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

FORM 10-K

(MARK ONE)
☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2025

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number: 001-39630

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

Cayman Islands	**98-1711963**
(State or Other Jurisdiction of Incorporation)	(IRS Employer Identification No.)
Dorfstrasse 29, 6300, Zug Switzerland	**N/A**
(Address of principal executive offices)	(ZIP Code)

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

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

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See definitions of "large accelerated filer", "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		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. ☐

Indicate by check mark whether the Registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the Registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the Registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the ordinary shares on The Nasdaq Capital Market ("Nasdaq") on June 30, 2025, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $1.34 billion. Ordinary shares held by each officer and director and by each person who is known to own 10% or more of the outstanding ordinary shares have been excluded in that such persons may be deemed to be affiliates of the Registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 1, 2026, there were 71,727,875 Class A Ordinary Shares, $0.0001 par value (the "Class A Ordinary Shares"), and no Class C Ordinary Shares, $0.0001 par value (the "Class C Ordinary Shares"), issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2026 Annual Meeting of Shareholders, to be held on or about June 4, 2026, are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. Such proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

MOONLAKE IMMUNOTHERAPEUTICS

FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2025
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Note on Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical fact contained in this Annual Report on Form 10-K, including without limitation, statements regarding the following, are forward-looking statements: our future results of operations and financial position, our expectations regarding industry trends, the sufficiency of our cash and cash equivalents, anticipated sources and uses of cash, the anticipated investments in our business, our business strategy, the plans and objectives of management for future operations and capital expenditures, and other information referred to in "Business", "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations". These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may", "will", "should", "expect", "plan", "anticipate", "could", "intend", "target", "project", "contemplate", "believe", "estimate", "predict", "potential", "might", "possible", or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this Annual Report on Form 10-K are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K contain forward-looking statements that reflect our plans and strategy for our business and related financing as well as expectations regarding the timing of regulatory submissions and potential commercialization for SLK. Our actual results and the timing of events could differ materially from those anticipated in the forward-looking statements.

These forward-looking statements are subject to a number of important risks, uncertainties and other factors that could cause actual results to differ materially from those in the forward-looking statements expressed or implied in this Annual Report on Form 10-K. Such risks, uncertainties and other factors include, among others, the risks, uncertainties and factors set forth in "Risk Factors", and the following risks, uncertainties and factors:

- our success in retaining or recruiting, or changes required in, our officers, key employees or directors;
- factors relating to our business, operations and financial performance, including, but not limited to:
    - we are substantially dependent on the success of our novel tri-specific Nanobody®, Sonelokimab ("SLK", also known as M1095/ALX 0761), which we license from Merck Healthcare KGaA, Darmstadt, Germany, an affiliate of Merck KGaA, Darmstadt, Germany ("MHKDG");
    - our ability to obtain regulatory approval for our products, and any related restrictions or limitations of any approved products;
    - competition and competitive pressures from other global companies in the industries in which we operate;
    - we have incurred significant losses since inception, and we expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future;
    - our ability to manage our growth effectively;
    - the impact of adverse business and economic conditions including inflationary pressures, general economic slowdown or a recession, fluctuating interest rates, new or increased tariffs and other barriers to trade, changes in fiscal and monetary policy or government budget dynamics, and the prospect of a shutdown of the U.S. federal government;
    - while we have initiated and completed clinical trials, we have no products approved for commercial sale;
    - we require substantial additional capital to finance our operations, and if we are unable to raise such capital when needed or on acceptable terms, we may be forced to delay, reduce, and/or eliminate one or more of our development programs or future commercialization efforts;
    - our ability to renew existing contracts;
    - our limited operating history;
    - our ability to respond to general economic conditions;

- securities litigation following periods of volatility in the marketplace or our share price; and
- the ability to adequately protect our intellectual property rights.

New risk factors emerge from time to time and it is not possible to predict all such risks, nor can we assess the impact of all such risks on our business or the extent to which any factor or combination of factors may cause actual results to differ materially from those contained in any forward-looking statements. Forward-looking statements are not guarantees of performance. You should not put undue reliance on these statements, which speak only as of the date hereof. All forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the foregoing cautionary statements. We undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

There may be other factors that may cause our actual results to differ materially from the forward-looking statements, including factors disclosed in “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”. You should read this Annual Report on Form 10-K and the documents that we reference herein completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

PART I

In this Annual Report on Form 10-K, unless the context otherwise requires or where otherwise indicated, references to "MoonLake", "we", "us", "our", "our Company", "the Company" and "our business" refer to MoonLake Immunotherapeutics and its consolidated subsidiaries following the Business Combination (as defined herein) and to Helix Acquisition Corp. ("Helix") prior to the Business Combination.

Item 1. Business

Overview

We are a clinical stage biotechnology company advancing therapies to address significant unmet needs in inflammatory skin and joint diseases. We are currently a single asset company focused on the development of SLK, a novel tri-specific IL-17A and IL-17F inhibiting Nanobody, that we exclusively licensed from MHKDG and that has the potential, based on response levels seen in clinical trials, to drive disease modification in dermatology and rheumatology patients.

SLK is a proprietary Nanobody that was discovered by Ablynx N.V., Belgium, a Sanofi company ("Ablynx"), and previously studied by MHKDG and Avillion LLP ("Avillion") under a 2017 co-development agreement. The terms "Nanobody" and "Nanobodies" used herewith are registered trademarks of Ablynx. Nanobodies are able to bind selectively to a specific antigen with high affinity. Nanobodies have a fraction of the molecular weight compared to traditional antibodies. They offer a number of potential advantages over traditional monoclonal antibodies, including the potential to create multivalent molecules with enhanced ability to penetrate inflamed tissue, especially when containing an additional albumin binding domain such as SLK, an easier manufacturing process and a higher thermostability.

We currently develop SLK in inflammatory diseases in dermatology and rheumatology where the pathophysiology is known to be driven by IL-17A and IL-17F. This group of diseases comprises our current target diseases, hidradenitis suppurativa ("HS"), psoriatic arthritis ("PsA"), axial spondyloarthritis ("axSpA"), palmoplantar pustulosis ("PPP"), and several other inflammatory conditions, including psoriasis ("PsO"). Our current target diseases affect millions of people worldwide, and we believe there is a need for improved treatment options. We believe that SLK has a differentiated mechanism of action and that its purposefully designed molecular characteristics, including its small size and its albumin binding site, facilitate deep tissue penetration in the skin and joints. We envision SLK as a key therapeutic alternative in our initial target indications and potentially in multiple other IL-17 driven inflammatory conditions.

HS Trials and Plans for Commercial Launch

In May 2022, we initiated a Phase 2b trial of SLK in patients with moderate-to-severe HS (the MIRA trial (M1095-HS-201)), and in June 2023, we announced positive top-line results from this trial, which met its primary endpoint of Hidradenitis Suppurativa Clinical Response ("HiSCR") 75 with 43% of patients treated with SLK 120mg achieving such response at week 12. In October 2023, we announced positive 24-week top-line results showing that the maintenance treatment with SLK led to further improvements in HiSCR75 response rates and other clinically relevant outcomes in patients with moderate-to-severe HS. In February 2024, we announced the successful outcome of our end-of-Phase 2 interactions with the U.S. Food and Drug Administration ("FDA"), as well as positive feedback from our interactions with the E.U. European Medicines Agency ("EMA"), with both regulatory bodies supporting our proposed approach for advancing our Phase 3 program of SLK in HS. In May 2024, we announced the screening of the first patients in the Phase 3 VELA-1 (M1095-HS-301) and VELA-2 trials (M1095-HS-302). In April 2025, we announced completion of enrollment of the VELA program and presented baseline characteristics of enrolled patients. In September 2025, we announced primary endpoint data from the VELA-1 and VELA-2 clinical trials. 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%, $p<0.001$). 34% of patients treated with SLK 120mg achieved a HiSCR75 response at the week 16 primary endpoint. In VELA-2, response rates associated with SLK were similar to those observed in VELA-1 (HiSCR75 response of 34%), but a 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%, $p=0.053$). Impact on HS lesions, including draining tunnels, was matched by improvements in all key Patient Reported

Outcomes ("PROs"), such as quality-of-life and pain scores, that are meaningful for HS patients and their treating physicians. The safety profile of SLK was consistent with previously reported studies with no new safety signals observed. This included the absence of new signals in key events of interest with IL-17A and F therapies such as Suicidal Ideation and Behavior, hepatic events, Inflammatory Bowel Disease ("IBD") and non-infectious diarrhea, Major Adverse Cardiovascular Events ("MACE"), and Eczema and Dermatitis. In February 2026, we presented an interim analysis of the long-term data from the VELA trials, which indicated that monthly maintenance treatment with SLK can lead to further improvements in clinically relevant outcomes in patients with moderate-to-severe HS, including an as-observed HiSCR75 response rate of 69% in VELA-1 (n=104) and 67% in VELA 2 (n=123) after 52 weeks of treatment with SLK 120mg. The VELA trials are expected to continue to week 52, followed by an open-label extension for up to two years (the VELA-OLE trial (M1095-HS-303)). We expect the full one-year data of VELA-1 and VELA-2 to become available in the second quarter of 2026. In parallel, we are conducting a Phase 3 trial of SLK in adolescent patients with HS (the VELA-TEEN trial (M1095-HS-304)), which we initiated in January 2025. In February 2026, we presented an interim analysis of the VELA-TEEN clinical trial which showed that 67% of patients achieved a HiSCR75 response at week 16 (n=21). We expect to complete the VELA-TEEN clinical trial in mid-2026.

In November 2025, we were granted a Type B meeting with the FDA to discuss adequacy of the current clinical evidence package of SLK in HS to support a Biologics License Application ("BLA") and in January 2026, we announced positive feedback from this interaction, confirming that we may establish substantial evidence of effectiveness ("SEE") without additional clinical trials in HS. The FDA specifically advised to include the results of the MIRA trial together with the results of the VELA trials in the submission to establish SEE. Based on the positive feedback, we expect to submit a BLA for SLK in adult and adolescent HS in the second half of 2026. Subject to FDA approval, we expect a first commercial launch in the United States in the second half of 2027.

PsA Trials

In December 2022, we initiated a Phase 2b trial in patients with active PsA (the ARGO trial (M1095-PSA-201)), and in November 2023, we announced positive top-line results from this trial, which met its primary endpoint of American College of Rheumatology ("ACR") 50 with 46% of patients on 60mg SLK achieving such response at week 12. In March 2024, we announced positive 24-week data from the ARGO trial in PsA showing that continued treatment with SLK led to significant improvements across all key outcomes. In June 2024, we announced the successful outcome of our end-of-Phase 2 interactions with the FDA, as well as positive feedback from our interactions with the EMA, with both regulatory bodies supporting our proposed approach for advancing our Phase 3 program of SLK in PsA. In November 2024, we announced the screening of the first patients in the IZAR-1 trial (M1095-PSA-301) and IZAR-2 trial (M1095-PSA-302). In February 2026, we announced completion of enrollment for the IZAR-1 trial. We expect a readout of the primary and key secondary endpoints of the IZAR-1 clinical trial in mid-2026 and of the IZAR-2 clinical trial in the second half of 2026. In addition, in January 2025, we initiated another Phase 2 clinical trial of SLK in patients with PsA where we are applying novel imaging techniques (the P-OLARIS trial (M1095-snSpA-202)). We expect results of the P-OLARIS trial to become available at the end of 2026.

PPP Trials

In November 2024, we initiated a Phase 2 trial in patients with PPP (the LEDA trial (M1095-PPP-201)) and in November 2025, we presented positive results of this trial, suggesting that SLK could provide clinically meaningful improvements in patients with PPP. 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 ≥75% reduction in the PPPASI ("PPPASI75"). In February 2026, we announced that we received Fast Track designation from the FDA for SLK in moderate-to-severe PPP. We expect to commence a Phase 3 clinical trial in PPP in the third quarter of 2026.

axSpA Trials

In February 2025, we initiated a Phase 2 trial in patients with axSpA (the S-OLARIS trial (M1095-axSpA-202)) and in February 2026, we presented positive results of this trial, suggesting that SLK could provide clinically meaningful improvements in patients with axSpA. Of the patients (n=26) treated with SLK, 81% achieved an Assessment of Spondyloarthritis International Society 40 ("ASAS40") response at week 12, showing at least 40% improvement and an absolute improvement of ≥2 units on a numerical rating scale (0 to 10) from baseline in at least three of the four key domains (Patient Global Assessment ("PGA") of disease activity, total back pain, physical function, inflammation). More than 80% of patients have achieved a "clinically important improvement" as per ASDAS-CRP score by week 12, confirming the strong result in this clinically relevant endpoint.

PET and MRI imaging data collected as part of the clinical trial confirm a significant reduction in inflammation in the deep tissue of the spine and sacroiliac joint affected by axSpA in a pooled analysis comparing baseline to week 12. Additional objective biomarker and tissue analyses conducted as part of the clinical trial reinforce rapid and sustained effect of the treatment with SLK in axSpA patients. The safety profile of SLK in the S-OLARIS trial was consistent with previous trials with no new safety signals detected.

Additional Trials for Other Indications

SLK was also studied in a Phase 2b trial in PsO patients where it showed a significant improvement in the primary end point as compared with placebo and for which results were presented in peer-reviewed scientific publications and conferences. In addition, Phase 1 single ascending and multiple ascending dosing trials were previously completed.

Our Vision and Our Strategy

Our vision is to elevate treatment goals for inflammatory skin and joint diseases. Our strategy is centered on developing SLK as, to our knowledge, the first ever Nanobody in clinical development for our selected indications. We seek to accomplish this strategy by:

- Completing the development of SLK in our current focus indications, HS, PsA, axSpA and PPP — In HS, we expect to complete the one-year VELA-1 and VELA-2 trials in the second quarter of 2026, and the six-month VELA-TEEN trial in mid-2026. We expect to submit a BLA for treatment of adult and adolescent patients in the second half of 2026, based on our MIRA, VELA-1, VELA-2 and VELA-TEEN clinical trials, with a potential commercial launch in the United States in the second half of 2027. In PsA, we expect primary endpoint readouts from our IZAR-1, IZAR-2 and P-OLARIS clinical trials in mid-2026, second half of 2026 and end of 2026, respectively, and expect to seek regulatory approval after completion of these studies through submission of a supplemental BLA. In PPP, we expect to initiate a Phase 3 clinical trial in the third quarter of 2026. In axSpA, we announced positive results from our S-OLARIS clinical trial in February 2026 and are currently evaluating the next steps to complete the clinical development of SLK in this indication.

- Strengthening the differentiation elements for future SLK patients — In parallel with our clinical trials, we conduct non-clinical research to continue refining our understanding of SLK/Nanobody biology and the potential impact in our selected therapeutic indications. This research will inform our clinical efforts and includes the study of SLK's pharmacokinetics and pharmacodynamics in a variety of cellular, deep-tissue, and disease models (in vitro and in vivo), including exploration of tissue penetration and targeting of SLK in disease models. We expect these studies to provide a more complete picture of IL-17A and IL-17F regulation. We expect this work to more clearly differentiate SLK, a Nanobody, from monoclonal antibody-based treatment options, including other IL-17A and IL-17F inhibitors. We also expect this work to contribute to the furthering of our intellectual property.
- Preparing for commercialization of SLK — We have started preparing the BLA to seek approval of SLK in the United States in HS and adolescent HS. We expect to submit the BLA in the second half of 2026 after completion of the VELA program, and, subject to FDA approval, we expect a commercial launch in the United States in the second half of 2027. We plan to further invest in our commercial capabilities. We intend to continue to build out our marketing, access and pricing functions to prepare for commercial launches of SLK in our target indications. We also expect to establish a presence in the United States in 2026 to build the sales, marketing and distribution infrastructure to commercialize SLK.
- Building our manufacturing capabilities — We intend to continue investing in our manufacturing capabilities. We have executed technology transfers for drug substance and drug product to commercial scale contract manufacturing organizations ("CMOs"), and we have successfully manufactured Process Performance Qualification batches. We may pursue additional technology transfers to establish second sourcing and increase manufacturing capacity. We are also continuously investing in process improvements which are important in driving efficiency, maintaining high standards of quality control, and providing adequate access to our product candidates, if approved, for investigators, physicians, and patients. We started stock-piling drug substance as pre-launch inventory during the third quarter of 2025 and expect to continue doing so in 2026.
- Deepening our intellectual property portfolio to support our Nanobody technology and product candidates — We intend to continue extending our global intellectual property portfolio consisting of patents and patent applications, trade secrets, trademarks, and know-how to protect the product candidates developed from our Nanobody technology. We plan to expand our intellectual property portfolio as we continue to advance and develop existing product candidates.
- Broadening our portfolio — We believe that there are other indications beyond HS, PsA, axSpA and PPP where SLK has the potential to represent a differentiated therapeutic alternative and we may initiate clinical trials of SLK in such other indications. In addition, to further enhance our overall potential and provide increased optionality, we may supplement our current strategy with the in-licensing or acquisition of additional product candidates for clinical development (beyond SLK), rather than discovering such candidates ourselves. We believe that our management team is well-positioned to identify assets that have attractive risk/reward profiles and that can be rapidly advanced to market approval, supplemented by our expertise and capabilities.

Our Focus: Inflammatory Diseases Involving IL-17A and IL-17F

SLK is an inhibitor of IL-17A and IL-17F that modulates cytokine activity in a fashion that is founded in current understanding of the importance of IL-17 biology in inflammatory disease. IL-17 cytokines can potently promote inflammation and also play a role in protection against some infectious agents. The inflammatory effects of IL-17 can be targeted directly by blocking the cytokine or its receptor, or indirectly by blocking cytokines upstream of IL-17-producing cells. IL-17 contributes to various lesions that are produced by Th17 cells, one subset of helper T cells, by gamma delta (γδ) T cells, and by innate lymphoid cells. In healthy tissue, IL-17A is largely absent, but is significantly upregulated in inflamed lesions in our focus indications. While IL-17F is present in healthy and non-lesional tissue at detectably higher concentrations than IL-17A, it is also significantly upregulated in inflamed tissue in our focus indications. The current view is that IL-17F contributes to inflammatory conditions such as HS and PsA, which is why IL-17A and F inhibition could well exert an increased anti-inflammatory therapeutic potential compared to just IL-17A inhibition.

Millions of people worldwide suffer from diseases in which overexpression of IL-17A and IL-17F are potentially implicated in the pathophysiology and we believe there are limited treatment options. Well-known diseases include HS, PsA, PsO, PPP, and axSpA among others. HS has an estimated worldwide prevalence of approximately 2%, though we believe it is currently underdiagnosed and undertreated with limited effective treatment options available. PsA and axSpA have an estimated worldwide prevalence of up to 1.0% and PPP has an estimated worldwide prevalence of 0.3%. Finally, PsO has an estimated worldwide prevalence of approximately 3%. Other diseases, where IL-17A and IL-17F play a role, will represent additional pools of diagnosed patients.

Our Pipeline

We are developing a portfolio of therapeutic indications for SLK (Figure 1).

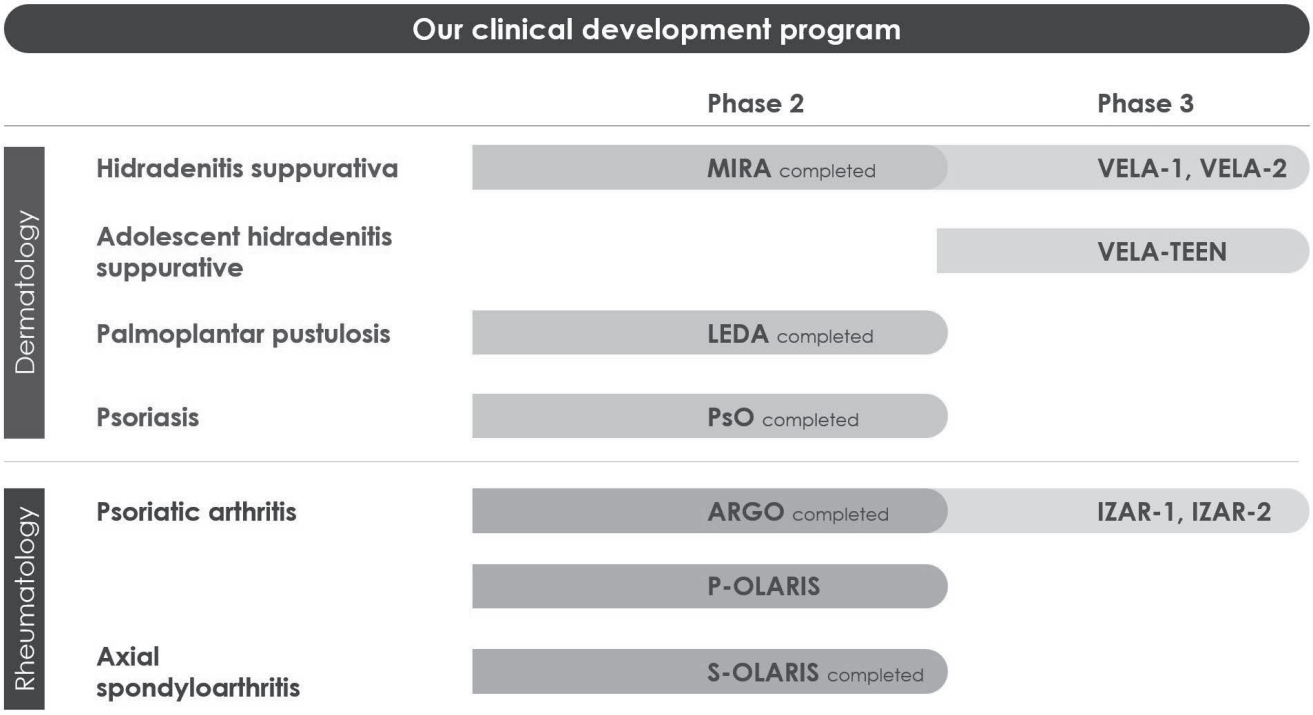


Figure 1 — Overview of development pipeline for SLK

Clinical Development of SLK

Phase 2b Clinical Trial in HS: The MIRA Trial

The MIRA trial is a global, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of SLK, administered subcutaneously, in the treatment of adult patients with active moderate-to-severe HS. The trial recruited 234 patients, with the aim to evaluate two different doses of SLK (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 HiSCR75, defined as a ≥75% reduction in total abscess and inflammatory nodule 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 in the Patient's Global Assessment of Skin Pain ("PGA Skin Pain").

In June 2023, the MIRA trial set a landmark milestone as the first placebo-controlled randomized trial in HS to use HiSCR75 as the primary endpoint which it met with a significantly greater proportion of patients treated with both SLK 120mg and 240mg achieving HiSCR75 compared to those on placebo at week 12. The primary analysis was based on a very stringent type of analysis for such trials, intent-to-treat non-responder imputation ("ITT-NRI"). Both doses performed similarly, with the 120mg dose providing the highest delta on HiSCR75 and HiSCR50. The 120mg dose achieved a 43% response rate on HiSCR75 and a 66% response rate on HiSCR50 at week 12.

In October 2023, 24-week results were presented, showing that ongoing treatment with SLK 120mg and 240mg dosed Q4W further increased HiSCR75 response rates compared to week 12. 57% of patients continuously treated with 120mg achieved a HiSCR75 response (more than 10 ppt improvement from week 12) and 38% achieved HiSCR90 (more than 14 ppt improvement versus week 12). The IHS4 score, which encompasses changes in all active HS lesions (nodules, abscesses, draining tunnels), decreased by 65% in patients treated with the 120mg maintenance dose.

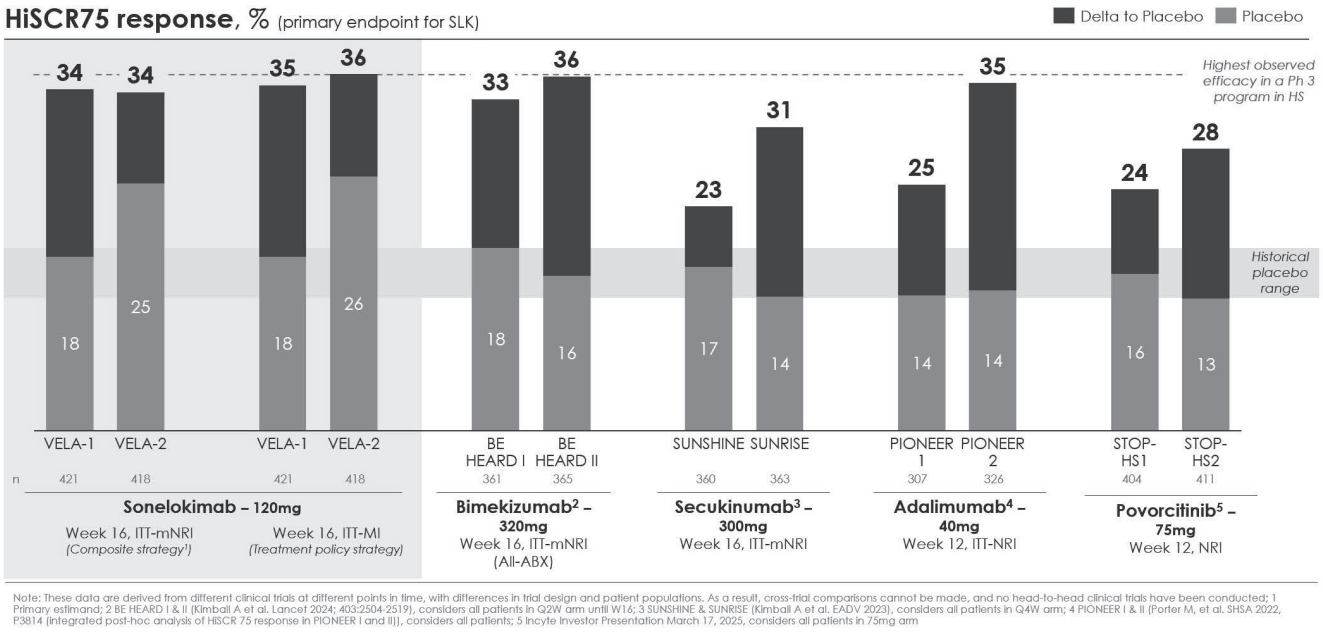
Phase 3 Clinical Trials in HS: The VELA Program

The Phase 3 VELA program consists of two global, randomized, double-blind, placebo-controlled trials, the VELA-1 and VELA-2 trials, that are identical in design to evaluate the efficacy and safety of SLK, administered subcutaneously, in adult patients with active moderate-to-severe HS. Across VELA-1 and VELA-2, we enrolled a total of 838 patients. The primary endpoint is the percentage of participants achieving HiSCR75 at week 16. The trials also evaluate 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 reduction of ≥4, the proportion of patients achieving at least 50% reduction from baseline in Numerical Rating Scale in the PGA Skin Pain and complete resolution of Draining Tunnels. The trials compare a single 120mg dose of SLK to placebo with HiSCR75 reading out at week 16. From week 16, all patients receive the 120mg dose of SLK through to 48 weeks, with a last assessment at week 52, followed by an open-label extension for up to two years. The Phase 3 program used a protocol design consistent with the Phase 2 MIRA trial, which identified the optimal dose of SLK for HS. 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. Results of the week 16 data were announced in September 2025.

In the combined Phase 3 VELA program, all endpoints reached statistical significance with p-values below 0.001, including lesion counts and PROs. SLK demonstrated the expected profile of response over time, with statistically significant HiSCR75 for both studies achieved as early as week 4. A preliminary analysis suggests that responses continue to improve beyond week 16 and that placebo patients crossing over at week 16 achieve similar responses to those originally randomized to the SLK 120mg arm, as of week 20 (pre-specified analysis).

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%, $p=0.053$). Using the treatment policy strategy as per protocol, both VELA-1 and VELA-2 showed a statistically significant increase in the percentage of participants achieving HiSCR75 at week 16 and provided a clinically meaningful benefit. Response rates for SLK 120mg were consistent between the two trials, with 34.8% and 35.9% of patients in VELA-1 and VELA-2 achieving HiSCR75 at week 16, respectively. The placebo response rate in VELA-1 of 17.5% at week 16 was within the historical Phase 3 range of 13% to 18%. The placebo response rate in VELA-2 of 24.9% at week 16 was higher than expected.



Note: These data are derived from different clinical trials at different points in time, with differences in trial design and patient populations. As a result, cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted; 1 Primary estimand; 2 BE HEARD I & II (Kimball A et al. Lancet 2024; 403:2504-2519), considers all patients in Q2W arm until W16; 3 SUNSHINE & SUNRISE (Kimball A et al. EADV 2023), considers all patients in Q4W arm; 4 PIONEER I & II (Porter M, et al. SHSA 2022, P3814 (integrated post-hoc analysis of HiSCR 75 response in PIONEER I and II)), considers all patients; 5 Incyte Investor Presentation March 17, 2025, considers all patients in 75mg arm

Figure 2 — HiSCR75 response rates across Phase 3 clinical trials in HS

Both VELA-1 and VELA-2 achieved p-values below 0.05 for all key secondary endpoints. This includes other lesion count based endpoints (HiSCR50 and IHS4-55). It also includes relevant PROs in HS. Around 30% of patients experienced a marked reduction of pain, as measured by an at least 3-point improvement in the worst pain NRS, in both VELA-1 and VELA-2 ($p \leq 0.002$). SLK showed a significant improvement of HS-specific Quality of Life ("HiSQOL") score at week 16 ($p < 0.001$), which was consistent between VELA-1 and VELA-2. Almost 60% of patients achieved a meaningful (4 points or more) improvement of DLQI, an approximately 20 percentage-point benefit over placebo ($p \leq 0.001$).

