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): November 4, 2026

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

Cayman Islands	001-39630	98-1711963
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Dorfstrasse 29
6300 Zug
Switzerland

(Address of Principal Executive Offices and Zip Code)

41 415108022
(Registrant's Telephone Number, Including Area Code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A ordinary share, par value $0.0001 per share	MLTX	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On November 4, 2026, MoonLake Immunotherapeutics (the "Company") issued a press release announcing its financial results for the quarter ended September 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 September 30, 2026, are being furnished to the U.S. Securities and Exchange Commission.

Item 9.01. Financial Statements and Exhibits.

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

Exhibit Number	Exhibit Title or Description
99.1	Press Release, dated November 4, 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: November 4, 2026

By: /s/ Matthias Bodenstedt

Name: Matthias Bodenstedt

Title: Chief Financial Officer

MoonLake Reports Third Quarter 2026 Financial Results and Provides a Business Update

- *Biologics License Application for sonelokimab submitted to the U.S. Food and Drug Administration for the treatment of adults and adolescents with moderate-to-severe hidradenitis suppurativa, marking an important step towards potential U.S. approval and commercialization*
- *Positive Week 16 results from the Phase 3 IZAR-1 trial in psoriatic arthritis reported, with all clinical endpoints met for sonelokimab 60 mg with induction*
- *Enrollment completed in the Phase 3 IZAR-2 trial in psoriatic arthritis, with initial topline results expected in Q1 2027 following the predefined unblinding protocol*
- *Phase 3 NOVA trial in palmoplantar pustulosis on track to start enrollment in November 2026*
- *MoonLake ended the third quarter with $498.5 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, November 4, 2026 – MoonLake Immunotherapeutics (NASDAQ: MLTX) ("MoonLake" or the "Company"), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today provided a business update and reported third quarter 2026 financial results.

Third Quarter 2026 Business Highlights

Hidradenitis suppurativa:

On September 30, 2026, the Company submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA), seeking approval of sonelokimab (SLK) for the treatment of moderate-to-severe hidradenitis suppurativa (HS) in adults and pediatric patients 12 years of age and older. MoonLake expects to be notified by the FDA whether the BLA submission is accepted for review within approximately 60 days of submission, and to receive the planned review timeline within approximately 74 days of submission. The BLA is supported by data from the MIRA and VELA (incl. VELA-TEEN) clinical programs.

The Company expects to complete the VELA-TEEN clinical trial in the fourth quarter of 2026 and plans to submit final results for presentation at a scientific conference in the first quarter of 2027.

The Company continues to advance its preparations, including market access, medical affairs, patient engagement and commercial infrastructure for the potential launch of sonelokimab in the U.S., if approved.

Psoriatic arthritis:

In August 2026, the Company announced positive results from an analysis of the Week 16 primary endpoint in the Phase 3 IZAR-1 trial in psoriatic arthritis (PsA), which met all clinical endpoints at Week 16 for 60 mg SLK. In the primary endpoint analysis, 42.1% of biologic-naïve patients treated with sonelokimab 60 mg with induction achieved an American College of Rheumatology 50 (ACR50) response at Week 16. In addition, sonelokimab demonstrated strong efficacy across multiple disease domains characteristic of PsA. Patients treated with sonelokimab demonstrated clinically meaningful improvements in patient-reported and physical outcomes. Consistent with the unblinding protocol defined with the FDA, topline disclosure at Week 16 included 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 trial.

In September 2026, MoonLake completed enrollment for the Phase 3 IZAR-2 trial in PsA. The Company expects to announce initial topline results following a predefined unblinding protocol in the first quarter of 2027. In addition, MoonLake expects results of the P-OLARIS trial to become available in early 2027.

Palmoplantar pustulosis:

The Company expects to commence enrollment in the Phase 3 NOVA trial as per plans in November 2026.

