

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, 2026

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:

- ☐ 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, 2026, MoonLake Immunotherapeutics (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 2026. 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 operations and financial condition for the quarter ended June 30, 2026, are being furnished to the U.S. Securities and Exchange Commission (“SEC”).

Item 7.01. Regulation FD Disclosure.

On August 10, 2026, the Company issued a press release announcing positive topline week 16 results from its Phase 3 IZAR-1 trial of sonelokimab (SLK) in psoriatic arthritis (PSA). A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

This Item 7.01 and the press release attached hereto as Exhibit 99.1 are being furnished to the SEC and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended.

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 August 10, 2026
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, 2026

By: /s/ Matthias Bodenstedt

Name: Matthias Bodenstedt

Title: Chief Financial Officer



MoonLake Announces Positive Topline Results from the Phase 3 IZAR-1 Trial of Sonelokimab in Psoriatic Arthritis Demonstrating Significant Improvements Across all Clinical Endpoints, and Reports Second Quarter 2026 Financial Results

- *Phase 3 IZAR-1 trial in bio-naïve patients met all clinical endpoints at Week 16 for 60 mg sonelokimab*
- *The primary endpoint of ACR50 was met with a high response of 42.1% for sonelokimab's 60 mg with induction, and significant responses were observed across key secondary endpoints, including ACR20 (66.5%), MDA (41.2%) and PASI90 (61%), supporting the broad multidomain efficacy profile of sonelokimab in psoriatic arthritis*
- *Meaningful and statistically significant improvements were seen across patient-reported outcomes and physical function measures, including HAQ-DI and SF-36 PCS*
- *Blinded safety analysis suggests a profile consistent with previous studies and no new safety signals were identified, reinforcing sonelokimab's potential to become a leading treatment option for patients living with psoriatic arthritis, and enabling MoonLake's entry into another multi-billion dollar indication*
- *The IZAR-1 trial remains blinded and will continue until Week 52 with MoonLake expecting the full readout in H1 2027 whereas the IZAR-2 trial (a trial in TNF-refractory patients) is expected to complete enrollment in Q3 2026*
- *MoonLake ended the second quarter with \$537.0 million in cash, cash equivalents and short-term marketable debt securities and expects to have a cash runway to mid-2028; additionally, up to \$400 million in non-dilutive funds remain available through its debt facility with Hercules Capital*

ZUG, Switzerland, August 10, 2026 – MoonLake Immunotherapeutics (NASDAQ: MLTX) (“MoonLake” or the “Company”), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announced positive topline results from the Phase 3 IZAR-1 trial evaluating sonelokimab in biologic-naïve adults with active psoriatic arthritis (PsA) and reported second quarter 2026 financial results.

IZAR-1 Phase 3 trial Week 16 positive topline results

The IZAR Phase 3 program consists of two registrational global randomized, double-blind trials, IZAR-1 and IZAR-2, designed to evaluate the efficacy and safety of sonelokimab in adults with active psoriatic arthritis (PsA). IZAR-1 is being conducted in biologic-naïve adults with active PsA. Following the Week 16 primary endpoint analysis, patients will continue participating in their respective studies through Week 52 to evaluate the durability of efficacy and safety of sonelokimab.

The primary endpoint of IZAR-1 is the percentage of patients achieving an American College of Rheumatology 50 (ACR50) response at Week 16. Key secondary clinical endpoints evaluate the broad multidomain efficacy of sonelokimab across musculoskeletal, skin, patient-reported and physical outcomes and include the percentage of patients achieving an ACR20 response, Minimal Disease Activity (MDA), and Psoriasis Area and Severity Index 90 (PASI90) response, as well as changes from baseline in the Health Assessment Questionnaire Disability Index (HAQ-DI) and SF-36 Physical Component Summary (PCS) score.

The Phase 3 IZAR-1 trial met all clinical endpoints at Week 16 for 60 mg sonelokimab. Consistent with the unblinding protocol defined with the FDA, topline disclosure at Week 16 includes absolute response levels and endpoint outcomes for the sonelokimab 60 mg with induction arm. Comparative analyses versus placebo and detailed treatment arm data remain blinded until completion of the Phase 3 program.