The safety profile of SLK was consistent with previously reported studies with no new safety signals observed. This includes the absence of new signals in key events of interest with IL-17A and F therapies: Suicidal Ideation and Behavior, hepatic events, IBD and non-infectious diarrhea, MACE and Eczema and Dermatitis.

The VELA program is conducted using a convenient sub-cutaneous dosing scheme with 1ml volume delivered every other week to week 6 in the induction phase (4 injections), and monthly from week 8 for maintenance, with no up-titration. This profile is matched by improvements of HS lesions, including draining tunnels, as well as in all key PROs, such as quality-of-life and pain scores, that are meaningful for HS patients and their treating physicians.

In February 2026, we presented an interim analysis of the long-term data from the VELA trials, which indicated that monthly maintenance treatment with SLK can lead to further improvements in clinically relevant outcomes in patients with moderate-to-severe HS, including an as-observed HiSCR75 response rate of 69% in VELA-1 (n=104) and 67% in VELA 2 (n=123) after 52 weeks of treatment with SLK 120mg. The VELA trials are expected to continue to week 52, followed by an open-label extension for up to two years. We expect the full one-year data of VELA-1 and VELA-2 to become available in the second quarter of 2026.

In November 2025, we were granted a Type B meeting with the FDA to discuss adequacy of the current clinical evidence package of SLK in HS to support a BLA and in January 2026, we announced positive feedback from this interaction, confirming that we may establish SEE without additional clinical trials in HS. In addition, FDA feedback confirms that we may establish SEE with a BLA consisting of data from our existing VELA-1, VELA-2 and MIRA trials. The FDA specifically advised us to include the results of the MIRA trial in the submission and to submit the results of the VELA-2 trial for the marketing application to inform the safety profile of SLK, regardless of decisions on

its utility in establishing SEE. Based on the positive final official records of this Type B meeting, we will continue our plans for BLA submission for SLK in adult and adolescent HS in the second half of 2026. Subject to FDA approval, we expect a first commercial launch in the United States in the second half of 2027.

Phase 3 Clinical Trial in Adolescent HS: VELA-TEEN

The Phase 3 VELA-TEEN trial is an open-label, single-arm trial designed to evaluate SLK 120mg administered subcutaneously once every two weeks until week six and once every four weeks from week eight onwards. The trial aims to enroll 30-35 adolescents, aged 12-17, with moderate-to-severe HS, 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 SLK. 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 CDLQI and the PGA Skin Pain.

An interim analysis of the VELA-TEEN clinical trial showed that 67% of patients achieved a HiSCR75 response at week 16 (n=21). The safety profile of SLK in patients with adolescent HS was consistent with the results from the adult HS trial (VELA-1, VELA-2, and MIRA) and no new safety signals were observed.

Phase 2b Clinical Trial in PsA: the ARGO Trial

The ARGO trial is a global, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of SLK, administered subcutaneously, in the treatment of adult patients with active PsA. The trial was designed to evaluate different doses of SLK, with placebo control and adalimumab as an active reference arm. The primary endpoint of the trial is the percentage of participants achieving ≥50% improvement in signs and symptoms of disease from baseline, compared to placebo, as measured by ACR50 response. The trial also evaluates a number of secondary endpoints, including improvement compared to placebo in ACR20, complete skin clearance as measured by at least a 100% improvement in the Psoriasis Area and Severity Index (PASI100), physical function as measured by the Health Assessment Questionnaire-Disability Index, enthesitis as measured by the Leeds Enthesitis Index and pain as measured by the Patients Assessment of Arthritis Pain. Important composite scores, such as ACR50+PASI100, measuring both joint and skin improvement in the same patients were also studied.

In November 2023, the ARGO trial, which enrolled 207 patients, met its primary endpoint with a statistically significant greater proportion of patients treated with either SLK 60mg or 120mg (with induction) achieving an ACR50 response compared to those on placebo at week 12. Specifically, for the 60mg and 120mg doses with induction, respectively, 46% and 47% of patients treated with SLK achieved ACR50 ($p<0.01$ versus placebo); 78% and 72% of patients achieved ACR20; and 29% and 26% achieved ACR70. The primary analyses were based on a very stringent type of analysis for such trials, ITT-NRI. As expected, the 60mg dose without induction did not reach statistical significance, confirming the 60mg and 120mg with induction as the potential dose regimens to carry forward into Phase 3. All key secondary endpoints were met for the 60mg and 120mg doses with induction. The key secondary endpoint PASI90 was met for all doses with induction. 77% of patients treated with SLK 60mg achieved a PASI90 response at week 12 (ITT-NRI, $p<0.001$ versus placebo) and 58% achieved complete skin clearance (PASI100). PASI responses across dose arms were consistent with the previously reported Phase 2b data of SLK in moderate-to-severe plaque-type PsO, with the 120mg dose achieving the highest responses for PASI100 (close to 60% of patients at week 12, ITT-NRI) in patients with more severe skin lesions (PASI score ≥ 10 at baseline). Up to 33% of patients achieved both ACR50 and PASI100 at week 12. Other clinically relevant secondary endpoints, such as Minimal Disease Activity (MDA), the modified Nail Psoriasis Severity Index (mNAPSI), the Leeds Enthesitis Index (LEI) and the patient self-reported Psoriatic Arthritis Impact of Disease (PsAID-12), each show promising levels of response at week 12. Adalimumab was used as an active reference to validate responses across arms (not powered for statistical comparisons to active treatment). SLK 60mg and 120mg (with induction) numerically outperformed adalimumab on the primary endpoint and all key secondary endpoints, with the observed deltas further supporting the potential for SLK as a future leading therapy. The results suggest that, as early as week 12, SLK reaches levels of clinical response at or above those seen with other therapies tested in similarly stringent trials.

The safety profile of SLK in the ARGO trial was consistent with previously reported studies with no new safety signals. Overall, SLK continued to show a favorable safety profile.

In March 2024, the ARGO trial demonstrated that the primary endpoint, ACR50, continued to improve from week 12 and exceeded 60% by week 24. The more rigorous ACR70 outcome was achieved by approximately 40% of patients by week 24. In addition, by week 24, over 80% and 60% of patients treated with SLK achieved PASI 90 and 100, respectively. Both doses of SLK yielded similar results. The responses surpassed those for adalimumab, the active reference arm in the study, and were also higher when indirectly compared to competitors using the same active reference arm as a standard.

Treatment with SLK resulted in unprecedented improvements in composite scores that reflect responses in different domains simultaneously. ACR50+PASI90 up to 59%, ACR 50+PASI 100 up to 52%, ACR 70+PASI 100 up to 48% and MDA up to 61% response. In all composite scores, SLK showed 16-29 ppt differences to the reference adalimumab arm, comparatively higher than competitors using the same reference arm. While the 60mg dose was found to be sufficient to reach high levels of response in the general trial population, the 120mg dose was found to improve responses further in specific patient sub-groups, which suggests two doses being carried over to Phase 3.

The safety profile of SLK was consistent with previous trials with no new safety signals detected. The discontinuation rate of the second part of ARGO remained low at 5%, in line with other SLK trials.

Phase 3 Clinical Trials in PsA: The IZAR Program

The IZAR program is expected to enroll approximately 1,500 adult patients across IZAR-1 and IZAR-2. Both are global, randomized, double-blind, placebo-controlled Phase 3 trials designed to evaluate the efficacy and safety of SLK compared with placebo in patients with active PsA, with a primary endpoint of superiority to placebo in ACR50 response at week 16. IZAR-1 enrolled biologic-naïve patients and includes an evaluation of radiographic progression, while IZAR-2 enrolls patients with an inadequate response to tumor necrosis factor-α inhibitors (TNF-IR) — reflecting patients commonly seen in clinical practice — and includes risankizumab, a monoclonal antibody that inhibits IL-23, as an active reference arm. Both trials are also designed to assess a range of secondary endpoints reflecting the multiple disease manifestations characteristic of PsA. These include skin, nail, and joint outcomes: ACR20 response at week 16, PASI90 response at week 16, vdHmTSS (van der Heijde modified Total Sharp Score) change from baseline at week 16, multidomain outcomes: MDA at week 16, and patient-reported outcome measures: HAQ-DI (Health Assessment Questionnaire-Disability Index (HAQ-DI) change from baseline at week 16, SF-36 PCS (short-form-36 Physical Component Summary) change from baseline at week 16.

The IZAR program will assess 60mg and 120mg doses of SLK (Figure 3). The readout of the primary endpoint for IZAR-1 is anticipated in mid-2026 and for IZAR-2 in the second half of 2026.

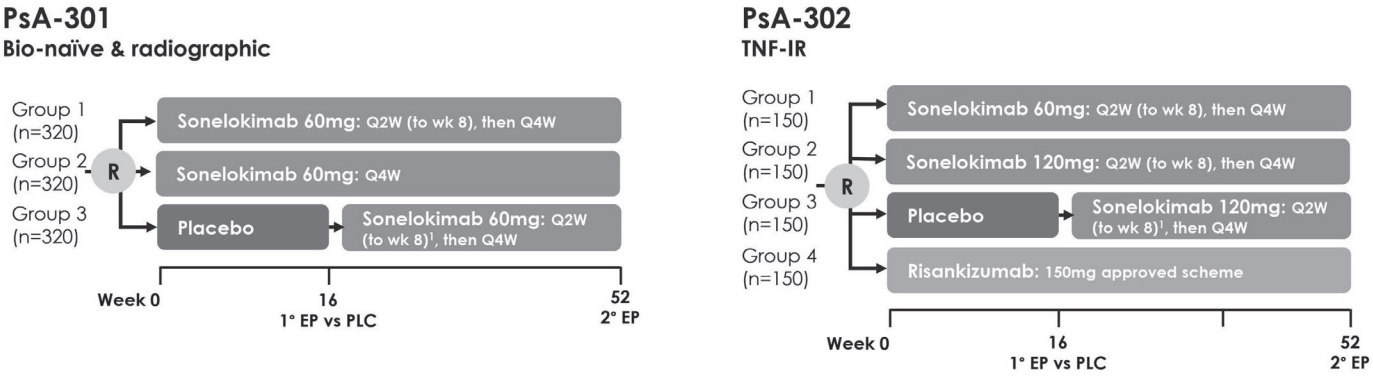


Figure 3 — Design of the Phase 3 IZAR program in PsA.

Additional Phase 2 Clinical Trial in PsA: The P-OLARIS Trial

The P-OLARIS trial is an open-label imaging Phase 2 trial designed to explore the effects of SLK 60mg administered subcutaneously in 30 patients with seronegative spondyloarthritis which includes PsA. The primary endpoint is the change from baseline (CfB) in [68Ga]-FAPI-46 SUVmax signal overall and per indication at week 12, as detected by FAPI-PET/low-dose CT scan. In addition, several other endpoints will be assessed including clinical disease activity scores and patient-related outcomes. The trial also features a peripheral blood and tissue biomarker program. We expect the P-OLARIS trial to provide a more complete picture of SLK's benefit in patients with active PsA and thereby more clearly differentiate SLK, a Nanobody, from monoclonal antibody-based treatment options, including other IL-17A and IL-17F inhibitors. The first P-OLARIS patient was screened in October 2025 and dosed in November 2025. We expect the topline primary endpoint readout in the second half of 2026.

Phase 2 Clinical Trial in PPP: The LEDA Trial

The LEDA trial is a Phase 2 trial designed to evaluate the efficacy and safety of SLK 120mg administered subcutaneously in adult patients with PPP. 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.

In November 2025, the Phase 2 LEDA clinical trial in PPP demonstrated clinically meaningful and statistically significant benefit for patients treated with SLK. Patients treated with SLK achieved a mean percent change from baseline in the PPPASI of 64% at week 16, and 39% of patients achieved a 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.

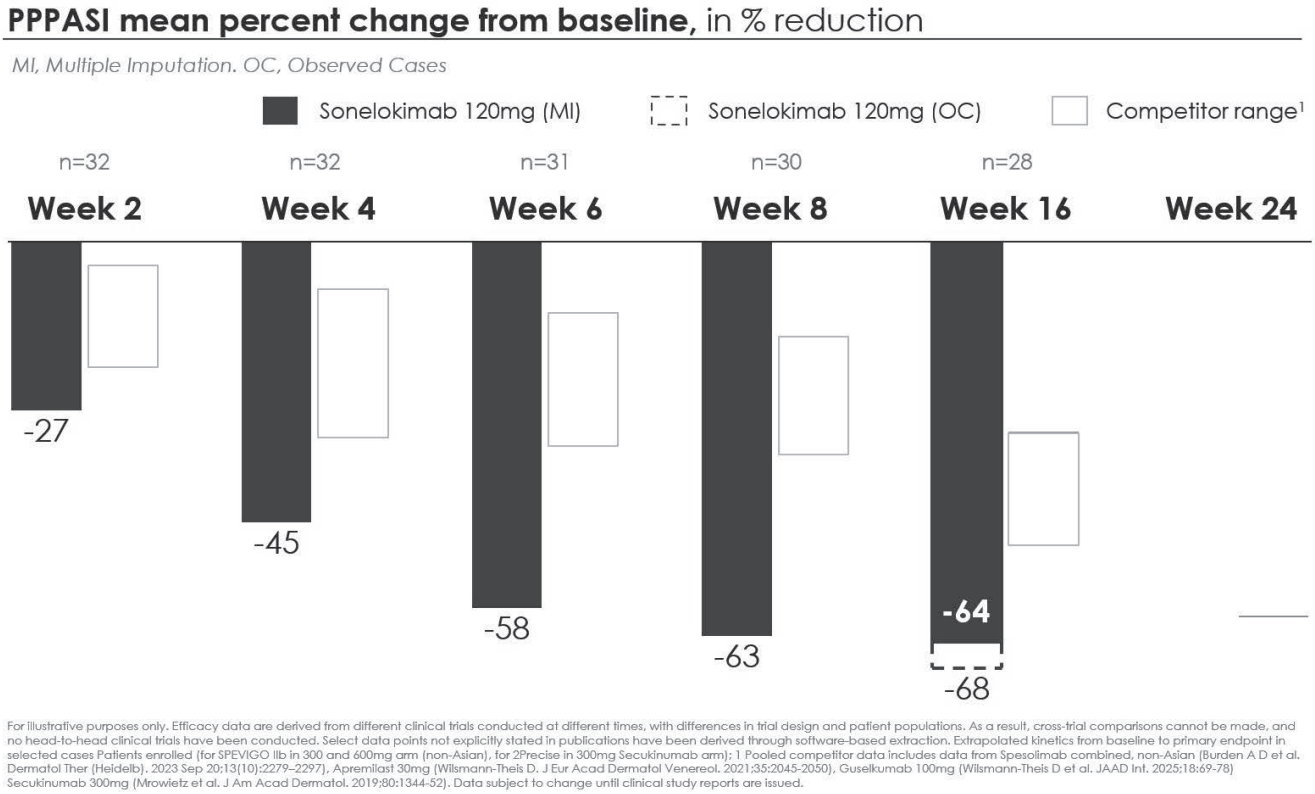


Figure 4 — PPPASI mean percent change from baseline in Phase 2 LEDA trial

Phase 3 Clinical Trial in PPP

The Phase 3 program for PPP is an anticipated global, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of SLK in adult patients with chronic moderate-to-severe PPP. The trial is expected to enroll approximately 370 patients.

The proposed Phase 3 trial design will assess the SLK 120 mg dose administered subcutaneously every two weeks ("Q2W") and every four weeks dosing, following an initial Q2W induction period, compared with placebo. The primary endpoint is the percentage of patients achieving a Palmoplantar Psoriasis Global Assessment score of 0 (clear with no signs of PPP) or 1 (almost clear with minimal residual signs of PPP) by week 12.

The trial will also assess a number of secondary endpoints, in line with those evaluated in the Phase 2 LEDA trial, including the proportion of patients achieving PPPASI75, PPPASI50, Pain Response, and a Minimally Clinically Important Difference ("MCID") response in the DLQI.

An end-of-Phase 2 meeting with the FDA is planned for the first half of 2026, with patient enrolment expected to begin in the third quarter of 2026. In February 2026, we announced that the Dermatology Division of the FDA has granted Fast Track designation for SLK in moderate-to-severe PPP, supported by positive results from the Phase 2 LEDA trial. As a result, the Phase 3 program is expected to benefit from earlier and more frequent interactions with the FDA under the Fast Track framework, potentially enabling a more efficient development pathway.

Phase 2 Clinical Trial in axSpA: the S-OLARIS Trial

The S-OLARIS trial is an open-label imaging Phase 2 proof-of-concept trial aiming to investigate SLK 60mg administered subcutaneously in approximately 25 patients with active axSpA. The primary endpoint is the change from baseline at week 12 in the uptake of 18F-NaF in the sacroiliac joints and spine using PET in combination with MRI imaging. Throughout the trial, several other endpoints will be assessed including established clinical disease activity outcomes, scores related to physical function, spinal mobility, and enthesitis as well as PROs. The trial also includes an exploratory peripheral blood and tissue biomarker program.

In February 2026, the Phase 2 S-OLARIS trial in axSpA demonstrated a clinically meaningful and statistically significant benefit. Of the patients (n=26) treated with SLK, 81% achieved an Assessment of Spondyloarthritis International Society 40 (ASAS40) response at week 12, showing at least 40% improvement and an absolute improvement of ≥2 units on a numerical rating scale (0 to 10) from baseline in at least three of the four key domains (PGA of disease activity, total back pain, physical function, inflammation). More than 80% of patients have achieved a "clinically important improvement" as per ASDAS-CRP score by week 12, confirming the strong result in this clinically relevant endpoint.

PET and MRI imaging data collected as part of the clinical trial confirm a significant reduction in inflammation in the deep tissue of the spine and sacroiliac joint affected by axSpA in a pooled analysis comparing baseline to week 12. Additional objective biomarker and tissue analyses conducted as part of the clinical trial reinforce rapid and sustained effect of the treatment with SLK in axSpA patients. The safety profile of SLK in the S-OLARIS trial was consistent with previous trials with no new safety signals detected.

Clinical Development in Other Indications

Building on the strong data generated with SLK to date, we believe that there are other indications beyond HS, PsA, axSpA and PPP where SLK has the potential to represent a differentiated therapeutic alternative and we may initiate clinical trials of SLK in such other indications.

Manufacturing

We do not own or operate manufacturing facilities and currently have no plans to establish any. We partner with third-party CMOs for both drug substance and finished drug product, through established contracts.

Our current drug substance supplier is Richter BioLogics GmbH & Co. KG ("Richter Biologics") based in Bovenau, Germany. Effective July 1, 2021, we entered into a contract manufacturing agreement with Richter Biologics with respect to the manufacture of SLK. We may terminate the contract manufacturing agreement for convenience in accordance with the terms of the agreement. Either party may also terminate the contract manufacturing agreement with respect to an uncured breach by the other party in accordance with the terms of the agreement. The agreement includes confidentiality and intellectual property provisions to protect our proprietary rights related to our product candidates.

MHKDG produced the drug product supply for our MIRA and ARGO Phase 2 clinical trials. In 2022, we successfully transferred the drug product process to Vetter Pharma International GmbH as part of our strategy to ensure sufficient supply for potential commercialization following all regulatory and related requirements.

In May 2023, we entered into a collaboration agreement with SHL Medical to develop an autoinjector for clinical and potential subsequent commercial supply of SLK. Necessary pharmacokinetic and human factor studies were completed in 2025 to support the potential launch of SLK with the autoinjector as an approved device for administration of SLK.

Intellectual Property

As of December 31, 2025, we have the exclusive license to a patent family directed to Il-17 Nanobodies, including SLK, and methods of making and using the same derived from International Patent Application PCT/EP2012/058313, published as WO 2012/156219, entitled "Amino Acid Sequences Directed Against IL-17A, IL-17F and/or IL17-A/F and Polypeptides Comprising the Same". Applications in this family have been filed in the United States, the European Patent Office (EPO), the Eurasian Patent Organization (EAPO), Australia, Brazil, Canada, Chile, China, Hong Kong, India, Israel, Japan, Korea, Malaysia, Mexico, New Zealand, Philippines, Singapore, and South Africa. To date, 24 patents have been issued, and several applications are pending. Three patents have been issued in the United States in this family thus far (U.S. Patent Nos. 10,017,568, 10,829,552 and 11,773,159), all three providing protection until May 2032, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other governmental fees. There are several non-U.S. patents that have been granted or are pending in this family, all of which are expected to have similar expiration dates, absent any extensions that may be available through supplementary protection certificates or similar mechanisms. Additional data exclusivity rights may be applicable.

As of December 31, 2025, our patent portfolio also includes three patent families owned by us directed to uses of Nanobodies, including SLK. One family is derived from International Patent Application PCT/IB2023/054122, published as WO2023/203549, titled "Methods of Achieving Safe and Sustained Control of IL-17-Dependent Conditions in Subjects Responsive to Treatment with an Anti-IL 17A/F Nanobody". The second family is derived from International Patent Application PCT/IB2024/053796, published as WO2024/218708, and titled "Biomarker-Based Treatment and Diagnostic Methods for IL-17-Dependent Conditions". The third family consists of a provisional U.S. patent application, titled "Treatment and Diagnostic Methods for Pustular Non-Infectious Inflammatory Skin Conditions". The pending patent applications from these families, if issued, have expected expiry dates of no earlier than between 2043 and 2044, not including any patent term extensions and/or patent term adjustments.

The Merck Healthcare KGaA (Darmstadt, Germany) License Agreement

On April 29, 2021, we entered into a license agreement with MHKDG (the "License Agreement"). The License Agreement is a sublicense of a license agreement between MHKDG and Ablynx, dated September 3, 2008 (the "Initial License Agreement"), pursuant to which MHKDG developed SLK, and subsequently acquired exclusive right and title to SLK, including the right to further develop and commercialize (and grant sublicenses to further develop and commercialize) SLK. Pursuant to the License Agreement, we acquired (i) a royalty- and milestone-bearing exclusive

(even as to MHKDG), sublicensable right and license under MHKDG's controlled patents, materials, and exclusive know-how to develop, manufacture, use, sell, offer for sale, export and import and otherwise commercialize SLK on a world-wide basis, (ii) a royalty- and milestone-bearing non-exclusive, sublicensable, right and sublicense under Ablynx's and certain others' controlled patents, materials, and know-how to develop, manufacture, use, sell, offer for sale, export and import and otherwise commercialize SLK on a world-wide basis, in each case subject to certain restrictions and compliance with the terms and conditions of the Initial License Agreement; and (iii) a royalty- and milestone-bearing non-exclusive, sublicensable right and sublicense under Research Cooperation Technologies ("RCT") patents and know-how related to the manufacturing process using the underlying yeast strain Pichia pastoris, to develop, manufacture, use, sell, offer for sale, export and import and otherwise commercialize SLK on a world-wide basis, in each case subject to certain restrictions and compliance with the terms and conditions of the underlying license granted to MHKDG from RCT. Under the terms of the License Agreement, we have the first right to file, prosecute and maintain the licensed patents as well as the first right to attempt to resolve any third-party infringement.

The License Agreement includes a development plan, subject to specified periodic updates, which describes the plan for developing the licensed products in the initial target indications of HS and PsA, including the plan for conducting clinical trials to obtain regulatory approval in the major European markets, Japan, and the United States (the "Major Markets"). In accordance with the foregoing, we, among other requirements, are obligated to use commercially reasonable efforts to develop one licensed product in at least two indications, including initiating certain Phase 2 trials for the licensed product within a specified period following conclusion of the License Agreement, and launching and commercializing the same in each of the Major Markets within a certain period following receipt of regulatory approval in such respective markets.

The aggregate purchase price in respect of the License Agreement was $29.9 million and consisted of an upfront cash payment by us to MHKDG and an issuance of equity by us to MHKDG, representing a 9.9% ownership stake in our subsidiary, MoonLake Immunotherapeutics AG, a Swiss stock corporation (Aktiengesellschaft) registered with the commercial register of the Canton of Zug, Switzerland under the number CHE-433.093.536 ("MoonLake AG"), following such issuance. Subject to the terms of the License Agreement, milestone cash payments of up to EUR 299.6 million ($351.7 million using a December 31, 2025 exchange rate) are potentially payable, of which EUR 7.5 million ($8.1 million using the then applicable exchange rate) has been recognized as R&D expense to date. Future milestones will become payable upon regulatory filing acceptances in the US, in the European Union ("EU") and Japan, first commercial sales in these geographies, and meeting certain annual thresholds in global net sales. In addition, the License Agreement requires us to pay royalties within the range of low to mid-teen percent of net sales. Our obligation to pay royalties are on a licensed product-by-licensed product and country-by-country basis and continue from the date of first commercial sale of a licensed product in a country until the later of (i) ten years from such first commercial sale of such licensed product in such country or (ii) the expiration or invalidation of the last remaining valid claim of a licensed patent covering such licensed product.

Unless sooner terminated, the term of the License Agreement continues until the expiration of the last-to-expire royalty term. Either party may terminate the License Agreement due to a material breach by the other party (subject to a cure period). We may terminate the License Agreement (i) at our convenience upon 90 days' prior written notice to MHKDG following receipt by MHKDG of the required upfront payment or (ii) upon 90 days' prior written notice to MHKDG if we have reasonable belief that the medical risk/benefit of SLK is unfavorable in light of the welfare of patients and not suitable for further development or commercialization. Obligations accrued prior to termination, such as milestone payments, will persist.

Concurrently with the License Agreement, on April 29, 2021, we also executed a Side Letter to the License Agreement with MHKDG, which provides that upon the termination of the Initial License Agreement, under the terms of the Initial License Agreement, for any reason, the License Agreement will be automatically assigned to Ablynx. Upon assignment to Ablynx, any intellectual property licensed to us by MHKDG, and the obligations and liability associated therewith, under the License Agreement, shall continue, provided that the continuing obligations and liability of MHKDG under the License Agreement shall be limited to only that intellectual property owned or held by MHKDG following termination of the Initial License Agreement.

On May 12, 2023, we entered into an agreement with RCT and MHKDG, effective as of June 1, 2023, pursuant to which we were granted a royalty-bearing, nonexclusive, sublicensable right and license under RCT's patents and know-how related to a manufacturing process using an underlying yeast strain, Pichia pastoris, to develop, manufacture, use, sell, offer for sale, and import and otherwise commercialize SLK on a world-wide basis, subject to certain restrictions. This agreement replaces our sublicense for similar rights under the License Agreement with MHKDG.

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. Generally, before a new therapeutic product can be marketed, considerable data demonstrating a biological product candidate's quality, safety, purity and potency, or a small molecule drug candidate's quality, safety and efficacy, must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority. For biological product candidates, potency is similar to efficacy and is interpreted to mean the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended to effect a given result.

Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-marketing may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications from the sponsor, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on our company and our products or product candidates.

U.S. Biologics Regulation

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), the Public Health Service Act ("PHSA"), and other federal, state, local, and foreign statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative action and judicial sanctions. The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices ("GLP") regulation;
- submission to the FDA of an Investigational New Drug Application ("IND"), which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent institutional review board ("IRB"), or ethics committee at each clinical site before the trial is commenced;
- manufacture of the proposed biologic candidate in accordance with Current Good Manufacturing Practices ("cGMPs");
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice ("GCP") requirements to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA, after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMPs, and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of a BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning any clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol or protocols for preclinical studies and clinical trials. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls information, and any available human data or literature to support the use of the investigational product. In April 2025, the FDA published a roadmap to reduce animal testing in preclinical safety studies, including those required in INDs, with scientifically validated new approach methodologies. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

In addition to the IND submission process, supervision of human gene transfer trials includes evaluation and assessment by an institutional biosafety committee ("IBC"), a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment and such review may result in some delay before initiation of a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing preclinical studies and clinical trials and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1. The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2. The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible

adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3. The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain FDA regulatory requirements in order to use the study as support for an IND or application for marketing approval or licensure, including that the study was conducted in accordance with GCP, including review and approval by an independent ethics committee and use of proper procedures for obtaining informed consent from subjects, and the FDA is able to validate the data from the study through an onsite inspection if the FDA deems such inspection necessary. The GCP requirements encompass both ethical and data integrity standards for clinical studies.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of the product, or from a number of alternative sources, including studies initiated and sponsored by investigators. The submission of a BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

In addition, under the Pediatric Research Equity Act ("PREA"), a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The Food and Drug Administration Safety and Innovation Act requires that a sponsor who is planning to submit a marketing application for a biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial pediatric study plan within sixty days after an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted, except that the PREA will apply to an original BLA for a new active ingredient that is orphan-designated if the biologic is a molecularly targeted cancer product intended for the treatment of an adult cancer and is directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems

incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. Once a BLA has been accepted for filing, the FDA's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy ("REMS") to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and data demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for more frequent interactions with the review team during product

development and, once a BLA is submitted, the product may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA. We have received fast track designation for SLK for the treatment of moderate-to-severe PPP.

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022, the FDA may require, as appropriate, that such studies be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

In 2017, the FDA established a new regenerative medicine advanced therapy ("RMAT") designation as part of its implementation of the 21st Century Cures Act (the "Cures Act"). The RMAT designation program is intended to fulfill the Cures Act requirement that the FDA facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (i) the drug qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (ii) the drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (iii) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides all the benefits of breakthrough therapy designation, including more frequent meetings with the FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review.

Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. When appropriate, the FDA can permit fulfillment of post-approval requirements for an RMAT that has received accelerated approval through: the submission of clinical evidence, preclinical studies, clinical trials, patient registries or other sources of real world evidence such as electronic health records; the collection of larger confirmatory datasets; or post-approval monitoring of all patients treated with the therapy prior to approval.

