

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 or 15(d) of the
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): May 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 May 10, 2026, MoonLake Immunotherapeutics (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 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 March 31, 2026, are being furnished to the U.S. Securities and Exchange Commission (“SEC”).

Item 7.01. Regulation FD Disclosure.

On May 10, 2026, the Company issued a press release announcing the positive outcome from its final pre-BLA (Biologics License Application) meeting with the U.S. Food and Drug Administration (the “FDA”), where the Company and the FDA aligned on submission plans and the label strategy for sonelokimab (SLK) in hidradenitis suppurativa (HS). 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:

<u>Exhibit Number</u>	<u>Exhibit Title or Description</u>
99.1	Press Release, dated May 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.

Date: May 11, 2026

MOONLAKE IMMUNOTHERAPEUTICS

By: _____ /s/ Matthias Bodenstedt

Name: Matthias Bodenstedt

Title: Chief Financial Officer

MoonLake Immunotherapeutics Announces Positive Outcome from its Final Pre-BLA Meeting with the U.S. FDA and Reports First Quarter 2026 Financial Results

- *MoonLake conducted a positive final pre-BLA (Biologics License Application) meeting with the U.S. Food and Drug Administration (FDA), where MoonLake and the FDA aligned on submission plans and the label strategy for sonelokimab (SLK) in hidradenitis suppurativa (HS)*
- *This included the acceptability of MIRA trial data to establish substantial evidence of effectiveness (SEE), full inclusion of the VELA-TEEN trial data for a label including patients aged 12 years and above, and the strategy for inclusion of safety data across the MIRA and VELA trials – this aligns with the scenario presented at the Investor Day on February 23, 2026*
- *The proposed label in HS is therefore expected to include the MIRA trial's ~43% HiSCR75 response and the ~29 percentage point delta-to-placebo at week 12, which are the highest values observed across any adequate well-controlled clinical trial conducted in HS to date*
- *With no remaining gaps identified, the pre-BLA process for HS is complete, and the BLA submission to the FDA is planned for the end of September 2026; acceptance, including a decision on Priority Review designation associated with the inclusion of VELA-TEEN adolescent data, is expected by end of November 2026*
- *Other clinical trials of SLK are progressing well and are expected to support a catalyst-rich roadmap over the next 12 months, including the release of 52 weeks data from the Phase 3 VELA clinical trials and week 16 read-outs from the Phase 3 IZAR clinical trials in Psoriatic Arthritis (PsA)*
- *MoonLake ended the first quarter with \$357.9 million in cash, cash equivalents and short-term marketable debt securities and expects to have a cash runway to the end of 2027; additionally, up to \$400 million in non-dilutive funds remain available through its debt facility with Hercules Capital*

ZUG, Switzerland, May 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 a positive outcome of its final pre-BLA meeting held on April 1, 2026, with the FDA on the HS program of its Nanobody® SLK.

During the meeting, MoonLake and the FDA aligned on the submission plans and the label strategy, the approach to include adolescent HS data in the BLA, and the safety data strategy. Specifically, the FDA re-confirmed the acceptability of including the data from the MIRA clinical trial as a key part to establish SEE and to analyze the data consistent with the approach used for the VELA clinical trials. The FDA also agreed to the inclusion of the VELA-TEEN trial data for adolescent HS patients with the trial considered final and pivotal at the time of final BLA submission. MoonLake therefore expects to include patients aged 12 years and above in its label proposal and has notified the FDA of its intent to apply for Priority Review. Furthermore, the FDA agreed to the proposed approach for the clinical safety section and that the safety data will be analyzed primarily based on the VELA-1 and VELA-2 data as per the previous discussion with the FDA. MoonLake thus expects to include the full safety data also for VELA-2 as planned. Finally, the FDA agreed that other key elements including non-clinical studies and the proposed safety pools and analyses appear complete and appropriate for BLA filing and review. No remaining gaps, including in the FDA's Chemistry, Manufacturing, and Controls regulations, precluding the planned BLA submission were identified and no additional meetings are required as agreed between the FDA and MoonLake. With the overall structure of the label for HS aligned with the FDA, the Company is proceeding to build out the relevant sections of the label as planned, and as presented at the Investor Day on February 23, 2026. The proposed label is expected to include the MIRA trial's ~43% HiSCR 75 response rate and ~29 percentage point delta-to-placebo which are the highest observed values across any adequate and well-controlled clinical trial conducted in HS to date.