A total of 42.1% of biologic-naïve patients treated with sonelokimab 60 mg with induction achieved an ACR50 response. In addition, sonelokimab demonstrated strong efficacy across multiple disease domains characteristic of PsA. Across key secondary clinical endpoints, 66.5% of patients achieved ACR20, and 41.2% achieved MDA at Week 16. In patients with concomitant skin involvement, 61% achieved PASI90 at Week 16. Patients treated with sonelokimab also demonstrated clinically meaningful improvements in patient-reported and physical outcomes. Mean change from baseline in HAQ-DI was -0.427, while improvements were observed in SF-36 Physical Component Summary (PCS) with a score of 6.54. IZAR-1 does not include a Standard of Care arm as ARGO had provided data in such context for the Bio-Naïve population (adalimumab arm). IZAR-2 will provide data in comparison with a Standard of Care (risankizumab) in TNF-refractory patients.

The blinded safety analysis of IZAR-1 suggests a profile consistent with previous clinical studies and no new safety signals were observed. In addition, the drop-out rate of IZAR-1 until Week 16 is low and in line with other trials in PsA.

These results further support the potential of sonelokimab to address, not just single symptoms of PsA, but rather the diverse manifestations of psoriatic arthritis through meaningful improvements across musculoskeletal symptoms, skin disease, patient quality of life and physical function. After the lead indication of hidradenitis suppurativa (HS) these results set the path for sonelokimab to compete in another multi-billion dollar indication.

Dr. Jorge Santos da Silva, Founder and Chief Executive Officer of MoonLake Immunotherapeutics, said: *“The positive topline results from IZAR-1 represent an important milestone for MoonLake and, more importantly, for patients living with psoriatic arthritis. We are particularly encouraged by the strong efficacy observed across multiple clinically relevant endpoints simultaneously, which has been our focus. These data are also encouraging as they are consistent with what was previously observed in other IL-17A/F programs. This reinforces our conviction that sonelokimab has the potential to become a leading treatment option in PsA and further validate the broad potential of our Nanobody® platform in inflammatory disease.”*

Prof. Kristian Reich, Founder and Chief Scientific Officer of MoonLake Immunotherapeutics, added: *“Psoriatic arthritis is a complex and heterogeneous disease, requiring therapies that can effectively address multiple manifestations simultaneously. The breadth of response observed in IZAR-1 across clinical, functional and patient-reported outcomes is highly encouraging. Taken together, these findings support the potential of sonelokimab to deliver meaningful benefits for patients across the diverse domains that define PsA.”*

Second Quarter 2026 Financial Results

Today, MoonLake also reported its financial results for the second quarter of 2026. As of June 30, 2026, MoonLake held cash, cash equivalents and short-term marketable debt securities of \$537.0 million. The Company expects to have sufficient capital to fund its operating expenses and capital expenditure requirements to mid-2028. MoonLake’s debt facility with Hercules Capital provides up to \$400 million in additional non-dilutive funds to support potential future funding needs. Research and development expenses were \$50.2 million for the three months ended June 30, 2026, compared to \$54.5 million for the three months ended March 31, 2026. General and administrative expenses were \$11.4 million for the three months ended June 30, 2026, compared to \$15.5 million for the three months ended March 31, 2026. The decrease of \$4.1 million was primarily related to \$4.8 million in accelerated expense recognition in the prior quarter due to a voluntary cancellation of unvested stock option awards for no consideration.

Important upcoming anticipated milestones for MoonLake:

- **HS:**
 - End Sep. 2026: Expected submission of Biologics License Application (BLA)
 - End Nov. 2026: Expected to receive Prescription Drug User Fee Act (PDUFA) date allocation and decision on Priority Review
- **Palmoplantar Pustulosis (PPP):** Expected to commence enrollment in H2 2026
- **PsA – IZAR-2:** Expected to complete enrollment in Q3 2026
- **PsA/axial spondyloarthritis (axSpA):** Expected to report results from the P-OLARIS trial at the end of 2026 or early 2027

-Ends-

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, psoriatic arthritis, axial spondyloarthritis and palmoplantar pustulosis – 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 <https://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 VHHs 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, including adolescent HS, palmoplantar pustulosis (PPP) and axial spondyloarthritis (axSpA).