A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible

for priority review if there is evidence it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Fast track designation, breakthrough therapy designation, RMAT designation and priority review do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act of 1983, the FDA may grant orphan drug designation to a product candidate intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or 200,000 or more individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that product candidate. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full BLA, to market the same product for the same approved use or indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or if the holder of the orphan drug exclusivity cannot assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the same use or indication for which the already-approved or licensed product was approved or licensed. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan drug designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

There is some uncertainty with respect to the FDA's interpretation of the scope of orphan drug exclusivity. Historically, exclusivity was specific to the orphan indication for which the drug was approved. As a result, the scope of exclusivity was interpreted as preventing approval of a competing product. However, in 2021, the federal court in Catalyst Pharmaceuticals, Inc. v. Becerra suggested that orphan drug exclusivity covers the full scope of the orphan-designated "disease or condition" regardless of whether a drug obtained approval for a narrower use.

Regulation of Diagnostic Tests

Our product candidates may require use of a diagnostic to identify appropriate patient populations for our product candidates. These diagnostics, often referred to as companion diagnostics, are medical devices, often in vitro devices, which provide information that is essential for the safe and effective use of a corresponding drug. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or

approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval ("PMA"). We expect that any companion diagnostic developed for our drug candidates will utilize the PMA pathway.

PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA application typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality Management System Regulation, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. FDA review of an initial PMA may require several years to complete. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

On August 6, 2014, the FDA issued a final guidance document addressing the development and approval process for "In Vitro Companion Diagnostic Devices." According to the guidance, for novel drugs such as our product candidates, a companion diagnostic device and its corresponding drug or biologic should be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product labeling. The guidance also explains that a companion diagnostic device used to make treatment decisions in clinical trials of a drug generally will be considered an investigational device, unless it is employed for an intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the diagnostic device generally will be considered a significant risk device under the FDA's Investigational Device Exemption ("IDE") regulations. Thus, the sponsor of the diagnostic device will be required to comply with the IDE regulations. According to the guidance, if a diagnostic device and a drug or biologic are to be studied together to support their respective approvals, both products can be studied in the same investigational study, if the study meets both the requirements of the IDE regulations and the IND regulations. The guidance provides that depending on the details of the study plan and subjects, a sponsor may seek to submit an IND alone, or both an IND and an IDE.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. After a BLA is approved for a biological product, the product also may be subject to official lot release. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, and potency or effectiveness of biologics. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the

manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The Affordable Care Act ("ACA") includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are highly similar, or "biosimilar", to or interchangeable with an FDA-approved reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, is generally shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. A product shown to be biosimilar or interchangeable with an FDA-approved reference biological product may rely in part on the FDA's previous determination of safety and effectiveness for the reference product for approval, which can potentially reduce the cost and time required to obtain approval to market the product. Complexities associated with the larger, and often more

complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

The FDA has issued guidance documents intended to inform prospective applicants and facilitate the development of proposed biosimilars and interchangeable biosimilars, as well as to describe the FDA's interpretation of certain statutory requirements added by the BPCIA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitted under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. On December 20, 2020, Congress amended the PHSA as part of the COVID-19 relief bill to further simplify the biosimilar review process by making it optional to show that conditions of use proposed in labeling have been previously approved for the reference product, which used to be a requirement of the application. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty. As discussed below, the Inflation Reduction Act of 2022 ("IRA") is a significant new law that intends to foster generic and biosimilar competition and to lower drug and biologic costs.

Patent Term Extension

In the United States, after a BLA is approved, owners of relevant drug patents may apply for up to a five-year patent extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory process. The allowable patent term extension is typically calculated as one-half the time between, the latter of the effective date of an IND and issue date of the patent for which extension is sought, and the submission date of a BLA, plus the time between BLA submission date and the BLA approval date up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue licensure with due diligence. The total patent term after the extension may not exceed 14 years from the date of product licensure. Only one patent applicable to a licensed biological product is eligible for extension and only those claims covering the product, a method for using it, or a method for manufacturing it may be extended and the application for the extension must be submitted prior to the expiration of the patent in question. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements.

Some, but not all, foreign jurisdictions possess patent term extension or other additional patent exclusivity mechanisms that may be more or less stringent and comprehensive than those of the United States.

Other Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation: the federal Anti-Kickback Statute ("AKS"); the federal False Claims Act ("FCA"); the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and similar foreign, federal and state fraud, abuse and transparency laws.

The AKS prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under any federal healthcare program. The term remuneration has been interpreted broadly to include anything of value. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand, and prescribers and purchasers on the other. The government often takes the position that to violate the AKS, only one purpose of the remuneration need be to induce referrals, even if there are other legitimate purposes for the remuneration. There are a number of statutory exceptions and regulatory safe harbors protecting some common commercial activities from AKS prosecution, but they are drawn narrowly and practices that involve remuneration, such as consulting agreements, for persons in a position to refer or recommend federally reimbursable healthcare business may be alleged to be intended to induce prescribing, purchasing or recommending, and may be subject to scrutiny if they do not qualify for an exception or regulatory safe harbor. Qualifying for a statutory exception or regulatory safe harbor requires satisfying all of the criteria for the exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS, but it does increase the risk of regulatory scrutiny. Ultimately, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The FCA, which can be enforced through civil whistleblower or qui tam actions, prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment of federal government funds, including in federal healthcare programs, that are false or fraudulent. Pharmaceutical and other healthcare companies have been prosecuted under these laws for engaging in a variety of different types of conduct that caused the submission of false claims to federal healthcare programs. Under the AKS, for example, a claim resulting from a violation of the AKS is deemed to be a false or fraudulent claim for purposes of the FCA.

HIPAA created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program, including private third-party payors, and making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate the statute in order to have committed a violation.

The FDCA addresses, among other things, the design, production, labeling, promotion, manufacturing, and testing of drugs, biologics and medical devices, and prohibits such acts as the introduction into interstate commerce of adulterated or misbranded drugs or devices. The PHSA also prohibits the introduction into interstate commerce of unlicensed or mislabeled biological products.

The U.S. federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to the Centers for Medicaid & Medicare Services ("CMS") information related to payments or other transfers of value to various healthcare professionals including physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse-midwives, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family

members. Beginning on January 1, 2023, California Assembly Bill 1278 requires California physicians and surgeons to notify patients of the Open Payments database established under the federal Physician Payments Sunshine Act.

We are also subject to federal price reporting laws and federal consumer protection and unfair competition laws. Federal price reporting laws require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/ or discounts on approved products. Federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.

We are also subject to additional similar U.S. state and foreign law equivalents of each of the above federal laws, which, in some cases, differ from each other in significant ways, and may not have the same effect, thus complicating compliance efforts. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations.

Data Privacy and Security

Numerous state, federal, and foreign laws govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations, that govern the collection, use, disclosure, and protection of health-related and other personal information and could apply to our operations or the operations of our partners. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their respective implementing regulations impose data privacy, security, and breach notification obligations on certain health care providers, health plans, and health care clearinghouses, known as covered entities, as well as their business associates and their covered subcontractors that perform certain services that involve using, disclosing, creating, receiving, maintaining, or transmitting individually identifiable protected health information ("PHI") for or on behalf of such covered entities. These requirements imposed by HIPAA and HITECH on covered entities and business associates include entering into agreements that require business associates protect PHI provided by the covered entity against improper use or disclosure, among other things; following certain standards for the privacy of PHI, which limit the disclosure of a patient's past, present, or future physical or mental health or condition or information about a patient's receipt of health care if the information identifies, or could reasonably be used to identify, the individual; ensuring the confidentiality, integrity, and availability of all PHI created, received, maintained, or transmitted in electronic form, to identify and protect against reasonably anticipated threats or impermissible uses or disclosures to the security and integrity of such PHI; and reporting of breaches of PHI to individuals and regulators.

Entities that are found to be in violation of HIPAA may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. A covered entity or business associate is also liable for civil money penalties for a violation that is based on an act or omission of any of its agents, which may include a downstream business associate, as determined according to the federal common law of agency. HITECH also increased the civil and criminal penalties applicable to covered entities and business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. To the extent that we submit electronic healthcare claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and HITECH, payments to us may be delayed or denied.

In addition, state health information privacy laws, such as California's Confidentiality of Medical Information Act and Washington's My Health My Data Act, govern the privacy and security of health-related information, specifically, may apply even when HIPAA does not and impose additional requirements.

Even when HIPAA and state health information privacy laws do not apply, according to the FTC and state attorneys general, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act and state consumer protection laws.

In addition, certain state laws, such as the California Consumer Privacy Act of 2018 ("CCPA"), as amended by the California Privacy Rights Act of 2020, govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA in various ways. Numerous other states have passed similar laws, but many differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. The CCPA applies to personal data of consumers, business representatives, and employees, and imposes obligations on certain businesses that do business in California, including to provide specific disclosures in privacy notices, and affords rights to California residents in relation to their personal information. Health information falls under the CCPA's definition of personal information where it identifies, relates to, describes, or is reasonably capable of being associated with or could reasonably be linked, directly or indirectly, with a particular consumer or household and is included under a new category of personal information, "sensitive personal information," which is offered greater protection. The CCPA and numerous other comprehensive privacy laws that have passed or are being considered in other states, as well as at the federal and local levels, exempt PHI that is subject to HIPAA; and others exempt covered entities and business associates subject to HIPAA altogether, further complicating compliance efforts, and increasing legal risk and compliance costs for us and the third parties upon whom we rely.

Additionally, our use of artificial intelligence and machine learning may be subject to laws and evolving regulations regarding the use of artificial intelligence and machine learning, controlling for data bias, and antidiscrimination.

Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Coverage and Reimbursement

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow it to establish or maintain pricing sufficient to realize a sufficient return on its investment. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product, if approved, depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement, if any, for such product by third-party payors. Decisions regarding whether to cover any of our product candidates, if approved, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations.

As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance

that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- cost-effective; and
- neither experimental nor investigational.

Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Decreases in third-party reimbursement for any product or a decision by a third-party not to cover a product could reduce physician usage and patient demand for the product.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. The IRA provides CMS with significant new authorities intended to curb drug costs and to encourage market competition. For the first time, CMS will be able to directly negotiate prescription drug prices and to cap out-of-pocket costs. Each year, CMS will select and negotiate a preset number of high-spend drugs and biologics that are covered under Medicare Part B and Part D that do not have generic or biosimilar competition. On August 29, 2023, HHS announced the list of the first ten drugs subject to price negotiations. These price negotiations occurred in 2024. In January 2025, CMS announced a list of 15 additional Medicare Part D drugs that will be subject to price negotiations. The IRA also provides a new “inflation rebate” covering Medicare patients that took effect in 2023 and is intended to counter certain price increases in prescriptions drugs. The inflation rebate provision requires drug manufacturers to pay a rebate to the federal government if the price for a drug or biologic under Medicare Part B and Part D increases faster than the rate of inflation. To support biosimilar competition, beginning in October 2022, qualifying biosimilars may receive a Medicare Part B payment increase for a period of five years. Separately, if a biologic drug for which no biosimilar exists delays a biosimilar’s market entry beyond two years, CMS will be authorized to subject the biologics manufacturer to price negotiations intended to ensure fair competition. Notwithstanding these provisions, the IRA’s impact on commercialization and competition remains largely uncertain.

In addition, net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we may commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

Finally, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement

or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

The ACA, which was enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, the IRA, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program.

Other legislative changes have been proposed and adopted since the ACA was enacted, including automatic aggregate reductions of Medicare payments to providers of on average 2% per fiscal year as part of the federal budget sequestration under the Budget Control Act of 2011. These reductions went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect until 2032 unless additional action is taken by Congress. In addition, the Bipartisan Budget Act of 2018, among other things, amended the Medicare Act (as amended by the ACA) to increase the point-of-sale discounts that manufacturers must agree to offer under the Medicare Part D coverage discount program from 50% to 70% off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs being covered under Medicare Part D.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state measures designed to, among other things, reduce the cost of prescription drugs, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, in May 2019, CMS adopted a final rule allowing Medicare Advantage Plans the option to use step therapy for Part B drugs, permitting Medicare Part D plans to apply certain utilization controls to new starts of five of the six protected class drugs, and requiring the Explanation of Benefits for Part D beneficiaries to disclose drug price increases and lower cost therapeutic alternatives, which went into effect on January 1, 2021. In May 2025, the Trump Administration renewed the idea of international reference pricing through an executive order entitled "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients," which, among other things, directs the HHS and other agencies to communicate most-favored-nation price targets to pharmaceutical manufacturers to bring prices for U.S. patients in line with comparably developed nations and to facilitate direct-to-consumer purchasing programs. The HHS subsequently issued guidance indicating the MFN target

price will be the lowest price paid in an Organisation for Economic Co-operation and Development country with a gross domestic product ("GDP") per capita of at least 60% of the U.S. GDP per capital. In addition, in December 2025, CMS proposed new drug payment models to lower drug prices for Medicare beneficiaries; under the models, CMS would explore potential adjustments to Medicare drug inflation rebate calculations by comparison to international drug pricing information. It is currently unclear whether and to what extent these measures will be implemented and what impact any such implementation would have on our business.

Notwithstanding the IRA, continued legislative and enforcement interest exists in the United States with respect to specialty drug pricing practices. Specifically, we expect government authorities to continue pushing for transparency to drug pricing, reducing the cost of prescription drugs under Medicare, reviewing the relationship between pricing and manufacturer patient programs, and reforming government program reimbursement methodologies for drugs. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for its drugs or put pressure on its drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

Other Government Regulation Outside of the United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, research and development, clinical trials, testing, manufacturing, safety, efficacy, quality control, labeling, packaging, storage, record keeping, distribution, reporting, export and import, advertising, marketing and other promotional practices involving biological products as well as authorization, approval as well as post-approval monitoring and reporting of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials.

The requirements and process governing the conduct of clinical trials, including requirements to conduct additional clinical trials, product licensing, safety reporting, post-authorization requirements, marketing and promotion, interactions with healthcare professionals, pricing and reimbursement may vary widely from country to country. No action can be taken to market any product in a country until an appropriate approval application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product, which would make launch of such products commercially unfeasible in such countries.

Regulation in the European Union

European Data Laws

The processing of personal data, including health-related personal data in the European Economic Area ("EEA") is mainly governed by the provisions of the European General Data Protection Regulation (EU) 2016/679 ("GDPR"), and related data protection laws in individual EEA countries. In the United Kingdom ("UK"), the processing of personal data is mainly governed by the GDPR as incorporated into UK law pursuant to the European Union (Withdrawal) Act

2018 (the "UK GDPR"). The GDPR and UK GDPR impose a number of strict obligations and requirements for the processing, including collecting, analyzing and transferring, of personal data of individuals in the EEA or in the UK, in particular with respect to health data from clinical trials and adverse event reporting. The GDPR and UK GDPR include requirements relating to the legal basis of the processing (such as consent of the individuals to whom the personal data relates), the information provided to the individuals prior to processing their personal data, the personal data breaches which may have to be notified to the national data protection authorities and data subjects, the measures to be taken when engaging processors, and obligations relating to the security and confidentiality of the personal data. EEA countries may also impose additional requirements in relation to the processing of health, genetic and biometric data through their national legislation.

In addition, the GDPR imposes specific restrictions on the transfer of personal data to countries outside of the EEA that are not considered by the European Commission ("EC") to provide an adequate level of data protection. Appropriate safeguards are required to enable such transfers. Among the appropriate safeguards that can be used, the data exporter may use the standard contractual clauses ("SCCs"). When relying on the appropriate safeguards, data exporters, with the assistance of the data importers, are also required to conduct a transfer risk assessment to verify if anything in the law and/or practices of the third country may impinge on the effectiveness of the safeguards in the context of the transfer at stake and, if so, to identify and adopt supplementary measures that are necessary to bring the level of protection of the data transferred to the EU standard of essential equivalence. Where no supplementary measure is suitable, the data exporter should avoid, suspend or terminate the transfer. With regard to the transfer of data from the EEA to the United States, on July 10, 2023, the EC adopted its adequacy decision for the EU-US Data Privacy Framework. On the basis of the new adequacy decision, personal data can flow from the EEA to U.S. companies participating in the framework.

With regard to the transfer of data from the EEA to the UK, based on the EC's adequacy decision of June 28, 2021 and subsequent renewals, personal data may continue to flow freely from the EEA to the UK on the basis that the UK is deemed to provide an adequate level of data protection until December 27, 2031. The adequacy decisions will automatically expire unless renewed.

With respect to transfers from the UK to other countries, these transfers are also subject to specific transfer rules under the UK regime. These UK international transfer rules broadly mirror the EU GDPR rules.

On February 2, 2022, the UK Secretary of State laid before the UK Parliament the international data transfer agreement ("IDTA") and the international data transfer addendum to the EC's standard contractual clauses for international data transfers ("UK Addendum") and a document setting out transitional provisions. The IDTA and UK Addendum came into force on March 21, 2022 and are the primary UK-approved mechanisms for putting in place appropriate safeguards for UK restricted transfers, subject to transitional arrangements for legacy SCCs. Regarding transfers from the UK to the EEA, the UK Information Commissioner's Office ("ICO") guidance indicates that organizations do not need new arrangements. With regard to the transfer of personal data from the UK to the United States, the UK government has adopted an adequacy decision for the UK Extension to the EU-US Data Privacy Framework, the UK-US Data Bridge, which came into force on October 12, 2023. The UK-US Data Bridge recognizes the United States as offering an adequate level of data protection where the recipient is a U.S. organization certified to the EU-US Data Privacy Framework and participating in the UK Extension to the EU-US Data Privacy Framework.

Failure to comply with the requirements of the GDPR or UK GDPR and the related national data protection laws of the EEA countries may result in significant monetary fines for noncompliance of up to €20 million or £17.5 million (as applicable), 4% of the total worldwide annual turnover (for higher-tier infringements). This is enforced by ICO and is entirely separate from fines under EU GDPR. In addition, violations of national laws can trigger additional, administrative penalties, investigations, corrective orders, temporary or definitive bans, and, in some jurisdictions, a number of criminal offenses for organizations and, in certain cases, their directors and officers, as well as civil liability claims from individuals whose personal data was processed.

Data protection authorities from the different EEA countries may still implement certain variations, enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing personal data in the EEA.

Furthermore, there are specific requirements relating to processing health data from clinical trials, including public disclosure obligations provided in the EU Clinical Trials Regulation No. 536/2014 ("CTR"), EMA disclosure initiatives and voluntary commitments by industry. Failure to comply with these obligations could lead to government enforcement actions and significant penalties against us, harm to our reputation, and adversely impact our business and operating results.

Drug and Biologic Development Process

Regardless of where they are conducted, all clinical trials included in applications for marketing authorization ("MA") for human medicines in the EU/EEA must have been carried out in accordance with EU regulations. This means that clinical trials conducted in the EU/EEA have to comply with EU clinical trial legislation but also that clinical trials conducted outside the EU/EEA have to comply with ethical principles equivalent to those set out in the EEA, including adhering to international good clinical practice and the Declaration of Helsinki.

The conduct of clinical trials in the EU is governed by the CTR, which entered into force on January 31, 2022. The CTR replaced the Clinical Trials Directive 2001/20/EC ("Clinical Trials Directive") and introduced a complete overhaul of the existing regulation of clinical trials for medicinal products in the EU.

Under the CTR, a sponsor is able to submit a single application for approval of a clinical trial through a centralized EU clinical trials portal (the "CTIS"). One national regulatory authority (the reporting EU member state proposed by the applicant) will take the lead in validating and evaluating the application and will consult and coordinate with the other concerned EU member states. If an application is rejected, it may be amended and resubmitted through the EU clinical trials portal. If an approval is issued, the sponsor may start the clinical trial in all concerned member states. However, a concerned EU member state may in limited circumstances declare an "opt-out" from an approval and prevent the clinical trial from being conducted in such member state. The CTR also aims to streamline and simplify the rules on safety reporting, and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to the EU database, including a layperson's summary. Since January 31, 2023, submission of initial clinical trial applications via CTIS is mandatory and CTIS serves as the single entry point for submission of clinical trial-related information and data. As of January 31, 2025, all ongoing trials approved under the former Clinical Trials Directive need to comply with the CTR and have to be transitioned to CTIS.

Under the CTR, national laws, regulations, and the applicable GCP and GLP standards must also be respected during the conduct of the trials, including the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ("ICH") guidelines on Good Clinical Practice and the ethical principles that have their origin in the Declaration of Helsinki. Under the current regime, all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial must be reported to the National Competent Authority and to the Ethics Committees of the EU member state where they occur.

During the development of a medicinal product, the EMA and national regulators within the EU provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Committee for Medicinal Products for Human Use ("CHMP") on the recommendation of the Scientific Advice Working Party ("SAWP"). A fee is incurred with each scientific advice procedure, but is significantly reduced for designated orphan medicines. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future Marketing Authorization Application ("MAA") of the product concerned.

Drug Marketing Authorization

In the EEA, after completion of all required clinical testing, pharmaceutical products may only be placed on the market after obtaining an MA. To obtain an MA of a drug under EU regulatory systems, an applicant can submit an MAA through, amongst others, a centralized or decentralized procedure.

To be used or sold in the UK, a drug must have an effective MA granted by the Medicines and Healthcare Products Regulatory Agency ("MHRA") under the Human Medicines Regulations 2012 (SI 2012/1916), as amended. MA applications are submitted electronically via the MHRA Submissions Portal. Under the MHRA's national assessment procedure, the MHRA generally aims to reach a decision within 210 "clock-on" days, excluding any "clock-stops" while the applicant prepares responses to MHRA questions.

On August 30, 2023, the MHRA published detailed guidance on its recently announced new International Recognition Procedure ("IRP") for MAAs. The IRP applies since January 1, 2024, and replaces existing EU reliance procedures to apply for authorizations from seven international regulators (e.g. Health Canada, Swiss Medic, FDA, EMA, among others). The IRP allows medicinal products approved in other jurisdictions that meet certain criteria to undergo a fast-tracked MHRA review to obtain and/or update a MA in the UK. Applicants can submit initial MAAs to the IRP but the procedure can also be used throughout the lifecycle of a product for post-authorization procedures including line extensions, variations and renewals.

Centralized Authorization Procedure

The centralized procedure provides for the grant of a single MA that is issued by the EC following the scientific assessment of the application by the EMA that is valid for all EU member states as well as in the three additional EEA member states (Norway, Iceland, and Liechtenstein). The centralized procedure is compulsory for specific medicinal products, including for medicines developed by means of certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products (gene therapy, somatic cell therapy, or tissue engineered medicines) and medicinal products with a new active substance indicated for the treatment of certain diseases (HIV/AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune diseases and other immune dysfunctions, and viral diseases). For medicinal products containing a new active substance not yet authorized in the EEA before May 20, 2004 and indicated for the treatment of other diseases, medicinal products that constitute significant therapeutic, scientific or technical innovations or for which the grant of a MA through the centralized procedure would be in the interest of public health at EU level, an applicant may voluntarily submit an application for a MA through the centralized procedure.

Under the centralized procedure, the CHMP is responsible for conducting the initial assessment of a drug. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA. Under the centralized procedure, the timeframe for the evaluation of an MAA by the EMA's CHMP is, in principle, 210 days from receipt of a valid MAA. However, this timeline excludes clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP, so the overall process typically takes a year or more, unless the application is eligible for an accelerated assessment. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. Upon request, the CHMP can reduce the time frame to 150 days if the applicant provides sufficient justification for an accelerated assessment. The CHMP will provide a positive opinion regarding the application only if it meets certain quality, safety and efficacy requirements. This opinion is then transmitted to the EC, which has the ultimate authority for granting MA within 67 days after receipt of the CHMP opinion.

Decentralized Authorization Procedure

Medicines that fall outside the mandatory scope of the centralized procedure have three routes to authorization: (i) they can be authorized under the centralized procedure if they concern a significant therapeutic, scientific or technical innovation, or if their authorization would be in the interest of public health; (ii) they can be authorized under a decentralized procedure where an applicant applies for simultaneous authorization in more than one EU member state; or (iii) they can be authorized in an EU member state in accordance with that state's national procedures and then be authorized in other EU countries by a procedure whereby the countries concerned agree to recognize the validity of the original, national MA (mutual recognition procedure).

The decentralized procedure permits companies to file identical MA applications for a medicinal product to the competent authorities in various EU member states simultaneously if such medicinal product has not received marketing approval in any EU member state before. This procedure is available for pharmaceutical products not falling within the mandatory scope of the centralized procedure. The competent authority of a single EU member state, the reference member state, is appointed to review the application and provide an assessment report. The competent authorities of the other EU member states, the concerned member states, are subsequently required to grant a MA for their territories on the basis of this assessment. The only exception to this is where the competent authority of an EU member state considers that there are concerns of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the EC, whose decision is binding for all EU member states.

Risk Management Plan

All new MAAs must include a Risk Management Plan ("RMP") describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. RMPs are continually modified and updated throughout the lifetime of the medicine as new information becomes available. An updated RMP must be submitted: (i) at the request of EMA or a national competent authority, or (ii) whenever the risk-management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit-risk profile or as a result of an important pharmacovigilance or risk-minimization milestone being reached. The regulatory authorities may also impose specific obligations as a condition of the MA. Since October 20, 2023, all RMPs for centrally authorized products are published by the EMA, subject only to limited redactions.

MA Validity Period

MAs have an initial duration of five years. After these five years, the authorization may subsequently be renewed on the basis of a reevaluation of the risk-benefit balance. Once renewed, the MA is valid for an unlimited period unless the EC or the national competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with only one additional five-year renewal. Applications for renewal must be made to the EMA at least nine months before the five-year period expires.

Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid.

For the UK, the period of three years during which the drug has not been marketed in Great Britain will be restarted from the date of conversion to a Great Britain MA. Following Windsor Framework changes, which became effective January 1, 2025, European Commission Union authorizations are no longer valid in Northern Ireland and centrally authorized products are instead authorized by the MHRA under UK-wide marketing authorizations; existing licenses for product licensed by the MHRA that covers Great Britain only become geographically valid UK-wide while retaining their license number/prefix.

On the other hand, for the EU, in the case the drug has been marketed in the UK, the placing on the UK market before the end of the period starting when the UK left the EU on January 31, 2020 and ending on December 31, 2020 (the "Brexit Transition Period") will be taken into account. If, after the end of the Brexit Transition Period, the drug is not placed on any other market of the remaining member states of the EU, the three year period will start running from the last date the drug was placed on the UK market before the end of the Brexit Transition Period.

Advanced Therapy Medicinal Products

In the EU, medicinal products, including advanced therapy medicinal products ("ATMPs") are subject to extensive pre- and post-market regulation by regulatory authorities at both the EU and national levels. ATMPs comprise gene therapy products, somatic cell therapy products and tissue engineered products, which are genes, cells or tissues that have undergone substantial manipulation and that are administered to human beings in order to cure, diagnose or prevent diseases or regenerate, repair or replace a human tissue. Pursuant to Regulation (EC) No 1394/2007, the Committee for

Advanced Therapies ("CAT") is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CHMP and CAT are also responsible for providing guidelines on ATMPs. These guidelines provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, among other things, the preclinical studies required to characterize ATMPs. Although such guidelines are not legally binding, compliance with them is often necessary to gain and maintain approval for product candidates.

In addition to the mandatory RMP, the holder of a MA for an ATMP must put in place and maintain a system to ensure that each individual product and its starting and raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the relevant healthcare institution where the product is used.

Data and Market Exclusivity

As in the United States, it may be possible to obtain a period of market and / or data exclusivity in the EU that would have the effect of postponing the entry into the marketplace of a competitor's generic, hybrid or biosimilar product (even if the pharmaceutical product has already received a MA) and prohibiting another applicant from relying on the MA holder's pharmacological, toxicological and clinical data in support of another MA for the purposes of submitting an application, obtaining MA or placing the product on the market. Innovative medicinal products, referred to as New Chemical Entities ("NCEs") approved in the EU qualify for eight years of data exclusivity and 10 years of marketing exclusivity.

An additional non-cumulative one-year period of marketing exclusivity is possible if during the data exclusivity period (the first eight years of the 10-year marketing exclusivity period), the MA holder obtains an authorization for one or more new therapeutic indications that are deemed to bring a significant clinical benefit compared to existing therapies.

The data exclusivity period begins on the date of the product's first MA in the EU. After eight years, a generic product application may be submitted, and generic companies may rely on the MA holder's data. However, a generic product cannot launch until two years later (or a total of 10 years after the first MA in the EU of the innovator product), or three years later (or a total of 11 years after the first MA in the EU of the innovator product) if the MA holder obtains MA for a new indication with significant clinical benefit within the eight-year data exclusivity period. Additionally, another noncumulative one-year period of data exclusivity can be added to the eight years of data exclusivity where an application is made for a new indication for a well-established substance, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication. Another year of data exclusivity may be added to the eight years, where a change of classification of a pharmaceutical product has been authorized on the basis of significant pre-trial tests or clinical trials (when examining an application by another applicant for or holder of market authorization for a change of classification of the same substance the competent authority will not refer to the results of those tests or trials for one year after the initial change was authorized).

Products may not be granted data exclusivity since there is no guarantee that a product will be considered by the EU's regulatory authorities to include a NCE. Even if a compound is considered to be a NCE and the MA applicant is able to gain the prescribed period of data exclusivity, another company nevertheless could also market another version of the medicinal product if such company can complete a full MAA with their own complete database of pharmaceutical tests, preclinical studies and clinical trials and obtain MA of its product.

On April 26, 2023, the EC submitted a proposal for the reform of the European pharmaceutical legislation and negotiations are still ongoing. The timing for finalization of these negotiations and entry into force are unclear.

