,566,242
<b>Loss before income tax</b>	<b>(12,343,238)</b>	<b>(12,207,977)</b>	<b>(24,551,217)</b>
Income tax expense	(10,149)	(11,010)	(21,157)
<b>Net loss</b>	<b>\$ (12,353,387)</b>	<b>\$ (12,218,987)</b>	<b>\$ (24,572,374)</b>
<i>Of which: net loss attributable to controlling interests shareholders</i>	<i>(10,139,279)</i>	<i>(9,004,856)</i>	<i>(19,144,135)</i>
<i>Of which: net loss attributable to noncontrolling interests shareholders</i>	<i>(2,214,108)</i>	<i>(3,214,131)</i>	<i>(5,428,239)</i>
Net unrealized loss on marketable securities and short term investments	(415,225)	24,472	(390,753)
Actuarial gain (loss) on employee benefit plans	(16,336)	(42,144)	(58,481)
<b>Other comprehensive income (loss)</b>	<b>(431,561)</b>	<b>(17,672)</b>	<b>(449,234)</b>
<b>Comprehensive loss</b>	<b>\$ (12,784,948)</b>	<b>\$ (12,236,659)</b>	<b>\$ (25,021,608)</b>
<i>Comprehensive loss attributable to controlling interests shareholders</i>	<i>(10,488,185)</i>	<i>(9,017,481)</i>	<i>(19,505,667)</i>
<i>Comprehensive loss attributable to noncontrolling interests</i>	<i>(2,296,763)</i>	<i>(3,219,178)</i>	<i>(5,515,941)</i>
Weighted-average number of Class A Ordinary Shares, basic and diluted	43,718,464	39,061,977	41,403,084
<b>Basic and diluted net loss per share attributable to controlling interests shareholders</b>	<b>\$ (0.23)</b>	<b>\$ (0.23)</b>	<b>\$ (0.46)</b>