For adults with HS, sonelokimab is being assessed in two identical Phase 3 trials, the VELA-1 and VELA-2 trials, using the higher clinical response level of HS Clinical Response (HiSCR) 75 as the primary endpoint, which defines a response as an at least 75% reduction in abscess and inflammatory nodule count, with no increase from baseline in abscess or draining tunnel count. In September 2025, the primary endpoint data from the VELA-1 and VELA-2 clinical trials were announced. In the combined VELA program, patients treated with sonelokimab experienced a clinically meaningful and statistically significant improvement across all primary and key secondary endpoints using both pre-specified strategies ($p < 0.001$). In VELA-1, sonelokimab achieved statistical significance for all primary and key secondary endpoints using both pre-specified strategies (HiSCR75, delta to placebo of 17%, $p < 0.001$). In VELA-2, intercurrent events in the higher-than-expected placebo arm precluded the study from achieving statistical significance in the Week 16 primary endpoint using the composite strategy (HiSCR75, delta to placebo of 9%, $p = 0.053$). In June 2026, Week 52 Results of sonelokimab from the VELA-1 and VELA-2 clinical trials were announced. Week 52 data for sonelokimab showed consistent and further improvement in all clinical scores, compared to Week 16 data. Across both VELA-1 and VELA-2, 67.2% of patients treated with sonelokimab achieved HiSCR75 and 33.1% of patients achieved HiSCR100 at Week 52 (as observed, $n = 396$). The safety profile of sonelokimab in the VELA trials was consistent with previous trials with no new safety signals detected.

Sonelokimab is currently undergoing evaluation in the VELA-TEEN Phase 3 trial, which is the first clinical study specifically focused on adolescent patients with moderate-to-severe HS. In June 2026, interim Week 24 data from the Phase 3 VELA-TEEN trial were announced. Interim analysis of Week 24 data show that ~68% of patients treated with sonelokimab achieved HiSCR75, alongside ~86% achieving HiSCR50 and ~45% achieving HiSCR100 (as observed, $n = 22$). HiSCR75 rates in VELA-TEEN were higher than those observed in the adult VELA program at comparable timepoints, indicating a pronounced clinical response in adolescent patients with earlier stage disease. Sonelokimab was generally well tolerated in this vulnerable patient population, and no new safety signals were observed.

For PsA, sonelokimab is being assessed in the Phase 3 trials, IZAR-1 and IZAR-2, following the announcement in March 2024 of the full dataset from the global Phase 2 ARGO trial (M1095-PSA-201) 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 American College of Rheumatology (ACR) 50 response and Minimal Disease Activity (MDA) at Week 24. This followed the positive topline results in November 2023, where the trial met its primary endpoint with a statistically significant greater proportion of patients treated with either sonelokimab 60 mg or 120 mg (with induction) achieving an ACR50 response compared to those on placebo at Week 12. All key secondary endpoints in the trial were met for the 60 mg and 120 mg doses with induction. The safety profile of sonelokimab in the ARGO trial was consistent with previous trials with no new safety signals detected. Absolute response levels and clinical endpoint outcomes for the 60 mg with induction dose at Week 16 in IZAR-1 were announced in August 2026. The primary endpoint of IZAR-1 is the percentage of patients achieving an American College of Rheumatology 50 (ACR50) response at Week 16. The Phase 3 IZAR-1 trial met all clinical endpoints at Week 16 for 60 mg sonelokimab. For the primary endpoint, a total of 42.1% of biologic-naïve patients treated with sonelokimab 60 mg with induction achieved an ACR50 response. In addition, sonelokimab demonstrated strong efficacy across multiple disease domains characteristic of PsA.

Sonelokimab is also being assessed in PPP, a debilitating inflammatory skin condition affecting a significant number of patients, including in the completed Phase 2 LEDA program. In the Phase 2 LEDA clinical trial in PPP, sonelokimab demonstrated clinically meaningful and statistically significant benefit. Patients treated with sonelokimab achieved a mean percent change from baseline in the Palmoplantar Pustular Psoriasis Area and Severity Index (PPPASI) of 64% at Week 16, and 39% of patients achieved a $\geq 75\%$ reduction in the PPPASI (PPPASI75), suggesting that sonelokimab could provide clinically meaningful improvements in this disease for which there are currently no approved therapies. The safety profile of sonelokimab in the LEDA trial was consistent with previous trials with no new safety signals detected.

Additionally, sonelokimab is being assessed in the ongoing Phase 2 S-OLARIS and P-OLARIS trials for active axSpA and PsA, respectively. Both trials feature an innovative design complementing traditional clinical outcomes with cellular imaging techniques.

Sonelokimab has also been assessed in a randomized, placebo-controlled third-party 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 generally presented a safety profile similar to the active control, secukinumab (Papp KA, et al. Lancet. 2021; 397:1564-1575).