The current drafts envisage:

- a shortening of the periods of data exclusivity from eight to six years (with transferrable vouchers for an additional year of market protection as an incentive for the development of new antibiotics),

- earlier regulatory guidance and extension of market exclusivity for orphan medicines (depending on certain conditions),
- four-year data exclusivity for additional indications of existing products, and
- rules governing the availability of products (including shortage prevention plans and some supply obligations for manufacturers).

Orphan Designation and Exclusivity

The criteria for designating an orphan medicinal product in the EU are similar in principle to those in the United States. The EMA grants orphan drug designation if the medicinal product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the EU (prevalence criterion). In addition, orphan drug designation can be granted if, for economic reasons, the medicinal product would be unlikely to be developed without incentives and if there is no other satisfactory method approved in the EU of diagnosing, preventing, or treating the condition, or if such a method exists, the proposed medicinal product is a significant benefit to patients affected by the condition. An application for orphan drug designation (which is not a MA, as not all orphan-designated medicines reach the authorization application stage) must be submitted first before an application for MA of the medicinal product is submitted. The applicant will receive a fee reduction for the MAA if the orphan drug designation has been granted, but not if the designation is still pending at the time the MA is submitted, and sponsors must submit an annual report to EMA summarizing the status of development of the medicine. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Designated orphan medicines are eligible for conditional MA.

The EMA's Committee for Orphan Medicinal Products ("COMP") reassesses the orphan drug designation of a product in parallel with the review for a MA; for a product to benefit from market exclusivity it must maintain its orphan drug designation at the time of MA review by the EMA and approval by the EC. Additionally, any MA granted for an orphan medicinal product must only cover the therapeutic indication(s) that are covered by the orphan drug designation. Upon the grant of a MA, orphan drug designation provides up to ten years of market exclusivity in the orphan indication.

During the 10-year period of market exclusivity, with a limited number of exceptions, the regulatory authorities of the EU member states and the EMA may not accept applications for MA, accept an application to extend an existing MA or grant a MA for other similar medicinal products for the same therapeutic indication. A similar medicinal product is defined as a medicinal product containing a similar active substance or substances as contained in a currently authorized orphan medicinal product, and which is intended for the same therapeutic indication. An orphan medicinal product can also obtain an additional two years of market exclusivity for an orphan-designated condition when the results of specific studies are reflected in the Summary of Product Characteristics ("SmPC") addressing the pediatric population and completed in accordance with a fully compliant Pediatric Investigation Plan ("PIP"). No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, i.e. the condition prevalence or financial returns criteria under Article 3 of Regulation (EC) No. 141/2000 on orphan medicinal products. When the period of orphan market exclusivity for an indication ends, the orphan drug designation for that indication expires as well. Orphan exclusivity runs in parallel with normal rules on data exclusivity and market protection. Additionally, a MA may be granted to a similar medicinal product (orphan or not) for the same or overlapping indication subject to certain requirements.

In the UK, following the post-Brexit transition period, a system for incentivizing the development of orphan medicines was introduced. Overall, the requirements for orphan designation largely replicate the requirements in the EU and the benefit of market exclusivity has been retained. Products with an orphan designation in the EU can be considered for an orphan MA in Great Britain, and marketing authorizations granted for products that fulfil UK orphan criteria are valid UK-wide regardless of whether there is an EU orphan designation. The MHRA will review applications for orphan designation at the time of a MA, and will offer incentives, such as market exclusivity and full or partial refunds for MA

fees to encourage the development of medicines in rare diseases. Separately, the MHRA has stated that it is considering updating its licensing framework for orphan medicines, with a draft framework expected by spring 2026.

Pediatric Development

In the EU, companies developing a new medicinal product are obligated to study their product in children and must therefore submit a PIP, together with a request for agreement to the EMA. The EMA issues a decision on the PIP based on an opinion of the EMA's Pediatric Committee. Companies must conduct pediatric clinical trials in accordance with the PIP approved by the EMA, unless a deferral (e.g. until enough information to demonstrate its effectiveness and safety in adults is available) or waiver (e.g. because the relevant disease or condition occurs only in adults) has been granted by the EMA. The MAA for the medicinal product must include the results of all pediatric clinical trials performed and details of all information collected in compliance with the approved PIP, unless a waiver or a deferral has been granted, in which case the pediatric clinical trials may be completed at a later date. Medicinal products that are granted a MA on the basis of the pediatric clinical trials conducted in accordance with the approved PIP are eligible for a six month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) or, in the case of orphan medicinal products, a two year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the approved PIP are developed and submitted. An approved PIP is also required when a MA holder wants to add a new indication, medicinal form or route of administration for a medicine that is already authorized and covered by intellectual property rights.

In the UK, the MHRA has published guidance on the procedures for UK Paediatric Investigation Plans which, where possible, mirror the submission format and requirements of the EU system. From January 1, 2025, EU pediatric requirements are addressed via Windsor Framework categorization: for Category 2 products, both UK and EU pediatric requirements apply, and an EU-agreed PIP must also be in place (unless waived).

PRIME Designation

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The Priority Medicines ("PRIME") scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from small-and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies on the basis of compelling non-clinical data and tolerability data from initial clinical trials. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted. Importantly, once a candidate medicine has been selected for the PRIME scheme, a dedicated contact point and rapporteur from the CHMP or from CAT are appointed facilitating increased understanding of the product at EMA's Committee level. A kick-off meeting with the CHMP/CAT rapporteur initiates these relationships and includes a team of multidisciplinary experts to provide guidance on the overall development plan and regulatory strategy. PRIME eligibility does not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or approval.

Post-Approval Regulation

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the EC and/or the competent regulatory authorities of the EU member states. This oversight applies both before and after grant of manufacturing licenses and MAs. It includes control of compliance with EU good manufacturing practices rules, manufacturing authorizations, pharmacovigilance rules and requirements governing advertising, promotion, sale, and distribution, recordkeeping, importing and exporting of medicinal products.

Failure by us or by any of our third-party partners, including suppliers, manufacturers and distributors to comply with EU laws and the related national laws of individual EU member states governing the conduct of clinical trials,

manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of MA, statutory health insurance, bribery and anti-corruption or other applicable regulatory requirements may result in administrative, civil or criminal penalties.

These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The holder of a MA for a medicinal product must also comply with EU pharmacovigilance legislation and its related regulations and guidelines, which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of medicinal products.

These pharmacovigilance rules can impose on holders of MAs the obligation to conduct a labor intensive collection of data regarding the risks and benefits of marketed medicinal products and to engage in ongoing assessments of those risks and benefits, including the possible requirement to conduct additional clinical studies or post-authorization safety studies to obtain further information on a medicine's safety, or to measure the effectiveness of risk-management measures, which may be time consuming and expensive and could impact our profitability. MA holders must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of Periodic Safety Update Reports ("PSURs"), in relation to medicinal products for which they hold MAs. The EMA reviews PSURs for medicinal products authorized through the centralized procedure. If the EMA has concerns that the risk benefit profile of a product has varied, it can adopt an opinion advising that the existing MA for the product be suspended, withdrawn or varied. The agency can advise that the MA holder be obliged to conduct post-authorization Phase IV safety studies. If the EC agrees with the opinion, it can adopt a decision varying the existing MA. Failure by the MA holder to fulfill the obligations for which the EC's decision provides can undermine the ongoing validity of the MA.

More generally, non-compliance with pharmacovigilance obligations can lead to the variation, suspension or withdrawal of the MA for the product or imposition of financial penalties or other enforcement measures.

The manufacturing process for pharmaceutical products in the EU is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations.

Manufacturing requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC (repealed by Directive 2017/1572 on January 31, 2022), Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice ("GMP"). These requirements include compliance with EU GMP standards when manufacturing pharmaceutical products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the EU with the intention to import the active pharmaceutical ingredients into the EU. Amendments or replacements of at least Directive 2001/83/EC and Regulation (EC) No 726/2004 are part of the reform proposal for European pharmaceutical legislation. Similarly, the distribution of pharmaceutical products into and within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU member states. The manufacturer or importer must have a qualified person who is responsible for certifying that each batch of product has been manufactured in accordance with GMP, before releasing the product for commercial distribution in the EU or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with GMP.

On October 27, 2025, the Council of the European Union approved a framework for compulsory licensing of crisis-relevant products (including medicinal products) in crisis situations. While the proposal focuses on voluntary agreements with intellectual property rights holders, it includes rules on compulsory licensing as a measure of last resort upon activation / declaration of a crisis or emergency mode. The European Parliament has not yet voted on the proposal.

Sales and Marketing Regulations

The advertising and promotion of our products is also subject to EU laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, other national legislation of individual EU member states may apply to the advertising and promotion of medicinal products and may differ from one country to another. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's SmPC as approved by the competent regulatory authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. It forms an intrinsic and integral part of the MA granted for the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion. All advertising and promotional activities for the product must be consistent with the approved SmPC and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription-only medicines is also prohibited in the EU. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on its promotional activities with healthcare professionals. EU regulation with regards to dispensing, sale and purchase of medicines has generally been preserved in the UK following Brexit, through the Human Medicines Regulations. However, organizations wishing to sell medicines online need to register with the MHRA. Following Brexit, the requirements to display the common logo no longer apply to UK-based online sellers, except for those established in Northern Ireland.

Anti-Corruption Legislation

In the EU, interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct both at EU level and in the individual EU member states. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the EU member states. Violation of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU member states also must be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her regulatory professional organization, and/or the competent authorities of the individual EU member states. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the individual EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. In the UK, the pharmaceutical sector is recognized as being particularly vulnerable to corrupt practices, some of which fall within the scope of the Bribery Act 2010. Due to the Bribery Act 2010's far-reaching territorial application, the potential penalized act does not have to occur in the UK to become within its scope. If the act or omission does not take place in the UK, but the person's act or omission would constitute an offense if carried out there and the person has a close connection with the UK, an offense will still have been committed. The Bribery Act 2010 is comprised of four offenses that cover (i) individuals, companies and partnerships that give, promise or offer bribes, (ii) individuals, companies and partnerships that request, agree to receive or accept bribes,(iii) individuals, companies and partnerships that bribe foreign public officials and (iv) companies and partnerships that fail to prevent persons acting on their behalf from paying bribes. The penalties imposed under the Bribery Act 2010 depend on the offence committed, harm and culpability and penalties range from unlimited fines to imprisonment for a maximum term of ten years and in some cases both.

Regulations in the UK and Other Markets

The UK formally left the EU on January 31, 2020 and EU laws now only apply to the UK in respect of Northern Ireland as laid out in the protocol on Ireland and Northern Ireland and as amended by the Windsor Framework sets out a long-term set of arrangements for the supply of medicines into Northern Ireland.

The EU and the UK agreed on a trade and cooperation agreement ("TCA"), which includes provisions affecting the life sciences sector (including on customs and tariffs). There are some specific provisions concerning pharmaceuticals, including the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP issued documents. The TCA does not, however, contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards.

The UK government has adopted the Medicines and Medical Devices Act 2021 (the "MMDA") to enable the UK's regulatory frameworks to be updated following the UK's departure from the EU. The MMDA introduces regulation-making, delegated powers covering the fields of human medicines, clinical trials of human medicines, veterinary medicines and medical devices. The MHRA has since been consulting on future regulations for medicines and medical devices in the UK.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Additional Regulation

In addition to the foregoing, local, state and federal laws, including in the United States and Israel, regarding such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous or biohazardous substances, we could be liable for damages, environmental remediation, and/or governmental fines. We believe that we are in material compliance with applicable environmental laws and occupational health and safety laws that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations. We may incur significant costs to comply with such laws and regulations now or in the future.

Human Capital

Our Employees

We have grown to a team of approximately 130 employees as of December 31, 2025. Our employees are based in the following countries: Switzerland, the United Kingdom, Portugal and Belgium. Our highly qualified and experienced team includes scientists, physicians and professionals across clinical development, regulatory affairs, manufacturing, medical affairs, commercialization, finance and other important functions that are critical to our success. We also leverage certain external experts in drug development and corporate functions to provide flexibility for our business needs.

We expect to continue to hire additional employees in 2026 and beyond to expand our expertise and bandwidth across functions. We expect to establish a presence in the United States in 2026. We continue to evaluate our business needs and opportunities.

Our Culture

We believe that the success of our human capital management investments is evidenced by our low employee turnover, a metric which is regularly reviewed by our board of directors (the "Board of Directors") as part of its oversight of our human capital strategy.

Employee Engagement, *Talent Development & Benefits*.

We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees. We provide our employees with competitive salaries, bonuses, and opportunities for equity ownership.

Employee and Visitor Safety Protocols

We strive to follow applicable health and safety guidelines to protect the well-being of our employees and visitors.

Inclusion

Much of our success is rooted in our commitment to inclusion and equal employment opportunity. We value diversity at all levels. We believe that our business benefits from the different perspectives a diverse workforce brings, and we pride ourselves on having a strong, inclusive and positive culture based on our shared mission and values.

Our Corporate Information

We are a Cayman Islands exempted company and were originally incorporated on August 13, 2020 as a special purpose acquisition company under the name Helix Acquisition Corp., formed for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses. On April 5, 2022, we consummated such business combination with MoonLake Immunotherapeutics AG ("MoonLake AG"), a stock-based company incorporated in Switzerland in 2021, pursuant to that certain business combination agreement, dated October 4, 2021 (the "Business Combination Agreement"), by and among Helix, MoonLake AG, the existing equityholders of MoonLake AG set forth on the signature pages to the Business Combination Agreement and the equityholders of MoonLake AG that executed joinders to the Business Combination Agreement (collectively, the "ML Parties"), Helix Holdings LLC, a Cayman Islands limited liability company and the sponsor of Helix, and the representative of the ML Parties (such transactions contemplated by the Business Combination Agreement, collectively, the "Business Combination"). Pursuant to the Business Combination Agreement, MoonLake AG merged with and into Helix, with MoonLake AG as the surviving company in the Business Combination and, after giving effect to such Business Combination, MoonLake AG became our subsidiary. In connection with the consummation of the Business Combination, we changed our name from Helix Acquisition Corp. to MoonLake Immunotherapeutics. The Business Combination was accounted for as a reverse recapitalization, in accordance with accounting principles generally accepted in the United States of America ("US GAAP"). Our principal executive office is located in Dorfstrasse 29, 6300, Zug, Switzerland.

Available Information

Our website address is www.moonlaketx.com. The contents of, or information accessible through, our website are not part of this Annual Report on Form 10-K. We make our filings with the SEC, including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports, available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the SEC. The reference to our website address does not constitute incorporation by reference of the information contained on or available through our website, and you should not consider such information to be a part of this Annual Report on Form 10-K.

PART I

Item 1A. Risk Factors

You should carefully consider the risks described below, as well as general economic and business risks and the other information in this Annual Report on Form 10-K. The occurrence of any of the events or circumstances described below or other adverse events could have a material adverse effect on our business, results of operations and financial condition and could cause the trading price of our common stock to decline. Additional risks or uncertainties not presently known to us or that we currently deem immaterial may also harm our business. Moreover, some of the factors, events and contingencies discussed below may have occurred in the past, but the disclosures below are not representations as to whether or not the factors, events or contingencies have occurred in the past and instead reflect our beliefs and opinions as to the factors, events, or contingencies that could materially and adversely affect us in the future.

Summary of Risk Factors

Investing in our common stock involves significant risks. You should carefully consider the risks described below before making a decision to invest in our common stock. If we are unable to successfully address these risks and challenges, our business, financial condition, results of operations, or prospects could be materially adversely affected. In such case, the trading price of our common stock would likely decline, and you may lose all or part of your investment. Below is a summary of some of the risks we face.

- We are substantially dependent on the success of SLK, and our ongoing and anticipated clinical trials of SLK may not be successful.
- Our business relies on certain licensing rights from MHKDG and RCT that can be terminated in certain circumstances. If we breach those agreements, or if we are unable to satisfy our diligence obligations under which we license rights to SLK from MHKDG, we could lose the ability to develop and commercialize SLK.
- We have incurred losses since inception, and we expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. We have not generated any revenue from SLK and may never generate revenue or become profitable.
- We have a limited operating history and have no products approved for commercial sale.
- We have never successfully completed the regulatory approval process for any of our product candidates and we may be unable to do so for any product candidates we acquire or develop.
- The results of preclinical testing and early clinical trials may not be predictive of the success of our later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA, or other comparable foreign regulatory authorities.
- Preclinical and clinical development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results.
- Preliminary, interim data from our clinical trials that we announce or publish may change as more patient data become available and are subject to audit and verification procedures.
- We may find it difficult to enroll patients in our clinical trials. If we experience delays or difficulties in the enrollment of patients in clinical trials, our successful completion of clinical trials or receipt of marketing approvals could be delayed or prevented.
- We face substantial competition, which may result in others discovering, developing, licensing or commercializing products before or more successfully than we do.
- SLK may have a safety profile that could prevent regulatory approval, marketing approval or market acceptance, or limit its commercial potential.
- If we are unable to raise capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our development programs or future commercialization efforts, which would have a negative impact on our business, prospects, operating results, and financial condition.
- We currently rely on third parties to produce and process SLK. Our business could be adversely affected if the third-party manufacturers fail to provide us with sufficient quantities of SLK or fail to do so at acceptable quality levels or prices.
- Our ability to protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage.

- Geopolitical events and global economic conditions, such as public health crises, the conflicts between Russia and Ukraine and in the Middle East, could seriously and adversely affect our preclinical studies and ongoing and anticipated clinical trials, business, financial condition and results of operations.

Risks Related to Our Limited Operating History, Business, Financial Condition, and Results of Operations

We have a limited operating history and have no products approved for commercial sale.

We are a clinical-stage company with limited operating history. To become and remain profitable, we must develop and eventually commercialize a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including establishing our business model and key third-party relationships with payors, completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing, selling those products for which we may obtain marketing approval and satisfying any post-marketing requirements.

Additional capital may not be available in sufficient amounts or on reasonable terms, if at all. The current market environment for small and midcap biotechnology companies like MoonLake, and broader macroeconomic factors may preclude us from successfully raising additional capital. For example, escalating trade tensions, elevated interest rates and regulatory uncertainty have caused significant market volatility in recent months, and particularly in the biotechnology and biopharmaceutical industries, which such volatility can have an adverse effect on the ability to raise capital.

We have no products approved for commercial sale and, since our inception, we have been incurring significant operating losses, and expect to incur significant losses in the foreseeable future. As with any clinical development, we cannot be certain that our planned clinical trials will begin or be completed on time or at all. In addition, we have not yet demonstrated an ability to obtain marketing approvals, manufacture a commercial-scale product or arrange for a third-party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete our ongoing and planned non-clinical and clinical studies for SLK;
- timely file and gain acceptance of IND applications for our programs in order to commence planned clinical trials or future clinical trials;
- successfully enroll subjects in, and complete, our ongoing and planned clinical trials;
- obtain data related to SLK and generated prior to the License Agreement, but not transferred from MHKDG, which may delay our development and commercialization;
- initiate and successfully complete all safety and efficacy studies required to obtain U.S. and foreign regulatory approval for our product candidates, and additional clinical trials or other studies beyond those planned to support the approval and commercialization of SLK;
- successfully demonstrate to the satisfaction of the FDA, EMA, or similar foreign regulatory authorities the safety and efficacy and acceptable risk to benefit profile of SLK or any future SLK product candidates;
- successfully manage the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates, if any;
- obtain the timely receipt of necessary marketing approvals from the FDA, EMA and similar foreign regulatory authorities;
- establish commercial manufacturing capabilities or make arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- obtain and maintain patent and trade secret protection or regulatory exclusivity for our product candidates;
- launch commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- obtain and maintain acceptance of the products, if and when approved, by patients, the medical community and third-party payors;
- position our product conducts to effectively compete with other therapies;
- obtain and maintain healthcare coverage and adequate reimbursement for our products;
- enforce and defend intellectual property rights and claims; and

- maintain a continued acceptable safety profile of SLK following approval.

Due to the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues, the extent of any further losses or if or when we might achieve profitability. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history. We may never succeed in these activities and, even if we succeed in commercializing SLK, we may never generate revenue that is significant enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we may continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure to become and remain profitable could decrease the value of our shares and impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. Further, we may encounter unexpected expenses, challenges and complications from known and unknown factors.

We have incurred losses since inception, and we expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. We have not generated any revenue from SLK and may never generate revenue or become profitable.

Investment in biopharmaceutical product development is a highly speculative undertaking and entails substantial upfront capital expenditures and risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale, we have not generated any revenue from product sales to date, and we continue to incur research and development and other expenses related to our ongoing operations. We do not expect to generate product revenue unless or until we successfully complete clinical development and obtain regulatory approval from the FDA, EMA and similar foreign regulatory authorities of, and then successfully commercialize, SLK in one or more indications. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. If we are unable to generate sufficient revenue through the sale of SLK, we may be unable to continue operations without additional funding.

We have incurred net losses in each period since we commenced operations in 2021. Our net losses were $230.3 million for the year ended December 31, 2025. We expect to continue to incur significant losses for the foreseeable future. Our failure to become profitable would decrease the value of our Company and could impair our ability to raise capital, maintain our research and development efforts, expand our business and/or continue our operations. A decline in the value of our Company could also cause you to lose all or part of your investment.

If we are unable to raise capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our development programs or future commercialization efforts, which would have a negative impact on our business, prospects, operating results and financial condition.

Developing biopharmaceutical products is a very long, time-consuming, expensive and uncertain process that takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval from the FDA, EMA, and similar foreign regulatory authorities for, SLK. Even if SLK is approved for commercial sale, we anticipate incurring costs associated with sales, marketing, manufacturing and distribution activities to launch SLK. Our expenses could increase beyond expectations if we are required by the FDA, EMA, or other regulatory agencies to perform preclinical studies or clinical trials in addition to those that we currently anticipate. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of funding that will be necessary to successfully complete the development and commercialization of SLK. Our future capital requirements depend on many factors, including factors that are not within our control. Based on our current operating plan, we believe our existing cash, cash equivalents and short-term marketable securities, will be sufficient to fund our operations into the second half of 2027. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

Other than the Loan and Security Agreement (as defined below), we do not have any committed external sources of funds and adequate additional financing may not be available to us on acceptable terms, or at all. We may be required to seek additional funds sooner than planned through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Such financing may dilute our shareholders or the failure to obtain such financing may restrict

our operating activities. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences and anti-dilution protections that adversely affect your rights as a shareholder. Debt financing may result in the imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through upfront payments or milestone payments pursuant to future collaborations with third parties, we may have to relinquish valuable rights to SLK, or grant licenses on terms that are not favorable to us. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide, including resulting from public health crises, the conflict between Russia and Ukraine or the conflicts in the Middle East. If our costs, in particular costs related to clinical development, manufacture and supply, were to become subject to significant inflationary pressures, it may adversely impact our business, operating results and financial condition. Our failure to raise capital as and when needed or on acceptable terms has in the past had, and in the future may have, a negative impact on our financial condition and our ability to pursue our business strategy, and we have in the past had to, and in the future may have to, delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

In our own required quarterly assessments, we may conclude that there is substantial doubt about our ability to continue as a going concern, and future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

Our business relies on certain licensing rights from MHKDG and RCT that can be terminated in certain circumstances. If we breach those agreements, or if we are unable to satisfy our diligence obligations under which we license rights to SLK from MHKDG, we could lose the ability to develop and commercialize SLK.

Our ability to continue to develop and commercialize SLK is dependent on the use of certain intellectual property that is licensed to us by MHKDG and RCT. These licenses are granted pursuant to agreements setting forth certain terms and condition for maintaining such licenses. In the event that the terms and conditions are not met, the licenses are at risk of being revoked and the granting process may be terminated. Our primary license agreement is the License Agreement. See "*Business — The Merck Healthcare KGaA (Darmstadt, Germany) License Agreement*".

On April 29, 2021, we entered into the License Agreement, a worldwide exclusive license agreement with MHKDG, for certain intellectual property covering SLK and to sublicense certain rights licensed to MHKDG to (i) develop and commercialize products containing SLK; and (ii) manufacture SLK using the underlying yeast strain Pichia pastoris. If there is any dispute between us and MHKDG regarding our rights under the License Agreement, including if we disagree with MHKDG's comments to our development plan for SLK or if we are unable to make our milestone obligations, our ability to develop and commercialize SLK may be adversely affected. Any uncured, material breach by us under the License Agreement could result in our loss of exclusive rights to SLK and may lead to a complete termination of our product development efforts for SLK.

We also have diligence obligations under the License Agreement, including: (a) developing one licensed product in at least two indications; (b) launching and commercializing one product in seven major markets, including with pricing approval if required for commercialization, within 12 months of receiving regulatory approval in the respective market; (c) securing within six months of the effective date of the exclusive license a contract research facility; and (d) initiating two Phase 2 clinical trials for a product within 12 months of the effective date of the exclusive license, taking into account any regulatory requirements from the FDA, EMA or other regulatory authorities, of which we satisfied upon the initiation of our MIRA and ARGO trials. We have not yet demonstrated our ability to obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Due to the uncertainties and risks associated with these activities, we may not be successful in meeting these diligence obligations within the required timeframes, and may lose the ability to develop and commercialize SLK.

On May 12, 2023, we entered into an agreement with RCT and MHKDG, effective as of June 1, 2023, pursuant to which we were granted a royalty-bearing, nonexclusive, sublicensable right and license under RCT's patents and know-how related to a manufacturing process using an underlying yeast strain, Pichia pastoris, to develop, manufacture, use, sell, offer for sale, and

import and otherwise commercialize SLK on a world-wide basis, subject to certain restrictions. This agreement replaces our sublicense for similar rights under the License Agreement with MHKDG.

Due to the significant resources required for the development of SLK, we must prioritize the pursuit of treatments for certain indications. We may expend our limited resources to pursue a particular indication and fail to capitalize on indications that may be more profitable or for which there is a greater likelihood of success.

We are developing therapies for patients with inflammatory skin and joint diseases with unmet needs. In particular, we are developing a portfolio of therapeutic indications for SLK, and are initially focused on the development of SLK in inflammatory diseases including HS, PsA, axSpA and PPP. In May 2022, we initiated our MIRA trial, and in June 2023, we announced positive top-line results from this trial. In May 2024, following positive end-of-Phase 2 interactions with the FDA and positive feedback from the EMA, we started enrollment in the Phase 3 VELA-1 and VELA-2 trials. In September 2025, we announced primary endpoint data from these trials. In November 2025, we were granted a Type B meeting with the FDA to discuss adequacy of the current clinical evidence package of SLK to support a BLA. In January 2026, we announced positive feedback from this interaction, confirming that we may establish substantial evidence of effectiveness without additional clinical trials in HS. In February 2026, we presented an interim analysis of the long-term data from the VELA trials, which will continue to week 52 followed by an open-label extension for up to two years. In December 2022, we initiated our ARGO trial, and in March 2024, we announced full 24-week data from the ARGO trial. In June 2024, we announced the successful outcome of our end-of-Phase 2 interactions with the FDA, as well as positive feedback from our interactions with the EMA, with both regulatory bodies supporting our proposed approach for advancing to Phase 3 with the IZAR program. In November 2024, we announced the screening of the first patients in the IZAR-1 and IZAR-2 trials. In February 2026, we announced completion of enrollment for the IZAR-1 trial.

Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular indications may not lead to the development of any viable commercial product and may divert resources away from opportunities for other indications that later prove to have greater commercial potential or a greater likelihood of success. The primary endpoints for the Phase 2 trials for the therapeutic indications of HS and PsA were the therapeutic scores of the HiSCR and ACR, respectively. The primary endpoints of such trials were met and SLK demonstrated meaningful increases in such therapeutic scores. However, there is no guarantee that the results will be replicated in Phase 3 studies. For example, in the VELA-2 trial, a higher-than-expected placebo arm precluded the study from achieving statistical significance in the week 16 primary endpoint using composite strategy. In addition, although SLK achieved statistical significance for all primary and secondary endpoints in the VELA-1 trial, there is no guarantee that such results or results from other Phase 3 studies, like the IZAR-1 and IZAR-2 trials, will lead to market acceptance or commercial success of SLK, if approved. Even if SLK receives marketing approval, it may not achieve commercial success. If we do not accurately evaluate the commercial potential or target market for SLK, we may relinquish valuable rights to SLK through future collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights. We may make incorrect determinations regarding the viability or market potential of SLK or misread trends in our industry.

We may be required to take write-downs or write-offs, restructuring and impairment or other charges that could have a significant negative effect on our financial condition, results of operations and stock price, which could cause you to lose some or all of your investment.

We may be required to later write-down or write-off assets, restructure our operations, or incur impairment or other charges that could result in losses. Even though these charges may be non-cash items and not have an immediate impact on our liquidity, the fact that we report charges of this nature could contribute to negative market perceptions about us or our securities. In addition, charges of this nature may cause us to violate net worth or other covenants to which we may be subject. Accordingly, any shareholders could suffer a reduction in the value of their shares. Such shareholders are unlikely to have a remedy for such reduction in value unless they are able to successfully claim that the reduction was due to the breach by our officers or directors of a duty of care or other fiduciary duty owed to them.

The only principal assets of our Company are cash and our interest in MoonLake AG, and accordingly we will depend on distributions from MoonLake AG to pay taxes and expenses.

PART I

We are a holding company and have no material assets other than cash and our ownership of Class V shares in MoonLake AG and common shares in MoonLake AG. As such, we have no independent means of generating revenue or cash flow, besides interest income on cash held depository institutions, if any, and our ability to pay taxes and operating expenses or declare and pay dividends in the future, if any, will be dependent upon the financial results and cash flows of MoonLake AG and its subsidiaries, and distributions we receive from MoonLake AG. There can be no assurance that MoonLake AG and its subsidiaries will generate sufficient profits and/or cash flow to distribute funds to us, or that applicable laws and contractual restrictions, including negative covenants in any debt agreements of MoonLake AG or its subsidiaries, will permit such distributions.