Based on this feedback, MoonLake expects to submit the BLA for SLK in adult and adolescent HS to the FDA at the end of September 2026. Following this, the acceptance of the BLA submission is expected to

be received within 60 days at which point the FDA will also notify MoonLake whether Priority Review has been granted. Subject to FDA approval, the first commercial launch in the United States is expected in the second half of 2027.

Today, MoonLake also reported its financial results for the first quarter of 2026. As of March 31, 2026, MoonLake held cash, cash equivalents and short-term marketable debt securities of \$357.9 million. The Company expects to have sufficient capital to fund its operating expenses and capital expenditure requirements to the end of 2027. MoonLake's debt facility with Hercules Capital provides up to \$400 million in additional non-dilutive funds to support future funding needs. Research and development expenses were \$54.5 million for the three months ended March 31, 2026, which was similar to the \$56.0 million for the three months ended December 31, 2025. General and administrative expenses were \$15.5 million for the three months ended March 31, 2026, compared to \$9.2 million for the three months ended December 31, 2025. The increase of \$6.3 million was primarily related to \$4.8 million in accelerated expense recognition due to a voluntary cancellation of unvested stock option awards for no consideration.

Important upcoming anticipated milestones for MoonLake in 2026:

- Q2 2026: 52-week data of the VELA-1 and VELA-2 trials in HS
- Mid 2026: Primary endpoint readout of the Phase 3 IZAR-1 trial in PsA
- Mid 2026: Primary endpoint readout of Phase 3 VELA-TEEN trial in adolescent HS
- September 2026: Submission of a BLA for HS
- Q4 2026: Primary endpoint readout of the Phase 3 IZAR-2 trial in PsA

-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 www.moonlaketx.com.

About Nanobodies®

Nanobodies® represent a new generation of antibody-derived targeted therapies. They consist of one or more domains based on the small antigen-binding variable regions of heavy-chain-only antibodies (VHH). Nanobodies® have a number of potential advantages over traditional antibodies, including their small size, enhanced tissue penetration, resistance to temperature changes, ease of manufacturing, and their ability to be designed into multivalent therapeutic molecules with bespoke target combinations.

The terms Nanobody® and Nanobodies® are trademarks of Ablynx, a Sanofi company.

About Sonelokimab

Sonelokimab (M1095) is an investigational ~40 kDa humanized Nanobody® consisting of three 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 SLK 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, SLK 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%, $p = 0.053$). From week 16, all patients are expected to continue to receive the 120mg dose of SLK through to 48 weeks, with a last assessment planned at week 52, followed by an open-label extension for up to two years. 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.

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 top-line results in November 2023, where the trial met its primary endpoint with a statistically significant greater proportion of patients treated with either sonelokimab 60mg or 120mg (with induction) achieving an ACR50 response compared to those on placebo at week 12. All key secondary endpoints in the trial were met for the 60mg and 120mg doses with induction. The safety profile of sonelokimab in the ARGO trial was consistent with previous trials with no new safety signals detected.

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, SLK demonstrated clinically meaningful and statistically significant benefit. Patients treated with SLK 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 SLK could provide clinically meaningful improvements in this disease for which there are currently no approved therapies. The safety profile of SLK 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 has enrolled over 800 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 ≥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 120mg dose of sonelokimab to placebo with HiSCR75 reading out at week 16. Results of the week 16 data were announced in September 2025. Further details are available under NCT06411899 and NCT06411379 at www.clinicaltrials.gov.

About the MIRA trial

The MIRA trial (M1095-HS-201) 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 (120mg and 240mg) with placebo control and adalimumab as an active reference arm. The primary endpoint of the trial is the percentage of participants achieving Hidradenitis Suppurativa Clinical Response 75 (HiSCR75), defined as a ≥75% reduction in total abscess and inflammatory nodule (AN) count with no increase in abscess or draining tunnel count relative to baseline. The trial also evaluated a number of secondary endpoints, including the proportion of patients achieving HiSCR50, the change from baseline in International Hidradenitis Suppurativa Severity Score System (IHS4), the proportion of patients achieving a Dermatology Life Quality Index (DLQI) total score of ≤5, and the proportion of patients achieving at least 30% reduction from baseline in Numerical Rating Scale (NRS30) in the Patient's Global Assessment of Skin Pain (PGA Skin Pain). Further details are available under NCT05322473 at 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 120mg administered subcutaneously once every two weeks (Q2W) until week six and once every four weeks (Q4W) from week eight onwards. The trial aims to enroll 30-35 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 Score (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 Patients Global Assessment of Skin Pain (PGA Skin Pain). Further details are available under NCT06768671 at 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 indicates 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 \$15bn 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 (NCT06641076) and IZAR-2 (NCT06641089) 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. Further details are available under NCT06641076 and NCT06641089 at www.clinicaltrials.gov.