In an earlier third-party Phase 1 trial in patients with moderate-to-severe plaque-type psoriasis, sonelokimab decreased (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 VELA program

The Phase 3 VELA program recruited a total of 838 patients across VELA-1 and VELA-2. Both global, randomized, double-blind, and placebo-controlled trials are identical in design evaluating 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 is the percentage of participants achieving Hidradenitis Suppurativa Clinical Response (HiSCR) 75, 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 trials 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 reduction of ≥ 4 , the proportion of patients achieving at least 50% reduction from baseline in Numerical Rating Scale (NRS50) in the Patient's Global Assessment of Skin Pain (PGA Skin Pain) and complete resolution of Draining Tunnels (DT100). The VELA protocols and statistical analysis plans were prepared in accordance with regulatory agency advice and include two analysis strategies. The composite strategy for the VELA trials (also referred to as the primary estimand) is the primary statistical analysis. The protocol specifies the treatment policy strategy as the alternative method of handling intercurrent events to test the robustness of the VELA data. The trials compare a single 120 mg dose of sonelokimab to placebo with HiSCR75 reading out at Week 16. Results of the Week 16 data were announced in September 2025. Results of the Week 52 data were announced in June 2026. Further details are available under NCT06411899 and NCT06411379 at <https://www.clinicaltrials.gov>.

About the MIRA trial

The MIRA trial is a global, randomized, double-blind, placebo-controlled Phase 2 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 (120 mg and 240 mg) 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 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 under NCT05322473 at <https://www.clinicaltrials.gov>.

About the VELA-TEEN trial

The Phase 3 VELA-TEEN trial is an open-label, single-arm trial designed to evaluate sonelokimab 120 mg administered subcutaneously once every two weeks (Q2W) until week six and once every four weeks (Q4W) from week eight onwards. The trial enrolled 35 adolescents, aged 12-17, with moderate-to-severe hidradenitis suppurativa, from U.S. sites experienced in clinical trials and pediatric dermatology. The primary trial phase will be 24 weeks with a primary endpoint evaluating the pharmacokinetics, safety, and tolerability of sonelokimab. VELA-TEEN will also evaluate several secondary endpoints, including the proportion of patients achieving the higher clinical response measure of the Hidradenitis Suppurativa Clinical Response (HiSCR) 75, in addition to HiSCR50. Other outcomes are the change from baseline in the International Hidradenitis Suppurativa Severity Score System (IHS4), which includes the quantitative measure of draining tunnels, and the proportion of patients achieving a meaningful reduction of the Children's Dermatology Life Quality Index (CDLQI) and the Patient's Global Assessment of Skin Pain (PGA Skin Pain). Results of the interim Week 24 data were announced in June 2026. Further details are available under NCT06768671 at <https://www.clinicaltrials.gov>.

About Hidradenitis Suppurativa

Hidradenitis suppurativa (HS) 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 an estimated 2% of the population, with three times more females affected than males. Real-world data in the United States indicate that at least 2 million unique patients have been diagnosed with and treated for HS between 2016 and 2023 alone, highlighting a significant unmet need and impact on healthcare systems, and a market opportunity projected to reach \$15 billion 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 the IZAR Program

IZAR-1 and IZAR-2 are global, randomized, double-blind, placebo-controlled Phase 3 trials designed to evaluate the efficacy and safety of sonelokimab compared with placebo in a total of approximately 1,500 adults with active psoriatic arthritis (PsA), with a primary endpoint of superiority to placebo in American College of Rheumatology (ACR) 50 response at Week 16. IZAR-1 is expected to enroll biologic-naïve patients and include an evaluation of radiographic progression, while IZAR-2 is expected to enroll patients with an inadequate response to tumor necrosis factor- α inhibitors (TNF-IR) – reflecting patients commonly seen in clinical practice – and is the first PsA trial to include a risankizumab active reference arm. Both trials will also assess a range of secondary endpoints reflecting the multiple disease manifestations characteristic of PsA. These include skin and nail outcomes, multidomain outcomes, and Patient-Reported Outcome measures such as pain and quality of life assessments. Absolute response levels and clinical endpoint outcomes for the 60 mg with induction dose at Week 16 in IZAR-1 were announced in August 2026. Further details are available under NCT06641076 and NCT06641089 at <https://www.clinicaltrials.gov>.