Distributions by MoonLake AG to the Company are subject to a Swiss federal dividend withholding tax at the statutory rate of 35%, unless and to the extent that such distributions constitute a repayment of duly reported capital contributions. Under the current structure, we are not entitled to any relief from Swiss federal dividend withholding tax, such that MoonLake AG will be required to deduct the Swiss federal dividend withholding tax at the statutory rate of 35% and that such tax deduction will result in a final tax burden for the Company. If our place of management is relocated to Switzerland such withholding tax on distributions from MoonLake AG to us may be eliminated (although such relocation would result in Swiss withholding taxes applying on distributions from us to our shareholders; depending on the specific shareholder, such shareholder may be entitled to a full or partial relief or credit for such Swiss withholding tax). There can be no assurances that our place of management will be relocated or that such withholding tax will be reduced or eliminated.

If the market opportunities for our approved product candidates, if any, are smaller than we expect, it could materially and adversely affect our financial condition and results of operation.

If the market opportunity for our products, if approved, is smaller than we expect, we may never become or remain profitable nor generate sufficient revenue growth to sustain our business even if we obtain significant market share for them. The potentially addressable patient population for our products may be limited or may not be amenable to treatment with our products, and new patients may become increasingly difficult to identify or access, which would adversely affect our results of operations and our business.

Even if SLK or other compounds we may develop are successful in clinical trials and receive regulatory approvals, we or our collaboration partners may not be able to successfully commercialize them.

The development and ongoing clinical trials for SLK and other compounds we may develop may not be successful and, even if they are, the resulting products may never be successfully developed into commercial products or gain market acceptance among physicians, patients, healthcare payors or the medical community. Even if we are successful in our clinical trials and in obtaining other regulatory approvals, our products may not reach or remain in the market for a number of reasons including ineffectiveness, harmful side effects, difficulty in scaling manufacturing, political and legislative changes, or competition from other existing or future alternatives. In addition, we currently have limited commercialization expertise, including sales, marketing or distribution capabilities. Advancing SLK through Phase 3 development and regulatory approval will require us to expand commercialization preparation activities and incur related expenses before we obtain final trial results and know whether the VELA-1, VELA-2, VELA-TEEN, IZAR-1 and IZAR-2 trials will support regulatory approval. If we are unable to adequately prepare the market for the potential future commercialization of SLK, we may not be able to generate product revenue once marketing authorization is obtained.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements on commercially reasonable terms, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

The Loan and Security Agreement contains certain covenants that could adversely affect our operations and, if an event of default were to occur, we could be forced to repay any outstanding indebtedness sooner than planned and possibly at a time when we do not have sufficient capital to meet this obligation.

Pursuant to the loan and security agreement (the "Loan and Security Agreement") we entered in March 2025 with Hercules Capital Inc. and certain of its affiliates, we have pledged substantially all of our assets, subject to customary exceptions. Additionally, the Loan and Security Agreement contains certain affirmative and negative covenants that could prevent us from taking certain actions without the consent of our lenders. These covenants may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our shareholders. The Loan and Security Agreement also contains customary affirmative and negative covenants that, among other things, limit our ability, subject to certain exceptions, to incur indebtedness, grant liens, enter into a merger or consolidation, enter into transactions with affiliates, or sell all or a portion of our property, business or assets. The Loan and Security Agreement contains customary events of default. Upon the occurrence and continuation of an event of default, all amounts due under the Loan and Security Agreement become (in the case of an insolvency or bankruptcy event), or may become (in the case of all other events of default and at the option of Hercules Capital, Inc.), immediately due and payable. If an event of default under the Loan and Security Agreement should occur, we could be required to immediately repay any outstanding indebtedness. If we are unable to repay such debt, the lenders would be able to foreclose on the secured collateral, including our cash accounts, and take other remedies permitted under the Loan and Security Agreement. Even if we are able to repay any indebtedness on an event of default, the repayment of these sums may significantly reduce our working capital and impair our ability to operate as planned.

Risks Related to Product Development

We have never successfully completed the regulatory approval process for any of our product candidates and we may be unable to do so for any product candidates we acquire or develop.

We have not yet demonstrated our ability to successfully obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. If we are required to conduct additional preclinical studies or clinical trials of SLK beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of SLK or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining regulatory approval from the FDA, EMA or other regulatory authorities for our product candidates;
- not obtain regulatory approval at all and lose our right and ability under our license from MHKDG to further develop and commercialize SLK;
- obtain regulatory approval for indications or patient populations that are not as broad as intended or desired;
- continue to be subject to post-marketing testing requirements from the FDA, EMA or other regulatory authorities; or
- experience having the product removed from the market after obtaining regulatory approval.

We are substantially dependent on the success of SLK, and our ongoing and anticipated clinical trials of SLK may not be successful.

Our future success is substantially dependent on our ability to successfully develop SLK for future marketing approval, and then successful commercialization. We are investing a majority of our efforts and financial resources into the research and development of SLK. In HS, we expect to complete the one-year VELA-1 and VELA-2 trials in the second quarter of 2026, and the six-month VELA-TEEN trial in mid-2026. We expect to submit a BLA for treatment of adult and adolescent patients in the second half of 2026, based on our MIRA, VELA-1, VELA-2 and VELA-TEEN clinical trials, with a potential commercial launch in the United States in the second half of 2027. In PsA, we expect primary endpoint readouts from our IZAR-1, IZAR-2 and P-OLARIS clinical trials in mid-2026, second half of 2026 and end of 2026, respectively, and expect to seek regulatory approval after completion of these studies through submission of a supplemental BLA. In PPP, we presented positive results from our LEDA clinical trial in November 2025, and announced receipt of Fast Track designation by the FDA in February 2026. We expect to initiate a Phase 3 clinical trial in the third quarter of 2026. In axSpA, we announced positive

results from our S-OLARIS clinical trial in February 2026 and are currently evaluating the next steps to complete the clinical development of SLK in this indication.

SLK may require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote SLK before we receive marketing approval from the FDA, EMA and comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of SLK will depend on a variety of factors. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any third parties with whom we choose to collaborate in the future. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of SLK, even if approved. If we are not successful in commercializing SLK, or are significantly delayed in doing so, our business will be materially harmed.

We may find it difficult to enroll patients in our clinical trials. If we experience delays or difficulties in the enrollment of patients in clinical trials, our successful completion of clinical trials or receipt of marketing approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for SLK if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials. Patient enrollment may be affected by various factors, including if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as SLK, and patients instead enroll in such clinical trials. Our inability to enroll a sufficient number of patients would result in significant delays in completing clinical trials or receipt of marketing approvals and increased development costs or may require us to abandon one or more clinical trials altogether.

The results of preclinical testing and early clinical trials may not be predictive of the success of our later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA, or other comparable foreign regulatory authorities.

We will be required to demonstrate with substantial evidence through well-controlled clinical trials that SLK is safe and efficacious before we can seek marketing approvals for commercial sale. Demonstrations of efficacy or an acceptable safety profile in prior preclinical studies and earlier stage clinical trials of SLK does not mean that future clinical trials will yield the same results. For instance, we do not know whether SLK will perform in future clinical trials as SLK has performed in preclinical studies and prior clinical trials conducted by us, MHKDG, Avillion or Ablynx. SLK may fail to demonstrate in later-stage clinical trials sufficient safety and efficacy to the satisfaction of the FDA, EMA, and other comparable foreign regulatory authorities despite having progressed through preclinical studies and earlier stage clinical trials. Regulatory authorities may also limit the scope of later-stage trials until we have demonstrated satisfactory safety or efficacy results in preclinical studies or earlier-stage trials, which could prevent us from conducting the clinical trials we currently anticipate. There is no guarantee that the FDA, EMA, and other comparable foreign regulatory authorities will consider the data obtained from prior SLK trials sufficient to allow us to initiate our planned clinical trials within the timelines we anticipate, or at all. Even if we are able to initiate our planned clinical trials on schedule, there is no guarantee that we will be able to complete such trials on the timelines we anticipate or that such trials will produce positive results. Any limitation on our ability to conduct clinical trials could delay or prevent regulatory approval or limit the size of the patient population that can be treated by SLK, if approved.

Preclinical and clinical development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results.

Before obtaining marketing approval from regulatory authorities for commercialization of SLK, we must complete clinical trials to demonstrate the safety and efficacy of SLK in humans and in selected diseases. Our clinical trials may not be conducted as planned or completed on schedule, if at all, and a failure of one or more clinical trials can occur at any stage. The outcome of preclinical studies and prior clinical trials may not be predictive of the success of later clinical trials, and the outcome of preclinical studies and prior clinical trials for a product candidate for a particular indication may not be predictive

of the success of preclinical studies and clinical trials for the same product candidate for a different indication. In HS, we expect to complete the one-year VELA-1 and VELA-2 trials in the second quarter of 2026, and the six-month VELA-TEEN trial in mid-2026, but we may not observe positive results from such trials. We expect to submit a BLA for treatment of adult and adolescent patients in the second half of 2026, based on our MIRA, VELA-1, VELA-2 and VELA-TEEN clinical trials, with a potential commercial launch in the United States in the second half of 2027. In PsA, we expect primary endpoint readouts from our IZAR-1, IZAR-2 and P-OLARIS clinical trials in mid-2026, second half of 2026 and end of 2026, respectively, and to seek regulatory approval after completion of these studies through submission of a supplemental BLA. In PPP, we presented positive results from our LEDA clinical trial in November 2025 and announced receipt of Fast Track designation by the FDA in February 2026. We expect to initiate a Phase 3 clinical trial in the third quarter of 2026, which may not yield a favorable outcome. In axSpA, we announced positive results from our S-OLARIS clinical trial in February 2026 and are currently evaluating the next steps to complete the clinical development of SLK in this indication. Unexpectedly favorable results of comparator arms in any trial could lead to unfavorable comparisons to SLK. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates.

We cannot guarantee that any clinical trials will be initiated or conducted as planned or completed on schedule, if at all. We also cannot be sure that submission of an IND or similar application will result in the FDA, EMA, or other regulatory authority, as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Events that may prevent successful or timely initiation or completion of clinical trials include: inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation or continuation of clinical trials; delays in reaching a consensus with regulatory authorities on study design or implementation of the clinical trials; delays or failure in obtaining regulatory authorization to commence a trial; delays in reaching agreement on acceptable terms with prospective contract research organizations (“CROs”) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites; delays in identifying, recruiting and training suitable clinical investigators; delays in obtaining required IRB approval at each clinical trial site; delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of SLK for use in clinical trials or the inability to do any of the foregoing; failure by our CROs, other third parties or us to adhere to clinical trial protocols; failure to perform in accordance with the FDA’s or any other regulatory authority’s GCPs or applicable regulatory guidelines in other countries; changes to the clinical trial protocols; clinical sites deviating from trial protocol or dropping out of a trial; changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data; transfer of manufacturing processes to larger-scale facilities operated by a CMO and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and third parties being unwilling or unable to satisfy their contractual obligations to us.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such clinical trials are being conducted, by the Data Safety Monitoring Board, if any, for such clinical trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA, EMA, or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from SLK, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we are required to conduct additional clinical trials or other testing of SLK beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of SLK, if the results of these trials are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs.

Preliminary, interim data from our clinical trials that we announce or publish may change as more patient data become available and are subject to audit and verification procedures.

From time to time, we may publicly disclose preliminary data from our preclinical studies and clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data. We might also make assumptions, estimations, calculations and

conclusions as part of our analyses of these data without the opportunity to fully and carefully evaluate complete data. As a result, the preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated or subsequently made subject to audit and verification procedures.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of SLK and our company in general. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the preliminary, or interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, SLK may be harmed, which could harm our business, operating results, prospects or financial condition.

We face substantial competition, which may result in others discovering, developing, licensing or commercializing products before or more successfully than we do.

We face substantial competition from major pharmaceutical companies and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

In particular, pharmaceutical companies that develop and/or market products for the indications we are pursuing, including HS and PsA, are likely to represent substantial competition. These include companies developing and/or marketing IL-17A inhibitors (such as Novartis AG, Eli Lilly and Co, Zura Bio Ltd and LEO Pharma), IL-23 inhibitors (such as AbbVie, Janssen, Sun Pharmaceutical and Almirall), IL-12/23 inhibitors (including Janssen), TNF alpha inhibitors (such as AbbVie, Pfizer, Janssen and UCB), TYK2 inhibitors (such as Bristol Myers Squibb), JAK inhibitors (such as AbbVie, Incyte and Pfizer), IL1a/IL1b inhibitors (such as Abbvie and Avalo Therapeutics), OX40L inhibitors (such as Sanofi), and IRAK4 degraders (such as Kymera Therapeutics Inc). It also includes UCB as the development and commercializing company for bimekizumab, the only other IL-17A and IL-17F inhibitor beyond SLK that has received approval or is in late-stage clinical development of which we are aware. Other IL-17A and IL-17F inhibitors are in earlier development stages, including molecules being developed by Protagonist Therapeutics, Inc., Oruka Therapeutics, Inc. and Scinai Immunotherapeutics Ltd. While SLK represents a novel mechanism of action, all of the above mechanisms are also of potential therapeutic use in one or more other indications that we are or may be pursuing. If SLK does not offer sustainable advantages over competing products, we may otherwise not be able to successfully compete against current and future competitors.

Our competitors may obtain regulatory approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize SLK. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than SLK and these competitors may also be more successful than us in manufacturing and marketing their products.

Furthermore, we also face competition more broadly across the market for existing cost-effective and reimbursable inflammatory skin and joint disease treatments. SLK, if approved, may compete with these existing drug and other therapies but may not be competitive with them in price. We expect that if SLK is approved, it will be priced at a significant premium over generic, including branded generic, or biosimilar products. In particular, the availability of biosimilar products of adalimumab and in the future secukinumab may intensify competition. As a result, obtaining market acceptance of, and gaining significant share of the market for, SLK will pose challenges.

SLK may have a safety profile that could prevent regulatory approval, marketing approval or market acceptance, or limit its commercial potential.

Patients in previous SLK trials have experienced adverse events, including oral Candida. If SLK is associated with undesirable side effects or has unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or INDs, we may need to interrupt, delay or abandon SLK's development or limit development to more narrow uses or subpopulations in which such potential undesirable side effects or other characteristics may be less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of SLK and may adversely affect our business, financial condition and prospects significantly. For details of the current understanding of the SLK safety profile, see the section entitled "Business".

Additionally, after SLK may receive marketing approval, we or others may later identify undesirable side effects or adverse events caused by SLK. In such cases, regulatory authorities may suspend, limit or withdraw approvals of SLK or seek an injunction against its manufacture or distribution, require additional warnings on the label, including "boxed" warnings, or issue safety alerts, require press releases or other communications containing warnings or other safety information about SLK, require us to change the way SLK is administered or conduct additional clinical trials or post-approval studies, require us to create a REMS which could include a medication guide outlining the risks of such side effects for distribution to patients, impose fines, injunctions or criminal penalties. We could also be sued and held liable for harm caused to patients, and our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of SLK, if approved, and could seriously harm our business.

Geopolitical events and global economic conditions, such as public health crises, the conflicts between Russia and Ukraine and in the Middle East, could seriously and adversely affect our preclinical studies and ongoing and anticipated clinical trials, business, financial condition and results of operations.

As a result of global economic conditions, including new or increased tariffs imposed by the U.S. government and potential retaliatory measures by foreign governments and other barriers to trade, especially in light of recent executive orders made by the presidential administration, trade and other international disputes, inflation and fluctuating interest rates, slower growth or recession, tighter credit, volatility in financial markets, high unemployment, labor availability constraints, public health crises, significant natural disasters, including as a result of climate change, changes to fiscal and monetary policy or government budget dynamics, particularly in the pharmaceutical and biotech areas, political and military conflict, including the conflicts between Russia and Ukraine and in the Middle East, we may in the future experience disruptions that could seriously harm our business. In addition, in September 2025, the United States announced the imposition of up to 100% tariffs on imported branded or patented pharmaceuticals, subject to certain exceptions. There remains substantial uncertainty as to when such tariffs may go into effect and whether such tariffs would apply to the importation of active pharmaceutical ingredients or bulk drug products that are intended for use in clinical trials and, more generally, about the duration of existing tariffs, tariff levels, implementation of announced tariffs, litigation challenging tariffs and whether additional tariffs or retaliatory actions may be imposed, modified or suspended. Other potential disruptions include but are not limited to: delays or difficulties in enrolling patients in, initiating or expanding our clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff; increased rates of patients withdrawing from our clinical trials following enrollment as a result of certain health conditions or being forced to quarantine; interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, processing and analyses, due to limitations on travel imposed; recommendations by federal, state or local governments, employers and others or interruptions of clinical trial subject visits, which may impact the collection and integrity of subject data and clinical trial endpoints; diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials; delays or disruptions in preclinical experiments and IND-enabling studies due to restrictions of on-site staff and unforeseen circumstances at CROs and vendors; interruption or delays in the operations of the FDA, EMA, and comparable foreign regulatory authorities including delays in receiving approval from local regulatory authorities to initiate our planned clinical trials; interruption of, or delays in receiving, supplies of SLK from our CMOs due to staffing shortages, raw materials shortages, production slowdowns or stoppages and disruptions in delivery systems; and limitations on employee or other resources that would otherwise be focused on the conduct of our clinical trials and preclinical work, including because of

sickness of employees or their families, the desire of employees to avoid travel or contact with large groups of people, an increased reliance on working from home, school closures or mass transit disruptions.

Geopolitical events and global economic conditions may also affect the ability of the FDA, EMA, and other regulatory authorities to perform routine functions. If such concerns prevent the FDA, EMA, or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA, EMA, or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Regulatory Process and Other Legal Compliance Matters

The regulatory approval processes of the FDA, EMA, and other comparable foreign regulatory authorities are complex, time-consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for SLK, we may not be able to commercialize, or may be delayed in commercializing, SLK, and our ability to generate revenue will be materially impaired.

The process of obtaining regulatory approvals in the United States, the EU, and other jurisdictions is complex, expensive and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. We cannot commercialize SLK in the United States without first obtaining regulatory approval from the FDA. Similarly, we cannot commercialize SLK outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of SLK, we must demonstrate through complex and expensive preclinical studies and clinical trials that SLK is both safe and effective for each targeted indication. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authorities. Further, SLK may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval. The FDA, EMA, and comparable foreign regulatory authorities have discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. SLK could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including: the FDA, EMA, or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; we may be unable to demonstrate to the satisfaction of the FDA, EMA, or comparable foreign regulatory authorities that SLK is safe and effective for its proposed indication; the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA, or comparable foreign regulatory authorities for approval; serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to SLK; we may be unable to demonstrate that SLK's clinical and other benefits outweigh its safety risks; the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; the data collected from clinical trials of SLK may not be acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials; the FDA, EMA, or the applicable foreign regulatory authority may disagree regarding the formulation, labeling and/or the specifications of SLK; the FDA, EMA, or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and the approval policies or regulations of the FDA, EMA, or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. Thus, the approval requirements for SLK are likely to vary by jurisdiction such that success in one jurisdiction is not necessarily predictive of success elsewhere. Further, the FDA and comparable foreign regulatory authorities may undergo leadership changes, change their policies, issue additional regulations or revise existing regulations, or take other actions, which may impact our clinical development plans or prevent or delay approval of our product candidates under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals and increase the costs of compliance.

Of the large number of drugs in development, only a small percentage successfully complete the FDA, EMA, or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future

clinical trial results may result in our failing to obtain regulatory approval to market SLK, which would significantly harm our business, results of operations and prospects.

If we were to obtain approval, regulatory authorities may approve SLK for fewer or more limited indications than we request, including failing to approve the most commercially promising indications, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve SLK with a label that does not include the labeling claims necessary or desirable for the successful commercialization of SLK. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for SLK, we may not be able to commercialize, or may be delayed in commercializing, SLK and our ability to generate revenue could be materially impaired.

We will be subject to extensive ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with SLK.

Any regulatory approvals that we may receive for SLK will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of SLK, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. In addition, if the FDA, EMA, or comparable foreign regulatory authorities approve SLK, SLK and the activities associated with its development and commercialization, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export will be subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA in the EU and comparable foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCPs for any clinical trials that we conduct following approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA, EMA, and other regulatory authorities for compliance with cGMPs.

If we or a regulatory authority discover previously unknown problems with SLK, such as adverse events of unanticipated severity or frequency, or problems with the facilities where SLK is manufactured, a regulatory authority may impose restrictions on SLK, the manufacturing facility or us, including requiring recall or withdrawal of SLK from the market or suspension of manufacturing, restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials, restrictions on the manufacturing process, warning or untitled letters, civil and criminal penalties, injunctions, product seizures, detentions or import bans, voluntary or mandatory publicity requirements and imposition of restrictions on operations, including costly new manufacturing requirements. The occurrence of any event or penalty described above may inhibit our ability to commercialize SLK and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's, EMA's and other regulatory comparable authorities' policies may change and additional government regulations may be enacted that could prevent, limit, delay, increase the cost or risks of obtaining regulatory approval of our product candidates, or change our continuing compliance obligations, including if as a result new or more costly or difficult to achieve clinical trial or manufacturing quality requirements are imposed. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad.

Disruptions at the FDA, the SEC and other government agencies and regulatory authorities caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review regulatory filings and our ability to commence human clinical trials can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the

payment of user fees, and statutory, regulatory and policy changes, disruptions caused by government shutdowns and public health crises. There have been mass layoffs of federal government employees since the start of the presidential administration in January 2025, the full impact of which is unclear at this time. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC, and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Furthermore, the presidential administration has made and is expected to continue to make changes in the leadership of various U.S. federal regulatory agencies and changes to U.S. federal government policy that have led to, in some cases, legal challenges and uncertainty around the funding, functioning and policy priorities of the U.S. federal regulatory agencies, including the FDA.

Disruptions at the FDA and other agencies or comparable foreign regulatory authorities, may also slow the time necessary for the review and approval of applications for clinical trial or marketing authorization, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. Additionally, action by the new Trump Administration to limit federal agency budgets or personnel may result in reductions to the FDA's budget, employees, and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We are unable to predict the extent to which the presidential administration may impose or seek to impose leadership or policy changes at the FDA or changes to rules and policies impacting our business and operations. For example, there can be no assurance that the FDA will implement or continue the plan it announced in December 2025 to change its default evidentiary requirement from two clinical trials to one clinical trial for new drug approvals. It is unclear how these executive actions or other potential actions by the federal government will impact the FDA or other regulatory authorities that oversee our business. Government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. These budgetary pressures may reduce the FDA's ability to perform its responsibilities, which could result in delays in our clinical trial timelines. If a significant reduction in the FDA's workforce occurs, the FDA's budget is significantly reduced or a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions or take other actions critical to the development or manufacturing of our product candidates, which could have a material adverse effect on our business.

If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Due to unfavorable pricing regulations and/or third-party coverage and reimbursement policies, we may not be able to offer SLK at competitive prices which would seriously harm our business.

Our ability to successfully commercialize SLK also will depend in part on the extent to which reimbursement for SLK and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

Failure to comply with the laws and regulations prohibiting the promotion of off-label uses can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

The FDA, EMA, and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If SLK is approved and we are found to have improperly promoted off-label uses of SLK, we may become subject to significant liability. See the section titled "*Business — Government Regulation*". If we cannot successfully manage the

promotion of SLK, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors acting for or on our behalf may engage in misconduct or other improper activities. We have adopted a code of conduct to more closely reflect our operations, but it is not always possible to identify and deter misconduct by these parties and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute SLK, if approved.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our future arrangements with third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates for which we obtain regulatory approval. See the section titled “Business — Government Regulation” for a more detailed description of the laws that may affect our ability to operate.

The healthcare system is under significant financial pressure to reduce costs, which could reduce payment and reimbursement rates for drugs.

Throughout the world and particularly in the United States, the healthcare system is under significant financial pressure to reduce costs. The price of pharmaceuticals has been a topic of considerable public discussion that could lead to price controls or other price-limiting strategies by payors that have the effect of lowering payment and reimbursement rates for drugs or otherwise making the commercialization of pharmaceuticals less profitable. Many federal, state and foreign legislatures have considered, and adopted, healthcare policies intended to curb rising healthcare costs, such as the Inflation Reduction Act of 2022, which, among other provisions, included several measures intended to lower the cost of prescription drugs and related healthcare reforms or the EU's Pharmaceutical Strategy of 2020. Cost-containment measures that we could face may include, among other measures: requirements for pharmaceutical companies to negotiate prescription drug prices with government healthcare programs; controls on government-funded reimbursement for drugs; new or increased requirements to pay prescription drug rebates to government healthcare programs, including if drug prices increase at a higher rate than inflation; controls on healthcare providers; challenges to or limits on the pricing of drugs, including pricing controls or limits or prohibitions on reimbursement for specific products through other means; requirements to try less expensive products or generics before a more expensive branded product; and public funding for cost effectiveness research, which may be used by government and private third-party payors to make coverage and payment decisions. Political, economic and regulatory developments may further complicate developments in healthcare systems and pharmaceutical drug pricing. These developments could, for example, impact our potential licensing agreements as commercial and collaborative partners may also consider the impact of these pressures on their licensing strategies.

Any new laws or regulations that have the effect of imposing additional costs or regulatory burden on pharmaceutical manufacturers, or otherwise negatively affect the industry, could adversely affect our ability to successfully commercialize

our product candidates. The implementation of any price controls, caps on prescription drugs or price transparency requirements could adversely affect our business, operating results and financial condition.

Pharmaceutical and biological product marketing is subject to substantial regulation in the United States and EU, and any failure by us or our future commercial and collaborative partners to comply with applicable statutes or regulations can adversely affect our business.

Any marketing activities associated with our product candidates, if approved for commercialization, will be subject to numerous federal, state and equivalent foreign laws governing the marketing and promotion of pharmaceutical and biological products. The FDA and EMA regulate post-approval promotional labeling and advertising in the United States and EU, respectively, to ensure that they conform to statutory and regulatory requirements. In addition to FDA and EMA restrictions, the marketing of prescription drugs is subject to laws and regulations prohibiting fraud and abuse under government healthcare programs. Similarly, many states have similar statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, and, in some states, such statutes or regulations apply regardless of the payor. In addition, government authorities may also seek to hold us responsible for any failure of our future commercialization or collaborative partners to comply with applicable statutes or regulations. If we, or our commercial or collaborative partners, fail to comply with applicable FDA or EMA regulations or other laws or regulations relating to the marketing of our product candidates, if approved for commercialization, we could be subject to criminal prosecution, civil penalties, seizure of products, injunctions and exclusion of our product candidates from reimbursement under government programs, as well as other regulatory or investigatory actions against our future product candidates, our commercial or collaborative partners or us.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and our external partners are subject to complex environmental, health and safety laws and regulations, including those governing laboratory procedures, the handling, use, storage, treatment and disposal of hazardous materials and wastes, and the rehabilitation of contaminated sites. Our operations, including those performed by our external partners, may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. In addition, we and/or our external partners may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We are subject to laws and regulations related to privacy, data protection, information security and consumer protection across different markets where we conduct our business. Our actual or perceived failure to comply with such obligations could harm our business.

We are subject to laws and regulations related to, among other things, privacy, data protection, information security and consumer protection across different markets where we conduct our business. Such laws and regulations are constantly evolving and changing and are likely to remain uncertain for the foreseeable future. Our actual or perceived failure to comply with such obligations could have an adverse effect on our business, operating results and financial operations. Complying with these numerous, complex, and often changing regulations is expensive and difficult, and failure to comply with any data protection, privacy laws or data security laws or any security incident or breach involving the potential or actual misappropriation, loss or other unauthorized processing, use or disclosure of sensitive or confidential patient, consumer or other personal information, whether by us, one of our collaborators or another third-party, could adversely affect our business, financial condition, and results of operations, including but not limited to investigation costs, material fines and penalties, compensatory, special, punitive, and statutory damages, litigation, consent orders regarding our privacy and security practices, requirements that we provide notices, credit monitoring services, and/or credit restoration services or other relevant services to impacted individuals, adverse actions against our licenses to do business, reputational damage and injunctive relief.

The collection and use of personal health data and other personal data in the EU is governed by the provisions of the GDPR, which became applicable in May 2018, and related data protection laws in individual EU member states. The GDPR imposes a number of strict obligations and restrictions on the ability to process (processing includes collecting, analyzing and

transferring) personal data of individuals, including with respect to health data from clinical trials and adverse event reporting. The GDPR includes requirements relating to the legal basis of the processing (such as consent of the individuals to whom the personal data relates), the information provided to the individuals prior to processing their personal data, the personal data breaches which may have to be notified to national data protection authorities and data subjects, the measures to be taken when engaging processors, and the security and confidentiality of the personal data. EU member states may also impose additional requirements in relation to health, genetic and biometric data through their national legislation.