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 (M1095-axSpA-201) is a Phase 2 trial designed to evaluate the efficacy and safety of sonelokimab 60mg 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 (M1095-PPP-201) is a Phase 2 trial designed to evaluate the efficacy and safety of sonelokimab 120mg 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, 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; the interactions and alignment with the FDA concerning the anticipated BLA submission; 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 data of the VELA-1 and VELA-2 trials in HS, the primary endpoint readouts of the Phase 3 IZAR-trial in PsA, Phase 3 VELA-TEEN trial in adolescent HS and Phase 3 IZAR-2 trial in PsA and submission of a BLA for HS; the FDA’s decision on Priority Review designation; and timing of first commercial launch in the United States. 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 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.

Contacts:

MoonLake Immunotherapeutics Media & Investors Relations

ir@moonlaketx.com

ICR Healthcare

Mary-Jane Elliott, Sarah Elton-Farr, Ashley Tapp

Tel: +44 (0) 20 3709 5700

MoonLake@ICRHealthcare.com

MOONLAKE IMMUNOTHERAPEUTICS
CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

	March 31, 2026 (Unaudited)	December 31, 2025
Assets		
Current assets		
Cash and cash equivalents	\$ 298,490	\$ 334,517
Short-term marketable debt securities	59,431	59,451
Other receivables	5,763	4,869
Prepaid expenses	32,957	22,857
Total current assets	396,641	421,694
Non-current assets		
Operating lease right-of-use assets	1,857	1,566
Property and equipment, net	532	577
Other non-current assets	1,344	596
Total non-current assets	3,733	2,739
Total assets	\$ 400,374	\$ 424,433
Liabilities and Equity		
Current liabilities		
Trade and other payables	\$ 23,380	\$ 29,553
Accrued expenses and other current liabilities	21,814	14,691
Short-term portion of operating lease liabilities	920	1,234
Total current liabilities	46,114	45,478
Non-current liabilities		
Long-term debt	99,018	74,100
Long-term portion of operating lease liabilities	865	374
Pension liability	353	—
Total non-current liabilities	100,236	74,474
Total liabilities	146,350	119,952
Shareholders' equity		
Class A Ordinary Shares: \$0.0001 par value per share; 500,000,000 shares authorized; 72,134,066 shares issued and outstanding as of March 31, 2026; 71,373,579 shares issued and outstanding as of December 31, 2025	7	7
Additional paid-in capital	786,313	766,781
Accumulated deficit	(532,618)	(462,911)
Accumulated other comprehensive income	322	604
Total shareholders' equity	254,024	304,481
Total liabilities and shareholders' equity	\$ 400,374	\$ 424,433

MOONLAKE IMMUNOTHERAPEUTICS

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

<i>(in thousands, except share and per share data)</i>	Three Months Ended March 31, 2026	Three Months Ended December 31, 2025
Operating expenses		
Research and development	\$ (54,515)	\$ (56,006)
General and administrative	(15,509)	(9,211)
Total operating expenses	(70,024)	(65,217)
Operating loss	(70,024)	(65,217)
Interest expense	(2,269)	(1,994)
Other income, net	3,208	4,442
Loss before income tax	(69,085)	(62,769)
Income tax expense	(622)	(247)
Net loss	\$ (69,707)	\$ (63,016)
<i>Of which: net loss attributable to controlling interests shareholders</i>	<i>(69,707)</i>	<i>(62,425)</i>
<i>Of which: net loss attributable to noncontrolling interests shareholders</i>	<i>—</i>	<i>(591)</i>
Net unrealized gain (loss) on marketable securities and short-term investments	77	(203)
Actuarial gain (loss) on employee benefit plans	(359)	525
Other comprehensive gain (loss)	(282)	322
Comprehensive loss	\$ (69,989)	\$ (62,694)
<i>Comprehensive loss attributable to controlling interests shareholders</i>	<i>(69,989)</i>	<i>(62,106)</i>
<i>Comprehensive loss attributable to noncontrolling interests</i>	<i>—</i>	<i>(588)</i>
Weighted-average number of Class A Ordinary Shares, basic and diluted	71,273,650	68,387,022
Basic and diluted net loss per share attributable to controlling interests shareholders	\$ (0.98)	\$ (0.91)