Third Quarter 2026 Financial Results
Today, MoonLake also reported its financial results for the third quarter of 2026. As of September 30, 2026, MoonLake held cash, cash equivalents and short-term marketable debt securities of $498.5 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 $68.9 million for the three months ended September 30, 2026, compared to $50.2 million for the three months ended June 30, 2026. The increase of $18.7 million is primarily related to accrued milestone license fees for a regulatory milestone associated with the expected acceptance of the Company's BLA submission. General and administrative expenses were $11.0 million for the three months ended September 30, 2026, compared to $11.4 million for the three months ended June 30, 2026.

Matthias Bodenstedt, Chief Financial Officer of MoonLake Immunotherapeutics, said: *"This quarter reflects the strength of execution across MoonLake. With the BLA for sonelokimab in HS now submitted to the FDA, positive Week 16 results from the Phase 3 IZAR-1 trial and IZAR-2 fully enrolled, we are making important progress across both our regulatory and clinical priorities. At the same time, we believe our financial position and projected cash runway into mid-2028 position us well to prepare for the expected commercial launch of sonelokimab in the U.S. next year, and to continue advancing its broader potential across inflammatory diseases."*

Important upcoming anticipated milestones for MoonLake:

- **HS:**
  - Expected to receive decision on BLA acceptance by the end of November 2026 and a Prescription Drug User Fee Act (PDUFA) date allocation and decision on Priority Review by mid December 2026
  - Expected mid-cycle review in H1 2027
  - Expected to conclude VELA-TEEN clinical trial in Q4 2026 and present final topline results at a scientific meeting in the first quarter of 2027
  - Expected commercial launch in U.S. in H2 2027
  - Expected to present year 1 VELA OLE data in H2 2027
- **PPP:** Expected to commence enrollment for the NOVA Phase 3 trial in November 2026
- **PsA:**
  - **IZAR-1:** Expected to announce Week 52 topline results in Q2 2027
  - **IZAR-2:** Expected to announce Week 16 topline results in Q1 2027 and Week 52 results in Q4 2027
- **PsA/axial spondyloarthritis:** Expected to announce results from the P-OLARIS trial in early 2027

-Ends-

About MoonLake Immunotherapeutics
MoonLake Immunotherapeutics ("MoonLake" or the "Company") 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 shows 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.

The VELA trials are followed by an open-label extension for up to two years.

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 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 ≥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. The company intends to continue the assessment of sonelokimab in PPP with its planned Phase 3 trial NOVA. The primary endpoint will be the percentage of participants achieving a PPP Investigator's Global Assessment (IGA) score of clear or almost clear (PPP-IGA 0/1) with at least 2-point improvement from baseline at Week 12.

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 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 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 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.

The VELA trials are followed by an open-label extension for up to two years.

Further details are available under NCT06411899, NCT06411379 and NCT07007637 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 HiSCR75, defined as a ≥75% reduction in total 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 IHS4, the proportion of patients achieving a DLQI total score of ≤5, and the proportion of patients achieving at least 30% reduction from baseline in Numerical Rating Scale in the 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 HiSCR75, in addition to HiSCR50. Other outcomes are the change from baseline in the 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 and the 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
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 PsA, with a primary endpoint of superiority to placebo in ACR50 response at Week 16. IZAR-1 enrolled biologic-naïve patients and included an evaluation of radiographic progression, while IZAR-2 enrolled 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 PsA or 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
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 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., Assessment of SpondyloArthritis International Society), 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
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 NOVA Trial
The NOVA trial is a Phase 3 trial designed to evaluate the efficacy and safety of sonelokimab 120 mg administered subcutaneously in adult patients with PPP. The trial aims to recruit approximately 370 patients. The primary endpoint is the percentage of participants achieving a PPP-IGA 0/1 with at least 2-point improvement from baseline at Week 12. Key secondary endpoints include PPPASI75, symptom burden (pain, itch), as well as quality-of-life outcomes (DLQI). The trial design was informed by previous successful sonelokimab studies, including the landmark Phase 2 MIRA trial in hidradenitis suppurativa, which identified the optimal dose and demonstrated sonelokimab’s potential to effectively target deep

tissue inflammation; the Phase 3 VELA trials, as well as the PPP Phase 2 LEDA trial, which showed the effects of sonelokimab in PPP.