About the P-OLARIS trial

The P-OLARIS trial is a Phase 2 trial designed to evaluate the efficacy and safety of sonelokimab 60 mg administered subcutaneously in adult patients with active psoriatic arthritis (PsA) or axial spondyloarthritis (axSpA) with a focus on characterizing how sonelokimab affects markers of inflammation and tissue damage within joints. The trial aims to recruit approximately 20 patients with PsA and 10 patients with axSpA. The primary endpoint is the change in disease activity at Week 12, as measured by [68Ga]-fibroblast activation protein inhibitor (FAPI)-tracer uptake (SUVmax) on FAPI-positron emission tomography (PET)/low-dose computed tomography (CT) scans, a novel imaging modality able to detect inflammation and early tissue damage within joints. Throughout the trial, several other endpoints will be assessed including established clinical disease activity outcomes, as well as patient reported outcomes that assess the impact of disease signs and symptoms. The trial also features an innovative exploratory peripheral blood and tissue biomarker program. The trial design has been informed by previous successful studies of sonelokimab, including the landmark Phase 2 ARGO trial in PsA as well as the Phase 2 S-OLARIS trial in axSpA which demonstrated the potential of sonelokimab to target deep tissue inflammation effectively. Further details are available under EUCT number 2024-514504-13-00 at <https://euclinicaltrials.eu>.

About Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic, progressive and complex inflammatory disease that manifests across multiple domains, leading to substantial functional impairment and decreased quality of life. The clinical features of PsA are diverse, comprising both musculoskeletal (peripheral arthritis, spondylitis, dactylitis, and enthesitis) and non-musculoskeletal (skin and nail disease) domains. PsA occurs in up to 30% of patients with psoriasis, most commonly those aged between 30 and 60 years. 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.

About the S-OLARIS trial

The S-OLARIS trial is a Phase 2 trial designed to evaluate the efficacy and safety of sonelokimab 60 mg administered subcutaneously in adult patients with active axial spondyloarthritis (axSpA). The trial recruited 26 patients. The primary endpoint is the change from baseline (CfB) in 18F-NaF SUVmax signals at Week 12 in the sacroiliac joints and spine as detected by PET. Throughout the trial, several other endpoints will be assessed including established clinical disease activity outcomes (e.g., ASAS), scores related to physical function, spinal mobility, and enthesitis as well as patient reported outcomes. The trial also features an innovative exploratory peripheral blood and tissue biomarker program. The trial design has been informed by previous successful studies of sonelokimab, including the landmark Phase 2 ARGO trial in psoriatic arthritis, which identified the optimal dosing and demonstrated the potential of sonelokimab to target deep tissue inflammation effectively. Further details are available under EUCT number 2024-513498-36-00 at <https://euclinicaltrials.eu>.

About Axial Spondyloarthritis

Axial Spondyloarthritis (axSpA) typically impacts young people, with diagnosis based on chronic inflammatory back pain lasting more than three months with onset under 45 years of age. Advanced disease can lead to progressive and pathologic bone formation and joint fusion, severely limiting spinal mobility. Global reported prevalence of axSpA ranges from 0.5% to 1.5%. AxSpA can be categorized by disease progression into two subtypes: non-radiographic axSpA and ankylosing spondylitis (AS), also known as radiographic axSpA, which is diagnosed based on radiographic evidence of structural changes to the sacroiliac joints. Patients with axSpA experience fatigue, persistent morning stiffness, and pain that worsens at night and can disrupt sleep. Many patients also face the burden of comorbidities such as psoriatic arthritis and psoriasis. Studies have found elevated IL-17 levels in the blood and synovial fluid of patients with axSpA, and IL-17A and IL-17F are both thought to be key contributors to pathogenesis across the spondyloarthropathies.

About the LEDA Trial

The LEDA trial is a Phase 2 trial designed to evaluate the efficacy and safety of sonelokimab 120 mg administered subcutaneously in adult patients with palmoplantar pustulosis (PPP). The trial recruited 32 patients. The primary endpoint of the trial is percent change from baseline in Palmoplantar Psoriasis Area and Severity Index (ppPASI) with important secondary endpoints including ppPASI75 (at least 75% improvement in the ppPASI). The LEDA trial features an innovative translational research program using peripheral blood and tissue biomarkers as trial controls. The trial design has been informed by previous successful studies of sonelokimab, including the landmark Phase 2 MIRA trial in hidradenitis suppurativa, which identified the optimal dosing and demonstrated the potential of sonelokimab to target deep tissue inflammation effectively. Further details are available under EUCT number 2024-513305-32-00 at <https://euclinicaltrials.eu>.