The GDPR also imposes specific restrictions on the transfer of personal data to countries outside of the EEA that are not considered by the EU Commission to provide an adequate level of data protection. Appropriate safeguards are required to enable such transfers. Among the appropriate safeguards that can be used, the data exporter may use the SCCs, as updated in 2021. In this respect, when relying on SCCs, the data exporters are required to conduct a transfer risk assessment to verify if anything in the law and/or practices of the third country may impinge on the effectiveness of the SCCs in the context of the transfer at stake and, if so, to identify and adopt supplementary measures that are necessary to bring the level of protection of the data transferred to the EU standard of essential equivalence. Where no supplementary measure is suitable, the data exporter should avoid, suspend or terminate the transfer. With regard to the transfer of personal data from the EEA to the United States, on July 10, 2023, the European Commission adopted its adequacy decision for the EU-US Data Privacy Framework. On the basis of the new adequacy decision, personal data can flow from the EEA to United States companies participating in the framework. With regard to the transfer of data from the EU to the United Kingdom, on June 28, 2021, the EC adopted two adequacy decisions for the UK – one under the GDPR and the other for the Law Enforcement Directive. Personal data may now freely flow between the EEA and the UK since the UK is deemed to have an adequate data protection level for purposes of the EU regime. However, the adequacy decisions include a ‘sunset clause’ which entails that the decisions will automatically expire four years after their entry into force, unless renewed.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU member states may result in significant monetary fines for noncompliance of up to €20 million or 4% of the annual global turnover of the noncompliant company, whichever is greater, other administrative penalties and a number of criminal offenses for organizations and, in certain cases, their directors and officers, as well as civil liability claims from individuals whose personal data was processed. Data protection authorities from the different EU member states may still implement certain variations, enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing personal data in the EU.

Furthermore, there are specific requirements relating to processing health data from clinical trials, including public disclosure obligations provided in the EU CTR, EMA disclosure initiatives and voluntary commitments by industry. Failing to comply with these obligations could lead to government enforcement actions and significant penalties against us, harm to our reputation, and adversely impact our business and operating results.

Additionally, following the UK’s withdrawal from the EEA, known as Brexit, companies also have to comply with the UK’s data protection laws (including the GDPR, as incorporated into UK national law), the latter regime having the ability to impose fines up to the greater of £17.5 million or 4% of global turnover. Furthermore, transfers from the UK to other countries are subject to UK international transfer rules, which broadly mirror the EU GDPR rules. Personal data may however freely flow from the UK to the EEA since the EEA is deemed to have an adequate data protection level for purposes of the UK regime. With regard to the transfer of personal data from the UK to the United States, from October 12, 2023, businesses in the UK can start to transfer personal data to US organizations certified to the “UK Extension to the EU-US Data Privacy Framework” under the UK GDPR, without the need for further safeguards. On March 21, 2022, the international data transfer agreement (IDTA) and the international data transfer addendum to the EC’s standard contractual clauses for international data transfers (Addendum), and a document setting out transitional provisions came into force and replaced the old EU SCCs for purposes of the UK regime.

Furthermore, processing of personal data in Switzerland is governed by restrictive regulations, in particular the Federal Act on Data Protection (the “FDAP”), of September 25, 2020, as revised by the new FDAP, which came into force on the September 1, 2023. The FDAP is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data and taking certain measures when

engaging processors. Breaches of or non-compliance with applicable data protection regulations and professional secrecy obligations could result in fines, or, under certain circumstances, criminal sanctions.

The collection and use of personal health data and other personal data in the US is governed by various federal and state laws, including comprehensive state privacy laws (including CCPA), data breach notification laws, health privacy laws (such as HIPAA and state health privacy laws), federal and state consumer protection laws, and Section 5 of the FTC Act. Failure to comply with these laws can result in fines (including statutory damages for certain privacy laws), third-party liabilities, regulatory inquiries and enforcement, legal fees, and legal claims.

Finally, we cannot assure that our third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personally identifiable, personal information, personal data, and other sensitive or confidential information will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, results of operations, and financial condition. We cannot assure that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, use, storage, and transmission of such information. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of these laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase in time. We engage third parties for clinical trials and to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

The Cayman Islands Economic Substance Act may affect our operations.

The Cayman Islands has recently enacted the International Tax Co-operation (Economic Substance) Act (As Revised) (the "Cayman Economic Substance Act"). The Cayman Economic Substance Act generally requires legal entities domiciled or registered in the Cayman Islands and carrying out specific "relevant activities" to have demonstrable substance in the Cayman Islands. The Cayman Economic Substance Act was introduced by the Cayman Islands to ensure that it meets its commitments to the EU, as well as its obligations under the OECD's global Base Erosion and Profit Shifting initiatives. We are required to comply with the Cayman Economic Substance Act. As we are a Cayman Islands company, compliance obligations include filing annual notifications for the Company, which need to state whether the Company is carrying out any relevant activities and, if so, whether we have satisfied economic substance tests to the extent required under the Cayman Economic Substance Act. As it is a relatively new regime, it is anticipated that the Cayman Economic Substance Act will evolve and be subject to further clarification and amendments. We may need to allocate additional resources to keep updated with these developments, and may have to make changes to our operations in order to comply with all requirements under the Cayman Economic Substance Act. Failure to satisfy these requirements may subject us to penalties under the Cayman Economic Substance Act. The Cayman Islands Tax Information Authority shall impose a penalty of CI$10,000 (or US$12,500) on a relevant entity for failing to satisfy the economic substance test or CI$100,000 (or US$125,000) if it is not satisfied in the subsequent financial year after the initial notice of failure. Following failure after two consecutive years the Grand Court of the Cayman Islands may make an order requiring the relevant entity to take specified action to satisfy the economic substance test or ordering it that it is defunct or be struck off.

Current and future legislation may increase the difficulty and cost for us, and any collaborators, to obtain marketing approval of and commercialize our drug candidates and affect the prices we, or they, may obtain.

Heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed drug products has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. We expect that additional state and federal healthcare reform measures may be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare therapies, which could result in reduced demand for our drug candidate, if approved for commercial use, or additional pricing pressures. On August 16, 2022, President Biden signed into law the IRA, which, among other provisions, included several measures intended to lower the cost of prescription drugs and related healthcare reforms. We cannot be sure whether additional legislation or rulemaking related to the IRA will be issued or enacted, or what impact, if any, such changes will have on the profitability of any of our drug candidates, if approved for commercial use, in the future.

We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition.

The rules governing U.S. federal, state and local income taxation are constantly under review and modification by persons involved in the legislative process and by the Internal Revenue Service ("IRS") and the U.S. Treasury Department. Changes to tax laws, including those with potential retroactive application, could adversely affect us or our shareholders. We regularly assess the potential impact of various tax reform proposals and modifications to existing tax treaties in jurisdictions where we have operations to understand their potential effect on our business and any assumptions we have made about our future taxable income. However, we cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our financial conditions or our shareholders, if they were to be enacted.

For example, beginning in 2022, the Tax Cuts and Jobs Act eliminated the previously available option to immediately deduct research and development expenditures and instead requires taxpayers to amortize them generally over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. On July 4, 2025, the U.S. Congress enacted the One Big Beautiful Bill Act, which includes a provision restoring the immediate deductibility of domestic research and development expenditures. The impact of this newly enacted law on our tax position will depend on how the provision is implemented and interpreted by the IRS and other regulatory authorities. In addition, we have no assurance as to whether, when and how this provision may be subject to further amendment or repeal. Such changes, among others, may adversely affect our effective tax rate, results of operation and financial condition.

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business

We are dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain qualified managerial, scientific and medical personnel. We are dependent on our managerial, scientific and medical personnel, including our Chief Executive Officer, our Chief Scientific Officer, and our Chief Financial Officer. If we do not succeed in attracting and retaining qualified personnel, it could materially adversely affect our business, financial condition and results of operations. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts. Furthermore, we are dependent on our ability to attract, hire, relocate and retain qualified managerial, scientific and medical personnel from jurisdictions other than Switzerland, the United Kingdom and Portugal. Therefore, Swiss, British and Portuguese immigration requirements have a significant influence on our human resources planning. Immigration applications can take several months or more to be finalized. If we are unable to complete the requisite visa applications, either as a result of changing requirements or otherwise, our ability to successfully implement our business strategy could suffer, which could have a material adverse effect on our business, financial condition, results of operations and prospects. We intend to establish a presence in the United States in order to build the sales, marketing and distribution infrastructure to commercialize SLK. Certain of the locations that we are considering for such presence are headquarters to many other biopharmaceutical

companies and many academic and research institutions. Competition for skilled personnel in such locations is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

In order to successfully implement our plans and strategies, we will need to grow the size of our organization and we may experience difficulties in managing this growth.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of medical affairs, marketing, sales, market access and pricing and, potentially, others. To manage our anticipated future growth, we must continue to implement and develop our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel.

A cybersecurity incident or failure in our information technology and storage systems or those of third parties upon whom we rely could significantly disrupt the operation of our business and adversely impact our financial condition.

Our ability to execute our business plan and maintain operations depends on the continued and uninterrupted performance of our information technology ("IT") systems or those of third parties upon whom we rely. IT systems are vulnerable to risks and damages from a variety of sources, including telecommunications or network failures, malicious human acts, and natural disasters (such as a tornado, an earthquake, or a fire). Moreover, despite network security and back-up measures, some of our and our vendors' servers are potentially vulnerable to physical or electronic break-ins, including cyber-attacks, computer viruses, and similar disruptive problems. The techniques used by criminal elements to attack computer systems are increasingly sophisticated, change frequently, and may originate from less regulated and remote areas of the world. In addition, the use of artificial intelligence by cybercriminals may increase the frequency and severity of cybersecurity attacks, including against us or the third parties on which we rely. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. If the IT systems are compromised, we could be subject to fines, damages, litigation, and enforcement actions, and we could lose trade secrets, the occurrence of which could harm our business. Despite precautionary measures designed to prevent unanticipated problems that could affect the IT systems, sustained or repeated system failures that interrupt our ability to generate and maintain data could adversely affect our ability to operate our business. In addition, the failure of our systems, maintenance problems, upgrading or transitioning to new platforms, or a cybersecurity incident could result in delays and reduce efficiency in our operations. Remediation of such problems could result in significant, unplanned capital investments.

Furthermore, parties in our supply chain may be operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen, and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and those of our third-party CROs, other contractors (including sites performing our clinical trials) and consultants, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners and/or other third parties, or from ransomware and other cyber-attacks by malicious third parties, which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data. In addition, techniques used to obtain unauthorized access to networks in which data is stored or through which data is transmitted change frequently and generally are not recognized until launched against a target. As a result, we may be unable to anticipate these techniques or implement adequate preventative measures to prevent such an event. Further, cybersecurity breaches or other cybersecurity incidents may allow hackers access to our preclinical compounds, strategies, discoveries, trade secrets, and/or other confidential

information. Additionally, sensitive data could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, vendors' or partners' use of generative AI technologies. To the extent that any disruption or cybersecurity incident were to result in a loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for it to be believed or reported that any of these occurred, we could incur liability, including under laws and regulations governing the protection of protected health information and other personal data, and reputational damage and the development and commercialization of SLK could be delayed. The risk of a cybersecurity incident or other informational technology disruption, particularly through cyber-attacks, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased.

Further, our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or security breach of, our systems or third-party systems where information important to our business operations or commercial development is stored. The successful assertion of one or more large claims against us that exceeds our available insurance coverage or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that any existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third-party service providers to comply with our data privacy, security, protection, or confidentiality, or to respond to any data security incidents, breaches or other unauthorized access, acquisition, or disclosure of sensitive information (including, without limitation personal information), may result in additional cost and/or liability to us, including costs from governmental investigations, enforcement actions, regulatory fines, litigation, costs of doing business, or damage to our reputation. Any of these events could cause harm to our reputation, business, financial condition, or operational results.

Risks Related to Reliance on Third Parties

We currently rely, and plan to rely in the future, on third parties to conduct and support our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize SLK.

We have utilized and plan to continue to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs and strategic partners, to conduct and support our preclinical studies and clinical trials under agreements with us. We will rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP regulations, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA, or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations, even if responsibilities have been outlined in agreements with external partners, such as CROs. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to SLK. These third

parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize SLK.

We currently rely on third parties to produce and process SLK. Our business could be adversely affected if the third-party manufacturers fail to provide us with sufficient quantities of SLK or fail to do so at acceptable quality levels or prices.

We do not currently own or operate any facility that may be used to produce SLK (including any drug substance or finished drug product) and must currently rely on CMOs to produce them for us. We have not yet caused SLK to be manufactured in a commercially validated and registered process and may not be able to do so.

We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP requirements and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of SLK. Beyond periodic audits, we have no control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA, or a comparable foreign regulatory authority does not approve these facilities for the manufacture of SLK or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and materially and adversely affect our ability to develop, obtain regulatory approval for or market SLK, if approved. Similarly, our failure, or the failure of our CMOs, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of SLK, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of SLK and harm our business and results of operations.

Moreover, if any CMOs on which we will rely fail to manufacture quantities of SLK at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition and prospects could be materially and adversely affected. Our business could be similarly affected by business disruptions to our third-party providers with potential impacts on our future revenue and financial condition and our costs and expenses. Each of these risks could delay or prevent the completion of our clinical trials or the approval of SLK by the FDA, result in higher costs or adversely impact commercialization of SLK.

Moreover, we have not yet completed the development of the autoinjector device for SLK, which includes the conduct of pharmacokinetic and human factor studies, and may not be able to do.

We may, in the future, form or seek collaborations or strategic alliances or enter into licensing arrangements, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.

We may, in the future, form or seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to SLK and/or our Company more broadly. Any of these relationships may require us to increase our near and long-term expenditures, issue securities that dilute our existing shareholders or disrupt our management and business.

Risks Related to Our Intellectual Property

Our ability to protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage.

We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to SLK and our technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market. Our success depends in large part on our ability to obtain

and maintain patent protection for SLK and its uses, components, formulations, methods of manufacturing and methods of treatment, as well as our ability to operate without infringing on or violating the proprietary rights of others. We own and have licensed rights to patent applications and pending patent applications, and expect to continue to file patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or drug candidates or which effectively prevent others from commercializing competitive technologies and drug candidates. The patent examination process may require us or our licensors to narrow the scope of the claims of our or our licensors' pending and future patent applications, which may limit the scope of patent protection that may be obtained. Accordingly, even if we or our licensors are able to obtain patents, the patents might be substantially narrower than anticipated. Thus, there is no assurance as to the degree and range of protections any of our patents, if issued, may afford us or whether patents will be issued. We cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent application from being issued as a patent.

We enjoy only limited geographical protection with respect to certain patents and may not be able to protect our intellectual property rights throughout the world.

We may not be able to protect our intellectual property rights throughout the world and the legal systems in certain countries may not favor enforcement or protection of patents, trade secrets and other intellectual property. Filing, prosecuting and defending patents on SLK worldwide would be prohibitively expensive and our intellectual property rights in some foreign jurisdictions can be less extensive than those in the United States. We have licensed patents in the most relevant countries but may not be able to obtain patents in all jurisdictions even if we apply for them. Our competitors may operate in countries where we do not have patent protection and can freely use our technologies and discoveries in such countries to the extent such technologies and discoveries are publicly known or disclosed in countries where we do have patent protection or pending patent applications. Our pending and future patent applications may not result in patents being issued. Any issued patents may not afford sufficient protection of SLK or its intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or product candidates. Further, even if these patents are granted, they may be difficult to enforce.

In addition, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Many countries also limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business and financial condition may be adversely affected.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the United States Patent and Trademark Office ("USPTO") and foreign patent agencies over the lifetime of a patent. In addition, the USPTO and other foreign patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which such non-compliance will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, and non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our drug candidates or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which

would hurt our competitive position and could impair our ability to successfully commercialize our drug candidates in any indication for which they are approved.

Issued patents covering one or more of our drug candidates could be found invalid or unenforceable.

Any issued patents that we may license or own covering SLK could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the USPTO. Also, patent terms, including any extensions or adjustments that may or may not be available to us, may be inadequate to protect our competitive position with respect to SLK for an adequate amount of time, and we may be subject to claims challenging the inventorship, validity, enforceability of our patents and/or other intellectual property. Finally, changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect SLK. Further, if we encounter delays in our clinical trials or delays in obtaining regulatory approval, the period of time during which we could market SLK under patent protection would be reduced. Thus, the patents that we own and license may not afford us any meaningful competitive advantage.

Moreover, we or our licensors may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, revocation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or SLK and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize SLK. In addition to seeking patents for some of our technology and SLK, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with our collaborators, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. As our organization grows, so does the risk of unauthorized disclosure of confidential information. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors and those affiliated with or controlled by state actors. In addition, while we undertake efforts to protect our trade secrets and other confidential information from disclosure, others may independently discover trade secrets and proprietary information, and in such cases, we may not be able to assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using our trade secrets is challenging and the outcome is unpredictable. In addition, courts outside of the U.S. may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed confidential information of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

As is common in the biotechnology and pharmaceutical industries, we employ individuals and engage the services of consultants who previously worked for other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that our consultants have used or disclosed trade secrets or other proprietary information of their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are

successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our Class A Ordinary Shares. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings.

Some of our competitors may be able to absorb the costs of such litigation or proceedings more effectively than we can. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

Patent terms may be inadequate to protect our competitive position with respect to SLK for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering SLK are obtained, once the patent life has expired, we may be subject to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for SLK, our business may be materially harmed.

In the United States, the patent term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in the EU and certain other non-United States jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when SLK receives FDA approval, we expect to apply for patent term extensions on patents covering SLK, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially harmed.

It is possible that we will not succeed in obtaining patent term extension under the Hatch-Waxman Act for a U.S. patent covering SLK that we may identify even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought. Further, for our licensed patents, we may not have the right to control prosecution, including filing with the USPTO, a petition for patent term extension under the Hatch-Waxman Act. Thus, if one of our licensed patents is eligible for patent term extension under the Hatch-Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the USPTO.

Also, we may be unable to obtain patents covering SLK that contain one or more claims that satisfy the requirements for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If SLK is approved and a patent covering SLK is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of SLK.

Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect SLK.

Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith America Invents Act (the "Leahy-Smith Act") could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications and the maintenance, enforcement or defense of our owned and in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to challenge the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Also, under the Leahy-Smith Act, the United States transitioned from a first-to-invent to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. Foreign counterparts to this law are also not uniform, and there is no worldwide policy governing the subject matter and scope of claims granted in a pharmaceutical or biotechnology patent. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and altered the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future legislation by the U.S. Congress, decisions by the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future. Similarly, changes in the patent laws of other jurisdictions could adversely affect our ability to obtain and effectively enforce our patent rights, which would have a material adverse effect on our business and financial condition.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market SLK.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of SLK in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market SLK.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering SLK or

technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could require us to obtain rights to issued patents covering such technologies.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing SLK or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to patent infringement claims or may need to file claims to protect our intellectual property, which could result in substantial costs and liability and prevent us from commercializing SLK.

Because the intellectual property landscape in the biotechnology industry is rapidly evolving and is interdisciplinary, it is difficult to conclusively assess our freedom to operate without infringing on or violating third-party rights. If a third-party successfully brings a claim against us, we may be required to pay substantial damages, be forced to abandon SLK and/or seek a license from the patent holder. In addition, any intellectual property claims (e.g. patent infringement or trade secret theft) brought against us, whether or not successful, may cause us to incur significant legal expenses and divert the attention of our management and key personnel from other business concerns. We cannot be certain that patents owned or licensed by us will not be challenged by others in the course of litigation. Some of our competitors may be able to absorb the costs of complex intellectual property litigation more effectively than we can. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise funds and on the market price of our Class A Ordinary Shares.

Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or other violations, we may be required to file claims, which can be expensive and time-consuming. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court or administrative body may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. Similarly, if we assert trademark infringement claims, a court or administrative body may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In such a case, we could ultimately be forced to cease use of such marks. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be commercially valuable.

Further, we may be required to protect our patents through procedures created to challenge the validity of a patent at the USPTO. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent

claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

In addition, if SLK is found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our future licensees and other parties with whom we have business relationships and we may be required to indemnify those parties for any damages they suffer as a result of these claims, which may require us to initiate or defend protracted and costly litigation on behalf of licensees and other parties regardless of the merits of such claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain a license for SLK.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

We license patent rights from third-party owners and thus our rights to develop and commercialize our technology and product candidates are subject, in part, to the terms and conditions of licenses granted to us by others.

We are a party to certain licenses, including with our licensor with MHKDG, that provide us rights to intellectual property that are necessary or useful for SLK and its respective components, formulations, methods of manufacturing and methods of treatment. These license agreements require us to satisfy certain obligations and, if these agreements are terminated (e.g., as a result of our failure to satisfy such obligations), our technology and our business could be adversely affected.
We may also enter into additional licenses to third-party intellectual property in the future; however, we may not be able to obtain such licenses on economically feasible terms or other reasonable terms and conditions, or at all. Additionally, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. In those instances, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected.

If we, or our licensors, are not able to obtain and maintain patent protection for any products that we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or substantially identical to ours, which could adversely affect our competitive business position and harm our business prospects. Even if patents are issued in respect of these patent applications, we or our licensors may determine not to pursue litigation against other companies that are infringing these patents, or may not be able to pursue such litigation at a reasonable cost or in a timely manner.

Our license from MHKDG may be subject to retained rights.

MHKDG retains certain rights under its license agreement with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether MHKDG limits its use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

We may not be able to effectively secure first-tier technologies when competing against other companies or investors.

Our future success may require that we acquire patent rights and know-how to new or complimentary technologies. However, we compete with a substantial number of other companies that may also compete for technologies we desire. In addition, many venture capital firms and other institutional investors, as well as other biotechnology companies, invest in companies seeking to commercialize various types of emerging technologies. Many of these companies have greater financial, scientific and commercial resources than us. Therefore, we may not be able to secure the technologies we desire. Furthermore, should any commercial undertaking by us prove to be successful, there can be no assurance competitors with greater financial resources will not offer competitive products and/or technologies.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third-party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The factors that may limit any potential competitive advantage provided by our intellectual property rights include:

- pending patent applications that we own or license may not lead to issued patents;
- patents, should they issue, that we own or license, may not provide us with any competitive advantages, or may be challenged and held invalid or unenforceable;
- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of any of our owned or in-licensed patents, should any such patents issue;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we (or our licensors) might not have been the first to make the inventions covered by a pending patent application that we own or license;
- we (or our licensors) might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- we may develop patents that could expire prior to or shortly after commencing commercialization of a product;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business and results of operation.

If approved, our product candidates that are regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"), was enacted as part of the ACA to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, a reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still develop and receive approval of a competing biologic, so long as their BLA does not reply on the reference product, sponsor's data or submit the application as a biosimilar application. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty, and any new policies or processes adopted by the FDA could have a material adverse effect on the future commercial prospects for our biological products.

We believe that SLK approved in the United States as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still

developing. The approval of a biosimilar of our product candidates could have a material adverse impact on our business due to increased competition and pricing pressure.

Risks Related to Our Class A Ordinary Shares

The price of our shares has been, and may continue to be volatile, and you could lose all or part of your investment.

The trading price of our Class A Ordinary Shares has been and may continue to be highly volatile and is subject to wide fluctuations in response to various factors, some of which are beyond our control, including the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K. The realization of any of these factors has had and may continue to have an adverse impact on the market price of our Class A Ordinary Shares. For example, escalating trade tensions, elevated interest rates and regulatory uncertainty have caused significant market volatility in recent months, and particularly in the biotechnology and biopharmaceutical industries.

In addition, the stock market in general, and the market for biotechnology companies in particular, have experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Class action securities litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation. In addition, broad market and industry factors may negatively affect the market price of our Class A Ordinary Shares, regardless of our actual operating performance. The market price for our Class A Ordinary Shares may be influenced by many factors, including:

- the success of competitive products or technologies;
- results of clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our programs and product candidates or preclinical and clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the pharmaceutical and biotechnology sectors;
- significant market volatility in recent months, particularly in the biotechnology and biopharmaceutical industries, caused by escalating trade tensions, elevated interest rates and regulatory uncertainty;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

If our share price is volatile, we may be subject to securities litigation, which is expensive and could divert management attention.

Securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. Such class action lawsuits have been initiated against us, and we may become subject to additional securities class action lawsuits in the future. Additional information on such class action lawsuits is discussed in Item 3 "Legal Proceedings". This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would materially adversely affect our business, financial condition and results of operation.

Sales of our Class A Ordinary Shares, or the perception that such sales may occur, may cause the market price of the Class A Ordinary Shares to decline significantly, even if our business is doing well.

Sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our Class A Ordinary Shares. As restrictions on resale end and registration statements (filed to provide for the resale of such shares from time to time) are available for use, the sale or possibility of sale of these shares could have the

effect of increasing the volatility in our share price or the market price of the Class A Ordinary Shares could decline if the holders of currently restricted shares sell them or are perceived by the market as intending to sell them.

Our principal shareholders and management own a significant percentage of our stock and are able to exert significant influence over matters subject to shareholder approval.

As of December 31, 2025, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own a significant portion of our outstanding voting common stock. These shareholders, acting together, may be able to impact matters requiring shareholder approval. They may be able to impact elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our capital stock that you may feel are in your best interest as one of our shareholders. The interests of this group of shareholders may not always coincide with your interests or the interests of other shareholders and they may act in a manner that advances their best interests and not necessarily those of other shareholders, including seeking a premium value for their shares, and might affect the prevailing market price for our Class A Ordinary Shares.

Anti-takeover provisions in our organizational documents could delay or prevent a change of control.

Certain provisions of our Memorandum and Articles of Association (the "Memorandum") and Cayman Islands Law may have an anti-takeover effect and may delay, defer or prevent a merger, acquisition, tender offer, takeover attempt or other change of control transaction that a shareholder might consider in its best interest, including those attempts that might result in a premium over the market price for the shares held by our members.

These provisions provide for, among other things:

- establishing a classified Board of Directors;
- allowing the Board of Directors to issue one or more series of preference shares;
- establishing advance notice for nominations of directors by members and for members to include matters to be considered at general meetings;
- eliminating the ability of members to fill vacancies on the Board of Directors;
- establishing advance notice requirements for nominations for election to the Board of Directors or for proposing matters that can be acted upon by at our annual general meetings;
- permitting the Board of Directors to establish the number of directors;
- eliminating the ability of members to call general meetings or act by written consent;
- requiring a special resolution to amend the Memorandum; and
- limit the jurisdictions in which certain shareholder litigation may be brought.

These anti-takeover provisions could make it more difficult for a third-party to acquire our Company, even if the third-party's offer may be considered beneficial by many of our shareholders. As a result, our shareholders may be limited in their ability to obtain a premium for their shares. These provisions could also discourage proxy contests and make it more difficult for you and other shareholders to elect directors of your choosing and to cause us to take other corporate actions you desire.

Our indemnification obligations to our officers and directors may result in a significant cost to us and hurt the interests of our shareholders.

Cayman Islands law does not limit the extent to which a company's memorandum and articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as to provide indemnification against willful default, willful neglect, actual fraud or the consequences of committing a crime. The Memorandum provides for indemnification of our officers and directors to the maximum extent permitted by law, including for any liability incurred in their capacities as such, except through their own actual fraud, willful default or willful neglect. We purchased a policy of directors' and officers' liability insurance that insures our officers and directors against the cost of defense, settlement or payment of a judgment in some circumstances and insures us against our obligations to indemnify our officers and directors. We have entered into indemnification agreements with each of our directors and executive officers that obligate us to indemnify, hold harmless, exonerate, and to advance

expenses as incurred, to the fullest extent permitted under applicable law, from damage arising from the fact that such person is or was an officer or director of our Company or its subsidiaries.

Our indemnification obligations may discourage shareholders from bringing a lawsuit against our officers or directors for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against our officers and directors, even though such an action, if successful, might otherwise benefit us and our shareholders. Furthermore, a shareholder's investment may be adversely affected to the extent we pay the costs of settlement and damage awards against our officers and directors pursuant to these indemnification provisions.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on its capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our Class A Ordinary Shares will be your sole source of gain for the foreseeable future.

Future issuances of debt securities and equity securities may adversely affect our Company, including the market price of our Class A Ordinary Shares and may be dilutive to existing shareholders.

There is no assurance that we will not incur debt or issue equity ranking senior to the Class A Ordinary Shares. Those securities will generally have priority upon liquidation. Such securities also may be governed by an indenture or other instrument containing covenants restricting its operating flexibility. Additionally, any convertible or exchangeable securities that we issue in the future may have rights, preferences and privileges more favorable than those of Class A Ordinary Shares. Separately, additional financing may not be available on favorable terms, or at all. Because our decision to issue debt or equity in the future will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing, nature or success of our future capital raising efforts. As a result, future capital raising efforts may reduce the market price of Class A Ordinary Shares and be dilutive to existing shareholders.

General Risk Factors

We may become a foreign private issuer within the meaning of the rules under the Exchange Act, and as such we would be exempt from certain provisions applicable to U.S. domestic public companies.

We may become a "foreign private issuer" as defined in Rule 3b-4 promulgated under the Exchange Act. If we do become a foreign private issuer, we would be exempt from certain rules and regulations in the United States that are applicable to U.S. domestic issuers, including:

- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q or current report on Form 8-K;
- the section of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;
- the section of the Exchange Act requiring directors, officers and 10% holders to file public reporting of their stock ownership and trading activities and imposing liability on insiders who profit from trades made in a short period of time; and
- the selective disclosure rules under Regulation FD restricting issuers from selectively disclosing material nonpublic information.

Accordingly, the information we would be required to file with or furnish to the SEC as a foreign private issuer is less extensive and less frequent as compared to the information required to be filed with the SEC by U.S. domestic issuers.