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 PPP. The trial recruited 32 patients. The primary endpoint of the trial is percent change from baseline in PPPASI with important secondary endpoints including PPPASI75. 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
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; the potential acceptance for review of the BLA for sonelokimab in HS, the potential grant of Priority Review, the timing of the Prescription Drug User Fee Act target action date, mid-cycle communication and other review milestones, and the outcome of the FDA’s review of the BLA; 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 and the timing and results thereof, including the Week 52 readout of the Phase 3 IZAR-1 trial in PsA, the Week 16 and Week 52 readouts of the Phase 3 IZAR-2 trial in PsA, results of the Phase 2 P-OLARIS trial in PsA and axSpA, final results of the Phase 3 VELA-TEEN trial, data from the VELA open-label extension and the commencement of enrollment of the Phase 3 NOVA 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 June 30, 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

(in thousands, except share and per share data)	September 30, 2026 (Unaudited)	June 30, 2026 (Unaudited)
Assets		
Current assets		
Cash and cash equivalents	$ 379,704	$ 477,905
Short-term marketable debt securities	118,758	59,125
Prepaid expenses	25,933	26,447
Other current assets	8,948	6,561
Total current assets	**533,343**	**570,038**
Non-current assets		
Operating lease right-of-use assets	1,713	2,078
Property and equipment, net	443	487
Other non-current assets	5,216	1,344
Total non-current assets	**7,372**	**3,909**
Total assets	**$ 540,715**	**$ 573,947**
Liabilities and Equity		
Current liabilities		
Trade and other payables	$ 13,850	$ 17,038
Accrued expenses and other current liabilities	43,621	27,108
Short-term portion of operating lease liabilities	959	1,246
Total current liabilities	**58,430**	**45,392**
Non-current liabilities		
Long-term debt	100,010	99,514
Long-term portion of operating lease liabilities	647	772
Pension liability	—	74
Total non-current liabilities	**100,657**	**100,360**
Total liabilities	**159,087**	**145,752**
Commitments and contingencies (Note 15)		
Shareholders' equity		
Class A Ordinary Shares: $0.0001 par value per share; 500,000,000 shares authorized; 85,106,685 shares issued and outstanding as of September 30, 2026; 83,606,685 shares issued and outstanding as of June 30, 2026.	8	8
Additional paid-in capital	1,053,301	1,021,980
Accumulated deficit	(673,968)	(594,423)
Accumulated other comprehensive income	2,287	630
Total shareholders' equity	**381,628**	**428,195**
Total liabilities and shareholders' equity	**$ 540,715**	**$ 573,947**

MOONLAKE IMMUNOTHERAPEUTICS

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

(in thousands, except share and per share data)	**Three Months Ended September 30, 2026**	**Three Months Ended June 30, 2026**
Operating expenses		
Research and development	$ (68,871)	$ (50,221)
General and administrative	(10,981)	(11,439)
Total operating expenses	**(79,852)**	**(61,660)**
Operating loss	**(79,852)**	**(61,660)**
Interest expense	(2,655)	(2,632)
Other income, net	3,593	2,577
Loss before income tax	**(78,914)**	**(61,715)**
Income tax expense	(631)	(90)
Net loss	**$ (79,545)**	**$ (61,805)**
Of which: net loss attributable to controlling interests shareholders	*(79,545)*	*(61,805)*
Of which: net loss attributable to noncontrolling interests shareholders	—	—
Net unrealized gain (loss) on marketable securities and short-term investments	868	16
Actuarial gain on employee benefit plans	789	292
Other comprehensive income (loss)	1,657	308
Comprehensive loss	**$ (77,888)**	**$ (61,497)**
Comprehensive loss attributable to controlling interests shareholders	*(77,888)*	*(61,497)*
Comprehensive loss attributable to noncontrolling interests	—	—
Weighted-average number of Class A Ordinary Shares, basic and diluted	85,380,482	73,915,296
Basic and diluted net loss per share attributable to controlling interests shareholders	**$ (0.93)**	**$ (0.84)**