About Palmoplantar Pustulosis

Palmoplantar Pustulosis (PPP) is characterized by the development of blister-like pustules within erythematous, scaly plaques on the palms and the soles of the feet. PPP typically develops in adulthood and more frequently impacts females. Patients frequently experience significant pain, burning, and itching sensations on the palms and soles of the feet which can be debilitating and impair their ability to work, sleep, or perform other activities of daily living. Currently, the treatment of PPP is challenging with a significant unmet need for novel therapies to reduce the symptom burden for patients. Evidence suggests that activation of the IL-17 pathway has an important role in 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: the efficacy and safety of sonelokimab for the treatment of moderate-to-severe HS, PsA and PPP; the anticipated interactions with regulatory authorities, including the FDA and the anticipated BLA-submission, PDUFA date allocation and Priority Review designation decision; the proposed label and labeling discussions with the FDA for sonelokimab in HS, including potential inclusion of clinical data from the MIRA trial; potential market opportunities for sonelokimab; upcoming anticipated clinical milestones, including the full readout of the Phase 3 IZAR-1 trial in PsA and Phase 2 P-OLARIS trial in PsA and axSpA, the completion of enrollment of the Phase 3 IZAR-2 trial in PsA, and the commencement of enrollment of the Phase 3 trial in PPP; timing of first commercial launch in the United States; and anticipated cash runway. 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; 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, 2025, Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, 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

<i>(in thousands, except share and per share data)</i>	June 30, 2026 (Unaudited)	March 31, 2026 (Unaudited)
Assets		
Current assets		
Cash and cash equivalents	\$ 477,905	\$ 298,490
Short-term marketable debt securities	59,125	59,431
Prepaid expenses	26,447	32,957
Other receivables	6,561	5,763
Total current assets	570,038	396,641
Non-current assets		
Operating lease right-of-use assets	2,078	1,857
Property and equipment, net	487	532
Other non-current assets	1,344	1,344
Total non-current assets	3,909	3,733
Total assets	\$ 573,947	\$ 400,374
Liabilities and Equity		
Current liabilities		
Trade and other payables	\$ 17,038	\$ 23,380
Accrued expenses and other current liabilities	27,108	21,814
Short-term portion of operating lease liabilities	1,246	920
Total current liabilities	45,392	46,114
Non-current liabilities		
Long-term debt	99,514	99,018
Long-term portion of operating lease liabilities	772	865
Pension liability	74	353
Total non-current liabilities	100,360	100,236
Total liabilities	145,752	146,350
Shareholders' equity		
Class A Ordinary Shares: \$0.0001 par value per share; 500,000,000 shares authorized; 83,606,685 shares issued and outstanding as of June 30, 2026; 72,134,066 shares issued and outstanding as of March 31, 2026.	8	7
Additional paid-in capital	1,021,980	786,313
Accumulated deficit	(594,423)	(532,618)
Accumulated other comprehensive income	630	322
Total shareholders' equity	428,195	254,024
Total liabilities and shareholders' equity	\$ 573,947	\$ 400,374

MOONLAKE IMMUNOTHERAPEUTICS

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

	Three Months Ended June 30, 2026	Three Months Ended March 31, 2026
<i>(in thousands, except share and per share data)</i>		
Operating expenses		
Research and development	\$ (50,221)	\$ (54,515)
General and administrative	(11,439)	(15,509)
Total operating expenses	(61,660)	(70,024)
Operating loss	(61,660)	(70,024)
Interest expense	(2,632)	(2,269)
Other income, net	2,577	3,208
Loss before income tax	(61,715)	(69,085)
Income tax expense	(90)	(622)
Net loss	\$ (61,805)	\$ (69,707)
Net unrealized gain on marketable securities and short-term investments	16	77
Actuarial gain (loss) on employee benefit plans	292	(359)
Other comprehensive income (loss)	308	(282)
Comprehensive loss	\$ (61,497)	\$ (69,989)
Weighted-average number of Class A Ordinary Shares, basic and diluted	73,915,296	71,273,650
Basic and diluted net loss per share attributable to controlling interests shareholders	\$ (0.84)	\$ (0.98)