In addition, if we become a foreign private issuer whose securities are listed on Nasdaq, we would be permitted to, and may elect to, follow certain home country corporate governance practices in lieu of the requirements of the Nasdaq Rules pursuant

to Nasdaq Rule 5615(a)(3). Certain corporate governance practices in the Cayman Islands, which is our home country, may differ significantly from the Nasdaq corporate governance listing standards applicable to U.S. domestic issuers and may afford our shareholders less protection than they otherwise would enjoy under the Nasdaq corporate governance listing standards applicable to U.S. domestic issuers. We would be required to disclose any significant ways in which our corporate governance practices differ from those followed by U.S. domestic issuers under Nasdaq corporate governance listing standards in an annual report on Form 20-F filed with the SEC or on our website.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

In the ordinary course of our business, we collect, use, store, and transmit digitally large amounts of confidential, sensitive, proprietary, personal, and health-related information. The secure maintenance of this information and our information technology systems is important to our operations and business strategy. To this end, we have implemented processes designed to assess, identify, and manage risks from potential unauthorized occurrences on or through our information technology systems that may result in adverse effects on the confidentiality, integrity, and availability of these systems and the data residing therein. These processes are managed and monitored by a dedicated information technology team, which is led by our Associate Vice President of IT, and include mechanisms, controls, technologies, systems, and other processes designed to prevent or mitigate data loss, theft, misuse, or other security incidents or vulnerabilities affecting the data and maintain a stable information technology environment. For example, we perform daily vulnerability scans on our endpoints; we have a dedicated security operations center ("SOC"), which is run by a third-party; and we conduct data recovery testing, security audits, and ongoing risk assessments, including due diligence on our key vendors, CROs, and other contractors and suppliers. We also conduct regular employee trainings on cyber and information security, among other topics. In addition, we consult with outside advisors and experts, including our SOC, on a regular basis to assist with assessing, identifying, and managing cybersecurity risks, including to anticipate future threats and trends, and their impact on the Company's risk environment. Recently, we implemented a Data Loss Prevention ("DLP") solution designed to identify, monitor, and protect sensitive information from unauthorized access, transfer, or exfiltration. Our DLP controls provide real time detection and alerting for anomalous data movement, enforce policies governing the use and sharing of confidential and personal information, and help confirm that data remains protected across endpoints, cloud applications, email, and other communication channels. These capabilities, combined with ongoing monitoring and periodic policy reviews, are designed to mitigate risks associated with data leakage, insider threats, and accidental or malicious misuse of sensitive information.

Our Associate Vice President of IT, who reports directly to the Chief Financial Officer and has over 10 years of experience managing information technology and cybersecurity matters and holds various EC-Council certifications including "Certified Chief Information Security Officer", "Certified Ethical Hacker" and "Computer Hacking Forensic Investigator", together with our senior leadership team, is responsible for assessing and managing cybersecurity risks. We consider cybersecurity, along with other significant risks that we face, within our overall enterprise risk management framework. Since the beginning of the last fiscal year, we have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, but we face certain ongoing cybersecurity risks threats that, if realized, are reasonably likely to materially affect us. Additional information on cybersecurity risks we face is discussed in Part I, Item 1A, "Risk Factors", under the headings "*A cybersecurity incident or failure in our information technology and storage systems or those of third parties upon whom we rely could significantly disrupt the operation of our business and adversely impact our financial condition*" and "*Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations*."

PART I

The Board of Directors, as a whole and at the committee level, has oversight for the most significant risks facing us and for our processes to identify, prioritize, assess, manage, and mitigate those risks. The Audit Committee, which is comprised solely of independent directors, has been designated by our Board of Directors to oversee cybersecurity risks. The Audit Committee receives regular updates on cybersecurity and information technology matters and related risk exposures from our Chief Financial Officer, as well as our Associate Vice President of IT. The Board of Directors also receives updates from management and the Audit Committee on cybersecurity risks on at least an annual basis.

Item 2. Properties

Our corporate headquarters are located in Zug, Switzerland, where we occupy approximately 4,000 square feet of office space under two open-ended office lease agreements. We use this facility for administrative purposes. In addition, we have facilities in Cambridge, UK, where we occupy approximately 6,000 square feet of office space under a 3-year term agreement set to expire in October 2026. This facility serves as working space primarily for our research and development teams. Lastly, we have facilities in Porto, Portugal, where we occupy approximately 3,900 square feet of office space under a 3-year initial term agreement set to expire in October 2026, with two extendable periods of 3 years each, the first of which we expect to exercise through October 2029, and approximately 2,000 square feet of office space under a 2-year initial term agreement set to expire in October 2026, with two extendable periods of 3 years each, the first of which we expect to exercise through October 2029. These facilities serve as working space for our general and administrative teams. We believe that our facilities are sufficient to meet our current needs. We also believe we will be able to obtain additional space, as needed, on commercially reasonable terms.

Item 3. Legal Proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors, and there can be no assurances that favorable outcomes will be obtained.

On October 15, 2025, a lawsuit captioned *Bridgewood v. MoonLake Immunotherapeutics, et al.*, Case No. 1:25-cv-8500 (the "Bridgewood Action") was filed in the United States District Court for the Southern District of New York, naming the Company, its Chief Executive Officer, and its Chief Financial Officer as defendants. The Bridgewood Action was purportedly brought on behalf of a class of all investors who purchased or otherwise acquired the Company's common stock between March 10, 2024, through September 29, 2025 (the "Class Period"). The complaint alleged claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended ("Exchange Act"), based on allegedly false or misleading statements related to the clinical benefits and prospects of SLK. The lawsuit sought unspecified damages and other relief. On October 22, 2025, the plaintiff voluntarily dismissed without prejudice the Bridgewood Action.

On October 17, 2025, a second putative class action captioned *Peters v. MoonLake Immunotherapeutics, et al.*, Case No. 1:25-cv-8612 (the "Peters Action" and, together with the Bridgewood Action, the "Class Actions") was filed in the United States District Court for the Southern District of New York (the "Court"). The Peters Action names the same defendants, contains identical allegations of alleged violations of the Exchange Act, covers the same Class Period, and seeks the same relief as the Bridgewood Action. On January 6, 2026, the Court appointed lead plaintiff and lead counsel.

The defendants deny the allegations of wrongdoing in the Class Actions and intend to vigorously defend against the claims. The Company is unable to predict the ultimate outcome of the Peters Action and therefore cannot estimate the reasonably possible loss or range of loss, if any, that may result from the lawsuit.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our Class A Ordinary Shares are currently listed on the Nasdaq Capital Market ("Nasdaq") and trade under the symbol "MLTX".

Holders

As of February 1, 2026, there were seven holders of record of our Class A Ordinary Shares.

Dividend Policy

We have not paid any cash dividends on our ordinary shares to date and do not intend to pay any cash dividends for the foreseeable future. The payment of cash dividends in the future will be dependent upon our revenues and earnings, if any, capital requirements and general financial condition. The payment of any cash dividends is within the discretion of our Board of Directors.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Recent Sales of Unregistered Securities

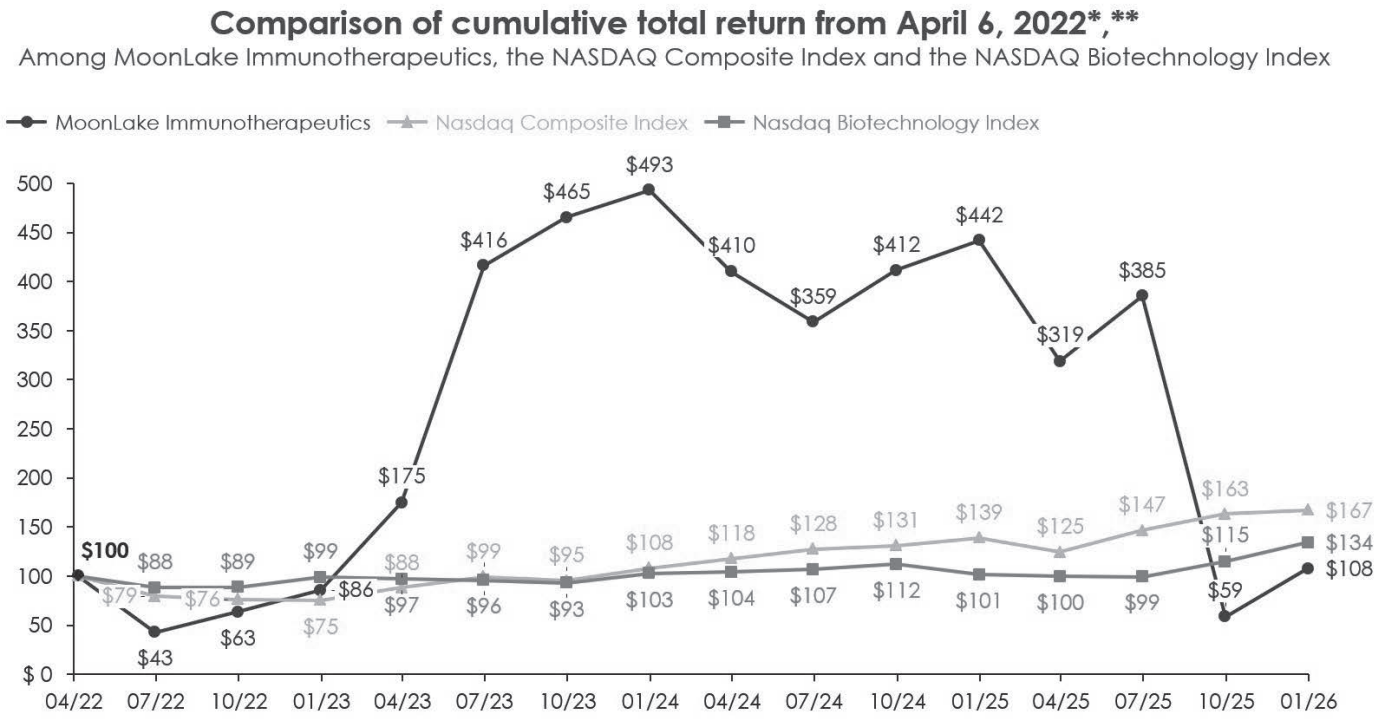
None.

Performance Graph

The following is not deemed "filed" with the Securities and Exchange Commission and is not to be incorporated by reference into any filing we make under the Securities Act of 1933, as amended, whether made before or after the date hereof and irrespective of any general incorporation by reference language in such filing.

The graph below compares the cumulative total shareholder return of $100 (and the reinvestment of any dividends thereafter) on April 6, 2022 (the first day our shares traded on Nasdaq following our consummation of the Business Combination in (i) our Class A Ordinary Shares, (ii) the Nasdaq Composite Index and (iii) the Nasdaq Biotechnology Index. The share price performance reflected in the graph below is not necessarily indicative of future performance.

PART II



April 6, 2022, represents the first day that our shares traded on Nasdaq following our consummation of the Business Combination (as defined in Item 1 – Our Corporate Information)

*** The comparisons in the graph are based on historical data and are not indicative of, or intended to forecast, future performance of our ordinary shares.*

Item 6. Reserved

PART II

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this Annual Report on Form 10-K. This discussion and analysis contain forward-looking statements based upon our current plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and beliefs. Our actual results and the timing of events could differ materially from those anticipated as a result of various factors, including those set forth under the section titled "Risk Factors" and included elsewhere in this Annual Report on Form 10-K. You should carefully read the sections titled "Note on Forward-Looking Statements" and "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from the results described below.

A discussion regarding our results of operations for the year ended December 31, 2024 compared to December 31, 2023 can be found under Part II - Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2024, which was filed with the Securities and Exchange Commission ("SEC") on February 26, 2025.

Overview

We are a clinical stage biotechnology company advancing therapies to address significant unmet needs in inflammatory skin and joint diseases. We are currently a single asset company focused on the development of Sonelokimab (*"SLK")*, a novel tri-specific IL-17A and IL-17F inhibiting Nanobody, that we exclusively licensed from Merck Healthcare KGaA, Darmstadt, Germany, an affiliate of Merck KGaA, Darmstadt, Germany ("MHKDG") and that has the potential, based on response levels seen in clinical trials, to drive disease modification in dermatology and rheumatology patients.

SLK is a proprietary Nanobody that was discovered by Ablynx N.V., Belgium, a Sanofi company ("Ablynx"), and previously studied by MHKDG and Avillion LLP ("Avillion") under a 2017 co-development agreement. The terms "Nanobody" and "Nanobodies" used herewith are registered trademarks of Ablynx. Nanobodies are able to bind selectively to a specific antigen with high affinity. Nanobodies have a fraction of the molecular weight compared to traditional antibodies. They offer a number of potential advantages over traditional monoclonal antibodies, including the potential to create multivalent molecules with enhanced ability to penetrate inflamed tissue, especially when containing an additional albumin binding domain such as SLK, an easier manufacturing process and a higher thermostability.

We currently develop SLK in inflammatory diseases in dermatology and rheumatology where the pathophysiology is known to be driven by IL-17A and IL-17F. This group of diseases comprises our current target diseases, hidradenitis suppurativa ("HS"), psoriatic arthritis ("PsA"), axial spondyloarthritis ("axSpA"), palmoplantar pustulosis ("PPP"), and several other inflammatory conditions, including psoriasis ("PsO"). Our current target diseases affect millions of people worldwide, and we believe there is a need for improved treatment options. We believe that SLK has a differentiated mechanism of action and that its purposefully designed molecular characteristics, including its small size and its albumin binding site, facilitate deep tissue penetration in the skin and joints. We envision SLK as a key therapeutic alternative in our initial target indications and potentially in multiple other IL-17 driven inflammatory conditions.

HS Trials and Plans for Commercial Launch

In May 2022, we initiated a Phase 2b trial of SLK in patients with moderate-to-severe HS (the MIRA trial (M1095-HS-201)), and in June 2023, we announced positive top-line results from this trial, which met its primary endpoint of Hidradenitis Suppurativa Clinical Response ("HiSCR") 75 with 43% of patients treated with SLK 120mg achieving such response at week 12. In October 2023, we announced positive 24-week top-line results showing that the maintenance treatment with SLK led to further improvements in HiSCR75 response rates and other clinically relevant outcomes in patients with moderate-to-severe HS. In February 2024, we announced the successful outcome of our end-of-Phase 2 interactions with the U.S. Food and Drug Administration ("FDA"), as well as positive feedback from our interactions with the E.U. European Medicines Agency ("EMA"), with both regulatory bodies supporting our proposed

approach for advancing our Phase 3 program of SLK in HS. In May 2024, we announced the screening of the first patients in the Phase 3 VELA-1 (M1095-HS-301) and VELA-2 trials (M1095-HS-302). In April 2025, we announced completion of enrollment of the VELA program and presented baseline characteristics of enrolled patients. In September 2025, we announced primary endpoint data from the VELA-1 and VELA-2 clinical trials. 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%, $p<0.001$). 34% of patients treated with SLK 120mg achieved a HiSCR75 response at the week 16 primary endpoint. In VELA-2, response rates associated with SLK were similar to those observed in VELA-1 (HiSCR75 response of 34%), but a 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%, $p=0.053$). Impact on HS lesions, including draining tunnels, was matched by improvements in all key Patient Reported Outcomes ("PROs"), such as quality-of-life and pain scores, that are meaningful for HS patients and their treating physicians. The safety profile of SLK was consistent with previously reported studies with no new safety signals observed. This included the absence of new signals in key events of interest with IL-17A and F therapies such as Suicidal Ideation and Behavior, hepatic events, Inflammatory Bowel Disease ("IBD") and non-infectious diarrhea, Major Adverse Cardiovascular Events ("MACE"), and Eczema and Dermatitis. In February 2026, we presented an interim analysis of the long-term data from the VELA trials, which indicated that monthly maintenance treatment with SLK can lead to further improvements in clinically relevant outcomes in patients with moderate-to-severe HS, including an as-observed HiSCR75 response rate of 69% in VELA-1 (n=104) and 67% in VELA 2 (n=123) after 52 weeks of treatment with SLK 120mg. The VELA trials are expected to continue to week 52, followed by an open-label extension for up to two years (the VELA-OLE trial (M1095-HS-303)). We expect the full one-year data of VELA-1 and VELA-2 to become available in the second quarter of 2026. In parallel, we are conducting a Phase 3 trial of SLK in adolescent patients with HS (the VELA-TEEN trial (M1095-HS-304)), which we initiated in January 2025. In February 2026, we presented an interim analysis of the VELA-TEEN clinical trial which showed that 67% of patients achieved a HiSCR75 response at week 16 (n=21). We expect to complete the VELA-TEEN clinical trial in mid-2026.

In November 2025, we were granted a Type B meeting with the FDA to discuss adequacy of the current clinical evidence package of SLK in HS to support a Biologics License Application ("BLA") and in January 2026, we announced positive feedback from this interaction, confirming that we may establish substantial evidence of effectiveness ("SEE") without additional clinical trials in HS. The FDA specifically advised to include the results of the MIRA trial together with the results of the VELA trials in the submission to establish SEE. Based on the positive feedback, we expect to submit a BLA for SLK in adult and adolescent HS in the second half of 2026. Subject to FDA approval, we expect a first commercial launch in the United States in the second half of 2027.

PsA Trials

In December 2022, we initiated a Phase 2b trial in patients with active PsA (the ARGO trial (M1095-PSA-201)), and in November 2023, we announced positive top-line results from this trial, which met its primary endpoint of American College of Rheumatology ("ACR") 50 with 46% of patients on 60mg SLK achieving such response at week 12. In March 2024, we announced positive 24-week data from the ARGO trial in PsA showing that continued treatment with SLK led to significant improvements across all key outcomes. In June 2024, we announced the successful outcome of our end-of-Phase 2 interactions with the FDA, as well as positive feedback from our interactions with the EMA, with both regulatory bodies supporting our proposed approach for advancing our Phase 3 program of SLK in PsA. In November 2024, we announced the screening of the first patients in the IZAR-1 trial (M1095-PSA-301) and IZAR-2 trial (M1095-PSA-302). In February 2026, we announced completion of enrollment for the IZAR-1 trial. We expect a readout of the primary and key secondary endpoints of the IZAR-1 clinical trial in mid-2026 and of the IZAR-2 clinical trial in the second half of 2026. In addition, in January 2025, we initiated another Phase 2 clinical trial of SLK in patients with PsA where we are applying novel imaging techniques (the P-OLARIS trial (M1095-snSpA-202)). We expect results of the P-OLARIS trial to become available at the end of 2026.

PPP Trials

In November 2024, we initiated a Phase 2 trial in patients with PPP (the LEDA trial (M1095-PPP-201)) and in November 2025, we presented positive results of this trial, suggesting that SLK could provide clinically meaningful improvements in patients with PPP. 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 ≥75% reduction in the PPPASI ("PPPASI75"). In February 2026, we announced that we received Fast Track designation from the FDA for SLK in moderate-to-severe PPP. We expect to commence a Phase 3 clinical trial in PPP in the third quarter of 2026.

axSpA Trials

In February 2025, we initiated a Phase 2 trial in patients with axSpA (the S-OLARIS trial (M1095-axSpA-202)) and in February 2026, we presented positive results of this trial, suggesting that SLK could provide clinically meaningful improvements in patients with axSpA. Of the patients (n=26) treated with SLK, 81% achieved an Assessment of Spondyloarthritis International Society 40 ("ASAS40") response at week 12, showing at least 40% improvement and an absolute improvement of ≥2 units on a numerical rating scale (0 to 10) from baseline in at least three of the four key domains (Patient Global Assessment ("PGA") of disease activity, total back pain, physical function, inflammation). More than 80% of patients have achieved a "clinically important improvement" as per ASDAS-CRP score by week 12, confirming the strong result in this clinically relevant endpoint.

PET and MRI imaging data collected as part of the clinical trial confirm a significant reduction in inflammation in the deep tissue of the spine and sacroiliac joint affected by axSpA in a pooled analysis comparing baseline to week 12. Additional objective biomarker and tissue analyses conducted as part of the clinical trial reinforce rapid and sustained effect of the treatment with SLK in axSpA patients. The safety profile of SLK in the S-OLARIS trial was consistent with previous trials with no new safety signals detected.

Additional Trials for Other Indications

SLK was also studied in a Phase 2b trial in PsO patients where it showed a significant improvement in the primary end point as compared with placebo and for which results were presented in peer-reviewed scientific publications and conferences. In addition, Phase 1 single ascending and multiple ascending dosing trials were previously completed.

Financial summary

We do not have any product candidates approved for commercial sale, and we have not generated any revenue from product sales. Our ability to generate revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of SLK in one or more indications, which we expect to take a number of years. We expect to continue to incur substantial expenses and operating losses for at least the next two years as we continue the development of SLK and prepare for commercial launches. We expect that operating losses will fluctuate notably from year to year depending on the timing of our planned clinical development programs, efforts to achieve regulatory approval, and planned marketing and sales expenditures leading up to a commercial launch.

As of December 31, 2025, we had $334.5 million in cash and cash equivalents. Based on our current operating plans and the Loan and Security Agreement (as defined below), we believe that our existing cash, cash equivalents and short-term marketable securities, together amounting to $394.0 million, will be sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2027.

Financial Operations Overview

Revenue

To date, we have not generated any revenue from product sales. If our development efforts for SLK are successful and result in regulatory approval or new license agreements with third parties, we may generate revenue in the future from product sales or milestone payments. However, there can be no assurance as to when we will generate such revenue, if at all.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including third-party license fees and efforts relating to the development of SLK. We expense research and development costs as incurred, which include:

- employee-related expenses, including salaries, bonuses, benefits, share-based compensation, and other related costs for those employees involved in research and development efforts;
- external research and development expenses incurred under agreements with Clinical Research Organizations ("CROs") as well as consultants that conduct our research program and development services;
- costs incurred under collaboration agreements;
- costs related to manufacturing material for our research program, clinical studies, and pre-launch inventory;
- costs related to compliance with regulatory requirements; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent, utilities and insurance.

We estimate research and clinical trial expenses based on the services performed pursuant to contracts with research institutions, CROs, and Clinical Manufacturing Organizations ("CMOs") that conduct and manage research studies and clinical trials on our behalf based on actual time and expenses incurred by them or probable achievement of milestone events that are associated with contractually agreed milestone payments.

We account for advance payments for goods and services that will be used in future research and development activities as expenses when the services have been performed or when the goods have been received rather than when the payment is made.

We do not allocate employee costs, facilities costs, including depreciation, or other indirect costs to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily for managing our research program, clinical development, and manufacturing activities.

The successful development of SLK is highly uncertain. We expect to incur considerable research and development expenses for the foreseeable future as we continue the development and manufacturing partnerships for SLK, conduct research activities and potentially expand our pipeline by pursuing additional indications for SLK or including new product candidates in our portfolio. We cannot determine with certainty the timing of initiation, the duration, or the completion costs of current or future research studies and clinical trials of SLK due to the inherently unpredictable nature of research activities and clinical development. Clinical development timelines, the probability of success and the development costs can differ materially from expectations. We anticipate that we will make determinations as to which indications to pursue and how much funding to direct to each indication on an ongoing basis in response to the results of ongoing and future research studies and clinical trials, regulatory developments, and our ongoing assessments as to each indication's commercial potential.

Any changes in the outcome of any of these variables with respect to the development of SLK could mean a notable change in the costs and timing associated with its development. We may never succeed in achieving regulatory approval for SLK. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify

clinical trials or focus on other product candidates. For example, if the FDA, the EMA, or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience delays in enrollment in any of our planned clinical trials, we could be required to expend additional financial resources and time on the completion of SLK's clinical development.

General and Administrative Expenses

General and administrative expense ("G&A") consists primarily of employee related costs, including salaries, bonuses, benefits, share-based compensation and other related costs for our executive and administrative functions. G&A expense also includes professional services, including legal, accounting and audit services and other consulting fees, as well as facility costs not otherwise included in research and development expenses, insurance and other general administrative expenses.

Based on our strategy, there are a number of factors that we expect will impact the level of research and development expenses, G&A expenses, and capital expenditures incurred by the business.

These factors include:

- *Completing the development of SLK in our current focus indications, HS, PsA, axSpA and PPP* — We expect to incur considerable research and development expenses, and G&A expenses as we: (i) conduct clinical trials for SLK including the ongoing Phase 3 clinical trials in HS, PsA and adolescent HS, the ongoing Phase 2 clinical trial in PsA, and potential future Phase 3 clinical trials in PPP and axSpA; (ii) attract, hire and retain additional clinical, scientific, quality control, and administrative personnel; and (iii) add clinical, operational, financial and management information systems and personnel.
- *Strengthening the differentiation elements for future SLK patients* — In parallel with our clinical trials, we expect to incur additional research expenditures as we conduct non-clinical research to continue refining our understanding of SLK/Nanobody biology and the potential impact in our selected therapeutic indications.
- *Preparing for commercialization of SLK* — We have started preparing the BLA to seek approval of SLK in the United States in HS and adolescent HS. We expect to incur research and development expense, and G&A expenses in this process, as we make milestone and commercial payments under the In-License Agreement, dated April 29, 2021, by and between MoonLake AG and MHKDG (the "In-License Agreement") (based on regulatory filing acceptances, first commercial sales, and aggregate annual net sales) and as we establish a sales, marketing and distribution infrastructure to commercialize SLK including establishing a presence in the United States. We expect to submit the BLA in the second half of 2026 after completion of the VELA program, and, subject to FDA approval, we expect a commercial launch in the United States in the second half of 2027.
- *Building our manufacturing capabilities* — We do not own or operate manufacturing facilities, and currently have no plans to establish any. We partner with third-party CMOs for both drug substance and finished drug product. We obtain our supplies from these manufacturers based on purchase orders. Therefore, we expect to incur research and development costs for the purchase of our supplies on an as needed basis to conduct our clinical trials. We have executed technology transfers for drug substance and drug product to commercial scale CMOs, and we have successfully manufactured Process Performance Qualification batches, but we may pursue additional technology transfers and process improvements. This is designed to allow us to scale up while SLK is in clinical development and advance potential commercial requirements. The improvement of our manufacturing capabilities will be important in driving efficiency, maintaining high standards of quality control, and ensuring that investigators, physicians, and patients have adequate access to our product candidates, if approved. We began stock-piling drug substance as pre-launch inventory during the third quarter of 2025 and expect to continue doing so in 2026.
- *Deepening our intellectual property portfolio to support our Nanobody technology and product candidates* — We expect to continue to incur additional research and development expenditures as we continue extending our global intellectual property portfolio consisting of patents and patent applications, trade secrets, trademarks, and know-how to protect the product candidates developed from our Nanobody technology. We

plan to expand our intellectual property portfolio as we continue to advance and develop existing product candidates.

- *Broadening our portfolio* — We believe that there are other indications beyond HS, PsA, axSpA and PPP where SLK has the potential to represent a differentiated therapeutic alternative and we may initiate clinical trials of SLK in such other indications. In addition, to further enhance our overall potential and provide increased optionality, we may supplement our current strategy with the in-licensing or acquisition of additional product candidates for clinical development (beyond SLK), rather than discovering such candidates ourselves, which would lead to additional research and development expenses, G&A expenses, and capital expenditures.
- *Granting share-based compensation awards and vesting of existing plans* — We expect to continue to grant awards to selected employees, directors and non-employees pursuant to the MoonLake Immunotherapeutics 2022 Equity Incentive Plan. Further, we expect to continue to incur share-based compensation charges in connection with the above-mentioned plan and the vesting of awards made under MoonLake AG's Employee Share Participation Plan.

We also expect to incur additional IT, legal, accounting, leasing, and other expenses as we continue to grow our business. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We expect our existing cash and cash equivalents to be sufficient to advance the development of SLK in multiple indications, including the above-mentioned clinical trials in HS, PsA, adolescent HS, PPP and axSpA, and to submit a BLA for SLK. Clinical development involves a lengthy and expensive process with uncertain outcomes and is subject to risks described in Item 1A. Risk Factors, including that our non-clinical studies or clinical trials may not be conducted as planned or completed on schedule and may not satisfy the requirements of the FDA, EMA, or other comparable foreign regulatory authorities. If we are required to conduct additional preclinical studies or clinical trials of SLK beyond those that we currently contemplate, if we are delayed or unable to successfully complete clinical trials of SLK or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may require additional funding. Moreover, we will require additional capital to commercialize SLK and to discover, develop, obtain regulatory approval and commercialize any future product candidates, as applicable. We expect to finance future cash needs through public or private equity, additional debt, or product collaborations. Additional capital may not be available in sufficient amounts or on reasonable terms, if at all. The current market environment for small biotechnology companies, like us, and broader macroeconomic factors may preclude us from successfully raising additional capital.

If we do not raise additional capital, we may not be able to expand our operations or otherwise capitalize on our business opportunities, our business and financial condition will be negatively impacted and we may need to: significantly delay, scale back or discontinue research and discovery efforts and the development or commercialization of SLK or any other product candidates or cease operations altogether; seek strategic alliances for research and development programs when we otherwise would not, or at an earlier stage than we would otherwise desire or on terms less favorable than might otherwise be available; or relinquish, or license on unfavorable terms, our rights to technologies or SLK or any other product candidates that we otherwise would seek to develop or commercialize ourselves.

Foreign Currency

Our functional currency is the U.S. dollar. Balances and transactions denominated in foreign currencies are converted as follows: monetary assets and liabilities are translated using exchange rates in effect at the balance sheet dates and non-monetary assets and liabilities are translated at historical exchange rates. Income and expenses are translated at the daily exchange rate on the respective transaction date.

Gains or losses from foreign currency transactions are included in the consolidated statements of operations and comprehensive loss in "Other income, net". We recognized a net foreign currency transaction gain of $599 thousand for the year ended December 31, 2025, a net foreign currency transaction loss of $42 thousand for the year ended December 31, 2024, and a net foreign currency transaction gain of $151 thousand for the year ended December 31, 2023.

Results of Operations

Comparison of the years ended December 31, 2025 and 2024

(in thousands, except percentages)	Year Ended December 31, 2025	Year Ended December 31, 2024	Change	Change %
Operating expenses				
Research and development	$ (202,862)	$ (112,771)	$ (90,091)	79.9 %
General and administrative	(41,972)	(30,320)	(11,652)	38.4 %
Total operating expenses	**(244,834)**	**(143,091)**	**(101,743)**	**71.1 %**
Operating loss	**(244,834)**	**(143,091)**	**(101,743)**	**71.1 %**
Interest expense	(7,248)	—	(7,248)	100.0 %
Other income, net	22,372	22,129	243	1.1 %
Loss before income tax	**(229,710)**	**(120,962)**	**(108,748)**	**89.9 %**
Income tax expense	(611)	(282)	(329)	116.4 %
Net loss	**(230,321)**	**(121,244)**	**(109,077)**	**90.0 %**
Net unrealized gain (loss) on marketable securities and short-term investments	(5,123)	2,686	(7,809)	(290.7) %
Actuarial gain (loss) on employee benefit plans	641	(87)	728	(836.8) %
Other comprehensive income (loss)	**(4,482)**	**2,599**	**(7,081)**	**(272.5)%**
Comprehensive loss	**$ (234,803)**	**$ (118,645)**	**$ (116,158)**	**97.9 %**

Research and Development

Research and development expenses were $202.9 million for the year ended December 31, 2025, compared to $112.8 million for the year ended December 31, 2024. The increase of $90.1 million, or 79.9%, is primarily related to an increase of $54.5 million in expenses pertaining to clinical development trials with CROs, including the Phase 3 VELA program in HS and the Phase 3 IZAR program in PsA, as well as the additional trials in adolescent HS (the VELA-TEEN trial), PPP (the LEDA trial), axSpA (the S-OLARIS trial) and PsA (the P-OLARIS trial), an increase of $21.6 million in manufacturing, supply and logistics expenses through CMOs, which is primarily related to the production of stockpiled pre-launch inventory, and increases of $5.5 million and $4.7 million in personnel-related costs and consulting expenses, respectively, to support our research and development efforts.

General and Administrative

General and administrative expenses were $42.0 million for the year ended December 31, 2025, compared to $30.3 million for the year ended December 31, 2024. The increase of $11.7 million, or 38.4%, is primarily related to an increase of $7.0 million in personnel-related costs, an increase of $3.2 million in expenses for advisory and professional services, both to support organizational growth, an increase of $1.4 million in legal expenses to support the Loan and

Security Agreement, and an increase of $0.7 million in market research expenses. These increases were partially offset by a decrease of $0.7 million for insurance expenses.

Interest Expense

Interest expense was $7.2 million for the year ended December 31, 2025, compared to $nil for the year ended December 31, 2024. The interest expense during the current period is related to recognized interest on the Loan and Security Agreement.

Other Income, Net

Other income, net was $22.4 million for year ended December 31, 2025, compared to $22.1 million for the year ended December 31, 2024. The increase of $0.2 million, or 1.1%, is primarily related to an increase of $0.6 million in net currency gains, partially offset by a decrease of $0.5 million in realized interest on cash held in banks and cash investments in short-term marketable debt securities.

Income Tax Expense

Income tax expense was $0.6 million for the year ended December 31, 2025, compared to $0.3 million for the year ended December 31, 2024. The expense for each period is related to corporate income tax of our subsidiaries in the United Kingdom and Portugal.

Other Comprehensive Income (Loss)

Other comprehensive loss was $4.5 million for the year ended December 31, 2025, compared to other comprehensive income of $2.6 million for the year ended December 31, 2024. The decrease in other comprehensive income of $7.1 million, or (272.5)%, is primarily related to the reclassification of unrealized gains from investments in short-term marketable debt securities recorded in accumulated other comprehensive income to other income, net during the year ended December 31, 2025.

Liquidity and Capital Resources

We have no products approved for commercial sale, have not generated any revenue from product sales, and cannot guarantee when or if we will generate any revenue from product sales.

We expect our expenses and capital requirements to remain consistent with our current spending levels as we continue to:

- contract with third parties, including CROs and CMOs, to support the clinical trials of SLK, including trials in HS, PsA, adolescent HS, PPP and axSpA, and to produce pre-launch inventory;
- conduct other research and development activities related to SLK;
- prepare for regulatory filing and commercialization of SLK;
- attract, hire and retain additional management, scientific and administrative personnel;
- maintain, protect and expand our intellectual property portfolio, including patents, trade secrets and know how;
- implement operational, financial and management information systems; and
- operate as a public company.

For the year ended December 31, 2025, we incurred a loss of $230.3 million, which includes non-cash items such as share-based compensation expense of $12.9 million, and cash outflow from operations of $196.0 million. As of December 31, 2025, we had a total of $394.0 million in cash, cash equivalents and short-term marketable securities. Based on our current operating plans and the Loan and Security Agreement, we believe our available cash, cash

equivalents, and short-term marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2027.

We expect to incur notable expenses and operating losses for at least the next two years, assuming we continue the clinical development of, and seek regulatory approval for, our product candidate under an in-licensing agreement. It is expected that operating losses will fluctuate significantly from year to year due to the timing of clinical development programs, efforts to achieve regulatory approval, and sales and marketing efforts. We may require additional funding to bring our product candidate to market and support our continuing operations. In addition, with a change in the presidential administration in 2025, there has been an economic policy shift towards increasing tariffs, which in turn has led and could lead to further retaliatory tariffs. These may have the potential to impact expenses as well as our ability to, if ever, generate revenue or maintain profitability. Until such time that we can generate significant revenue from product sales or other sources, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, which may include income from collaborations, strategic partnerships, or marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. If we are unable to acquire additional capital or resources, we will be required to modify our operational plans to fund our operating expense requirements. Refer to *"Risk Factors—Risks Related to Our Limited Operating History, Business, Financial Condition, and Results of Operations"* in this Annual Report on Form 10-K for further details related to the risk of raising additional capital to fund our operations.

Term Loan Facility

In March 2025, we entered into a loan and security agreement (the "Loan and Security Agreement") with Hercules Capital, Inc. ("Hercules") and certain of its affiliates (collectively with Hercules, the "Lenders") for an aggregate principal amount of $500.0 million, of which $300.0 million was fully committed subject to achievement of milestones (the "Credit Facility"). An initial tranche of $75.0 million (the "Tranche 1 Loan") was funded under the Loan and Security Agreement on March 31, 2025. In addition to the Tranche 1 Loan, the Credit Facility provides for additional tranches as follows:

a. Subject to our announcement that the VELA-1 and VELA-2 Phase 3 studies of SLK in adult patients with moderate to severe hidradenitis suppurativa each achieved their protocol-specified primary endpoint with SLK having demonstrated an acceptable safety profile (the "Tranche 2 Milestone"), a second tranche with additional term loans in an aggregate principal amount of up to $125.0 million, available on the Tranche 2 Milestone achievement date through the earlier of (i) 30 days following such date and (ii) December 31, 2025,
b. Subject to our announcement that the IZAR-1 and IZAR-2 Phase 3 studies of SLK in patients with active psoriatic arthritis each achieved their protocol-specified primary endpoint with SLK having demonstrated an acceptable safety profile (the "Tranche 3 Milestone"), a third tranche with additional term loans in an aggregate principal amount of up to $50.0 million, available on the Tranche 3 Milestone achievement date through the earlier of (i) 60 days following such date and (ii) September 15, 2026,
c. Subject to our achievement of the Tranche 2 Milestone and Tranche 3 Milestone and the FDA's acceptance of the Company's submission of a BLA for SLK (collectively, the "Tranche 4 Milestone"), a fourth tranche with additional term loans in an aggregate principal amount of up to $50.0 million, available on the Tranche 4 Milestone achievement date through the earlier of (i) 60 days following such date and (ii) March 15, 2027, and
d. Subject to approval by the Lenders in their discretion, a fifth tranche of additional term loans in an aggregate principal amount of up to $200.0 million.

On September 28, 2025, we announced the primary endpoint results of the VELA-1 and VELA-2 Phase 3 studies. While VELA-1 met the primary endpoint, a higher-than-expected placebo response at week 16 precluded VELA-2 from meeting the pre-specified primary endpoint and, as a result, we did not achieve the Tranche 2 and Tranche 4 Milestones, reducing the committed amount under the Loan and Security agreement by $175.0 million. As of December 31, 2025, we had $250.0 million of remaining undrawn tranches, representing the aggregate principle amount available to be drawn under the Credit Facility.

The Credit Facility matures on April 1, 2030 (the "Maturity Date") and bears interest at an annual rate equal to the greater of (i) prime rate as reported in The Wall Street Journal plus 1.45% and (ii) 8.45% with the initial interest rate equal to 8.95%. As of December 31, 2025, the Credit Facility bears interest at 8.45%. This rate is subject to a 0.25% reduction upon achievement of the FDA's approval of a BLA for SLK. Certain additional commitment and undrawn amount fees are also payable in connection with the Credit Facility.

The Credit Facility does not provide for scheduled amortization payments during the term. All principal will be due on the Maturity Date. We may, at our option at any time, prepay all loans under the Credit Facility by paying the principal balance, plus accrued and unpaid interest, subject to (i) a prepayment premium equal to a range of 2.0% to 0.0% and (ii) an end of term charge equal to a range of 6.95% to 4.25%, each based on when the prepayment occurs. If the Credit Facility is repaid in full as a result of a change of control of the Company, the prepayment premium shall be waived.

The Loan and Security Agreement allows for us to satisfy a portion of the cash interest payments by capitalizing such interest payments as payment-in-kind ("PIK"). No PIK interest relating to the term loan has been recorded and included in the consolidated balance sheets as of December 31, 2025.

All obligations under the Loan and Security Agreement will be secured on a first-priority basis, subject to certain exceptions, by security interests in substantially all of our assets and our material subsidiaries, including our intellectual property, and will be guaranteed by our material subsidiaries, including foreign subsidiaries, subject to certain exceptions.

The Loan and Security Agreement contains customary covenants, such as financial covenants and certain events of default after which loans under the Credit Facility may be due and payable immediately. We were in compliance with all covenants as of December 31, 2025.

On February 20, 2026 (the "Amendment Date"), we executed a first amendment to the Loan and Security Agreement (the "Amendment"), pursuant to which the parties agreed to, among other things, revise available tranches, milestone dates, and financial covenants, resulting in $25.0 million drawn as a second tranche upon execution of the Amendment, and up to $400.0 million remaining available as future tranches.

We are permitted to use the proceeds of the Credit Facility for working capital and general corporate purposes of the Company and our subsidiaries.

Equity Offerings

At-the-Market Offerings

On May 11, 2023, we entered into a Sales Agreement (the "May 2023 Sales Agreement") with Leerink Partners LLC (formerly known as SVB Securities LLC) ("Leerink Partners"), through which we could issue and sell up to $200.0 million of our Class A Ordinary Shares (the "May 2023 ATM Shares"), through Leerink Partners as sales agent. The May 2023 ATM Shares to be sold under the May 2023 Sales Agreement, if any, would be issued and sold pursuant to our shelf registration statement on Form S-3 (File No. 333-271546), which was declared effective by the SEC on May 9, 2023, and a prospectus supplement thereto filed with the SEC on May 11, 2023.

On June 27, 2023, we reduced the maximum aggregate offering amount of our Class A Ordinary Shares that could be issued and sold under the May 2023 Sales Agreement to $0 and no longer intend to sell Class A Ordinary Shares under the May 2023 Sales Agreement unless we file a further prospectus supplement indicating an amount of shares proposed to be sold.

On August 31, 2023, we entered into a Sales Agreement with Leerink Partners (the "August 2023 Sales Agreement" and together with the May 2023 Sales Agreement, the "Sales Agreements"), through which we could issue and sell up

to $350.0 million of our Class A Ordinary Shares (the "August 2023 ATM Shares"), through Leerink Partners as sales agent. The August 2023 ATM Shares to be sold under the August 2023 Sales Agreement, if any, would be issued and sold pursuant to our shelf registration statement on Form S-3 (File No. 333-274286), which was declared effective by the SEC on September 11, 2023, and a prospectus supplement thereto filed with the SEC on August 31, 2023. As of December 31, 2025, there was $265.0 million remaining for future sales under the August 2023 ATM Sales Agreement.

For the year ended December 31, 2024, we sold 914,828 Class A Ordinary Shares through the Sales Agreements for net proceeds of $52.5 million after deducting sales agent's commissions and transaction costs. For the three months and year ended December 31, 2025, there were no sales under the August 2023 Sales Agreement.

Public Offering of Class A Ordinary Shares

On June 27, 2023, we entered into an underwriting agreement with Leerink Partners and Guggenheim Securities LLC as the representatives of the underwriters named therein to issue and sell 8,000,000 Class A Ordinary Shares at a public offering price of $50.00 per share (the "2023 Offering"). In addition, we granted the underwriters an option for a period of 30 days to purchase up to an additional 1,200,000 Class A Ordinary Shares at the public offering price less the underwriting discounts and commissions (the "Option"), and such Option was exercised in full by the underwriters.

The 2023 Offering closed on June 30, 2023, and net proceeds, including proceeds from the exercise in full by the underwriters of the Option, were $436.7 million, after deducting the underwriting discounts and commissions and the offering expenses in the amount of $23.3 million.

Following the completion of the 2023 Offering, we opted to direct a substantial portion of the net proceeds to MoonLake Immunotherapeutics AG, a Swiss stock corporation (Aktiengesellschaft) registered with the commercial register of the Canton of Zug, Switzerland under the number CHE-433.093.536 ("MoonLake AG"). This was executed as a two-step process: (i) we acquired the remaining 22,756 common shares in MoonLake AG ("MoonLake AG Common Shares") held in treasury through a share purchase and assignment agreement formally executed on July 09, 2023 ($38.9 million) and (ii) additional funds were contributed to MoonLake AG's capital reserves through a cash contribution agreement formally executed on July 10, 2023 ($275 million). A stamp duty tax of $2.8 million was levied on the aforementioned capital contribution which we have classified as cash flows from financing activities in order to correctly mirror the underlying nature of the transaction.

On March 8, 2024, we executed a similar transaction as a two-step process: (i) we acquired 501 MoonLake AG Common Shares held in treasury through a share purchase and assignment agreement ($0.8 million) and (ii) we contributed an additional $150.0 million of funds to MoonLake AG's capital reserves through a cash contribution. A stamp duty tax of $1.5 million, net of refund received, was levied on the capital contribution which we have classified as cash flows from financing activities in order to correctly mirror the underlying nature of the transaction. The aforementioned increase in treasury shares occurred during the three months ended March 31, 2024 as a result of an employee termination entitling MoonLake AG to repurchase such employee's unvested shares (501 MoonLake AG Common Shares and 16,853 Class C Ordinary Shares) previously awarded as part of a share-based compensation program. Since the shares were subsequently sold to MoonLake, the corresponding Class C Ordinary Shares were canceled.

On November 5, 2025, we entered into an underwriting agreement with Leerink Partners as the underwriter, to issue and sell 7,142,857 Class A Ordinary Shares at a public offering price of $10.50 per share (the "2025 Offering"). The 2025 Offering closed on November 6, 2025, and net proceeds from the 2025 Offering were $72.4 million, after deducting the underwriting discounts, commissions, and offering expenses in the amount of $2.6 million.

Cash Flows

The following table summarizes our cash flows for the periods indicated.

(in thousands)	Year Ended December 31, 2025	Year Ended December 31, 2024	Change	Change %
Net cash used in operating activities	$ (196,007)	$ (116,587)	$ (79,420)	68.1 %
Net cash provided by (used in) investing activities	202,992	(205,596)	$ 408,588	(198.7) %
Net cash provided by financing activities	145,997	51,312	94,685	184.5 %
Effect of movements in exchange rates on cash held	1,109	128	981	766.4 %
Net increase (decrease) in cash and cash equivalents	**$ 154,091**	**$ (270,743)**	**$ 424,834**	**(156.9)%**

Cash Flows from Operating Activities

We did not generate any cash inflows from our operating activities. Our cash flows from operating activities are significantly influenced by our use of cash for operating expenses and working capital requirements, and we have historically experienced negative cash flows from operating activities as we invested in clinical research and related development.

Net cash used in operating activities was $196.0 million and $116.6 million for the year ended December 31, 2025 and 2024, respectively. The increase of net cash used in operating activities of $79.4 million was primarily driven by the increase in net loss of $109.1 million, a decrease in cash from changes in accrued expenses and other current liabilities of $2.6 million and an increase in cash paid for changes in other non-current assets of $0.6 million. The increase in cash used was partially offset by a decrease in cash paid for changes in prepaid expenses of $13.5 million and an increase in cash from changes in trade and other payables of $13.4 million.

Cash Flows from Investing Activities

During the year ended December 31, 2025, net cash provided by investing activities was $203.0 million, consisting predominantly of $468.4 million in proceeds received from maturities of short-term marketable debt securities, partially offset by $265.4 million related to the purchase of short-term marketable debt securities. During the year ended December 31, 2024, net cash used in investing activities was $205.6 million, consisting predominantly of $350.3 million related to the purchase of short-term marketable debt securities, partially offset by $145.2 million in proceeds received from maturities of short-term marketable debt securities with original maturities longer than three months.

Cash Flows from Financing Activities

During the year ended December 31, 2025, net cash provided by financing activities was $146.0 million consisting primarily of $73.0 million in net proceeds from the Loan and Security Agreement and $72.4 million in net proceeds from the shares sold under the 2025 Offering. During the year ended December 31, 2024, net cash provided by financing activities was $51.3 million consisting primarily of $52.5 million in net proceeds from the shares sold under the August 2023 Sales Agreement.

Contractual Obligations and Commitments

The following summarizes our significant contractual obligations and other obligations as of December 31, 2025, which we generally expect to satisfy with cash on hand and the maturity of short-term marketable debt securities:

(in thousands)	Total	Less than 1 year	1 to 5 Years	More than 5 years
Purchase obligations[1]	$ 204,934	$ 141,706	$ 63,228	$ —
Lease commitments[2]	1,666	1,272	394	$ —
Long-term debt obligations[3]	107,517	5,880	101,637	$ —
Total contractual obligations	**$ 314,117**	**$ 148,857**	**$ 165,259**	**$ —**

(1) Purchase obligations refer to an agreement to purchase goods or services that is enforceable and legally binding on the Company that specifies all significant terms. The figures presented primarily relate to contractual commitments towards contract manufacturing and contract research organizations.

(2) We have committed ourselves to five leases, with terms that commenced on November 1, 2021, October 9, 2023, October 13, 2023, January 15, 2024, and September 8, 2024. These future lease commitments relate to the office leases for our headquarters in Zug, Switzerland, Cambridge, United Kingdom, and Porto, Portugal, and reflect minimum payments due.

(3) We have committed ourselves to a long-term debt obligation, with a term that commenced on March 31, 2025. This debt obligation relates to the Loan and Security Agreement and reflects the expected payments due, including principal repayment, interest payments, and an end of loan term charge.

Critical Accounting Policies and Estimates

The preparation of the consolidated financial statements in accordance with U.S. GAAP requires us to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. We continually evaluate these judgments, estimates and assumptions based on the most recently available information, our own historical experience and various other assumptions that we believe to be reasonable under the circumstances. Since the use of estimates is an integral component of the financial reporting process, actual results could differ from our expectations as a result of changes in estimates.

An accounting policy is considered critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time such an estimate is made, and if different accounting estimates that reasonably could have been used, or changes in the accounting estimates that are reasonably likely to occur periodically, could materially impact the financial statements. Accordingly, these are the policies we believe are the most critical to aid in fully understanding and evaluating our financial condition, results of operations, and cash flows.

Acquisitions

We evaluate acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first assessing whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. The In-License Agreement for the SLK program has been accounted for as an asset purchase on the basis that there were no tangible assets acquired or liabilities assumed by us under the In-License Agreement and substantially all of the fair value of the gross assets acquired related to the in-process research and development expenditure ("IPR&D") of SLK. IPR&D represents incomplete technologies we acquire, which at the time of acquisition, are still under development and have no alternative future use.

Share-Based Compensation

We measure all share-based awards granted to employees, directors and non-employees based on the fair value on the date of grant and recognize compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. Forfeitures are accounted for as they occur. We grant share options and restricted share awards that are subject to either service or performance-based vesting conditions.

We classify share-based compensation expense in our consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

All awards granted under our various share-based compensation plans are classified as equity-settled share-based arrangements and depending on the relevant equity plan, are settled with shares of MoonLake or MoonLake AG, as applicable.

Prior to the completion of the transactions (the "Business Combination") contemplated by that certain Business Combination Agreement, dated October 4, 2021 (the "Business Combination Agreement"), by and among the Company (formerly Helix Acquisition Corp. ("Helix")), MoonLake AG, the existing equityholders of MoonLake AG set forth on the signature pages to the Business Combination Agreement and the equityholders of MoonLake AG that executed joinders to the Business Combination Agreement (collectively, the "ML Parties"), Helix Holdings LLC, a Cayman Islands limited liability company and the sponsor of Helix, and the representative of the ML Parties, given that there had been no public market for MoonLake AG Common Shares, the estimated fair value of MoonLake AG Common Shares was determined by reference to separate market-based transactions involving the sale of its shares to two third-party investors that were not considered related parties to us or MHKDG.

Subsequent to the closing of the Business Combination, the fair value of each MoonLake AG Common Share granted is determined based on the closing price of MoonLake's Class A Ordinary Shares as reported by Nasdaq on the date of grant and multiplied by 33.638698.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model, which requires inputs based on certain subjective assumptions, including the expected share price volatility, the expected term of the award, the risk-free interest rate, and expected dividends.

We estimate our expected share price volatility based on the historical volatility of publicly traded peer companies and expect to continue to do so until such time as we have adequate historical data regarding the volatility of our own traded share price. The expected term of options granted has been determined based on the expected period that share-based awards are expected to be outstanding. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that we have never paid cash dividends on MoonLake AG Common Shares and do not expect to pay any cash dividends in the foreseeable future.

Recoverability of Deferred Tax Assets

In assessing the recoverability of our deferred tax assets, we considered whether it was more likely than not that some or all of our deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. We considered the scheduled reversal of deferred tax liabilities, the seven-year expiry of tax losses carried forward under Swiss tax legislation, projected future taxable income (including the risks associated with the completion of the development and obtaining regulatory approvals to commercialize the product), and tax planning strategies in making this assessment. Based on the weight of all evidence, we determined that it is not more likely than not that the net deferred tax assets will be realized. A valuation allowance has been recorded against the full amount of the deferred tax assets.

Research and Development Contract Costs and Accruals

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined

schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors, including research laboratories, in connection with preclinical development activities;
- CROs and investigative sites in connection with preclinical studies and clinical trials; and
- CMOs in connection with drug substance and drug product formulation of preclinical studies, clinical trial materials, and pre-launch inventory.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that supply, conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period.

Recently Issued Accounting Pronouncements

Refer to Note 2 — *Basis of Presentation and Significant Accounting Policies* to the consolidated financial statements included in Part IV, Item 15 of this Form 10-K for more information about recent accounting pronouncements, the timing of their adoption, and our assessment to the extent it has been made, of their potential impact on our financial condition, our results of operations, and cash flows.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

As of December 31, 2025, we have cash and cash equivalents and short-term marketable securities of $394.0 million, which consist primarily of bank deposits and certificates of deposit. The investments in these financial instruments are made in accordance with an investment policy which specifies the categories, allocations and ratings of securities permissible for investment. The primary objective of the investment activities is non-trading related and instead to preserve principal as well as maximizing income received without significantly increasing risk.

To minimize any inherent market risk, we maintain a diverse and highly liquid portfolio which includes cash, cash equivalents, and short-term investment securities available-for-sale in a variety of securities including certificates of deposit, all with various maturity dates. The fair value of the cash, cash equivalents, and short-term investments would not be significantly affected by either an increase or decrease in interest rates due to the short-term maturities of these instruments. Since they are classified as “available-for-sale”, no gains or losses are recognized in the consolidated statements of operations and comprehensive loss due to changes in interest rates unless such securities are sold prior to maturity or declines in fair value are due to credit losses. We have the ability to hold all such investments until maturity. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material effect on our financial results or financial condition as of December 31, 2025.

As of December 31, 2025, we had $74.1 million in variable rate debt outstanding. The Tranche 1 Loan, which had a principal balance of $75.0 million, matures in April 2030, with interest-only monthly payments. The Tranche 1 Loan

bears interest at a floating rate equal to 8.45% as of December 31, 2025, calculated as the greater of: (i) the prime rate as reported in the Wall Street Journal plus 1.45% and (ii) 8.45%. A hypothetical 1% change in interest rate during any of the periods presented would not have had a material effect on our financial results or financial condition as of December 31, 2025.

We do not hold or issue derivatives, derivative commodity instruments, or other financial instruments for speculative trading purposes.

Item 8. Financial Statements and Supplementary Data

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of those financial statements is found in Item 15, Exhibits and Financial Statement Schedules, of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed by us in our reports filed under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

As of December 31, 2025, our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2025, our disclosure controls and procedures were effective at the reasonable assurance level.

Management’s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) under the Exchange Act). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

As of December 31, 2025, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control - Integrated Framework (2013 Framework). Based on this assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2025.

The effectiveness of our internal control over financial reporting as of December 31, 2025 has been audited by Baker Tilly US, LLP, an independent registered public accounting firm, as stated in their report which is included in Item 15, Exhibits and Financial Statements Schedules, of this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act) during the three months ended December 31, 2025, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls and Procedures

The effectiveness of any system of internal control over financial reporting is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs. Lastly, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Item 9B. Other Information

Trading Arrangements

On October 26, 2025, Dr. Kristian Reich, the Chief Scientific Officer of the Company, terminated a trading plan that was originally adopted on June 26, 2025. This plan was intended to satisfy the affirmative defense of Rule 10b5-1(c) and provided for the sale, subject to certain conditions, of up to 300,000 Class A Ordinary Shares through March 31, 2026.

On December 10, 2025, Mr. Matthias Bodenstedt, the Chief Financial Officer of the Company, terminated a trading plan that was originally adopted on June 17, 2025. This plan was intended to satisfy the affirmative defense of Rule 10b-1(c) and provided for the sale, subject to certain conditions, of up to 300,000 Class A Ordinary Shares through March 31, 2026.

On December 10, 2025, Mr. Bodenstedt, the Chief Financial Officer of the Company, adopted a trading plan intended to satisfy the affirmative defense of Rule 10b-1(c). Mr. Bodenstedt's plan provides for the sale, subject to certain conditions, of up to 385,870 Class A Ordinary Shares through December 31, 2026.

During the three months ended December 31, 2025, no other director or Section 16 officer of the Company adopted or terminated any “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement”, as each term is defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 is incorporated herein by reference to information in our proxy statement for our 2026 Annual General Meeting of Shareholders (the "2026 Proxy Statement"), which we expect to be filed with the SEC within 120 days of the end of our fiscal year ended December 31, 2025, including under the headings "Election of Directors", "Corporate Governance", "Insider Trading Policy", "Executive Officers" and, as applicable, "Delinquent Section 16(a) Reports".

We have adopted a Code of Business Conduct and Ethics (the "Code of Ethics") that applies to all of our directors, officers and employees, including our principal executive, principal financial and principal accounting officers, or persons performing similar functions. Our Code of Ethics is posted on our website located at https://ir.moonlaketx.com/, under "Corporate Governance". We intend to disclose future amendments to certain provisions of the Code of Ethics, and waivers of the Code of Ethics granted to executive officers and directors, on the website within four business days following the date of the amendment or waiver.

Item 11. Executive Compensation

The information required by this Item 11 is incorporated herein by reference to information in the 2026 Proxy Statement, including under the headings "Compensation Committee Interlocks", "Director Compensation", "Executive Compensation" and "Report of the Compensation Committee".

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item 12 is incorporated herein by reference to information in the 2026 Proxy Statement, including under the heading "Certain Information About Our Ordinary Shares".

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item 13 is incorporated herein by reference to information in the 2026 Proxy Statement, including under the headings "Corporate Governance" and "Certain Relationships and Related Party Transactions".

Item 14. Principal Accountant Fees and Services

The information required by this Item 14 is incorporated herein by reference to information in the 2026 Proxy Statement, including under the heading "Ratification of Independent Auditor Selection".

PART IV. FINANCIAL INFORMATION

Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as part of this report:

(a) Financial Statements:

Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2025 and 2024	F-4
Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2025, 2024 and 2023	F-5
Consolidated Statements of Changes in Equity for the Years Ended December 31, 2025, 2024 and 2023	F-6
Consolidated Statements of Cash Flows for the Years Ended December 31, 2025, 2024 and 2023	F-9
Notes to Consolidated Financial Statements	F-10

(b) Financial Statement Schedules:

All financial statement schedules have been omitted because they are not applicable, not required, or the information required is shown in the financial statements or the notes thereto.

(c) Exhibits.

The following exhibits are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K.

No.	Description of Exhibit
2.1†	Business Combination Agreement, dated as of October 4, 2021, by and among Helix Acquisition Corp., MoonLake Immunotherapeutics AG, the existing shareholders and option rights holders of MoonLake Immunotherapeutics AG, Helix Holdings LLC, and Matthias Bodenstedt (incorporated by reference to Exhibit 2.1 of the Company's Form 8-K, filed with the SEC on October 4, 2021).
3.1	Memorandum and Articles of Association of MoonLake Immunotherapeutics (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on April 11, 2022).
4.1*	Description of Securities.
10.1	Amended and Restated Shareholders' Agreement, dated as of April 5, 2022, by and among MoonLake Immunotherapeutics, MoonLake Immunotherapeutics AG and the investors signatory thereto (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K, filed with the SEC on April 11, 2022).
10.2	Amended and Restated Registration Rights Agreement, dated as of April 5, 2022, by and among MoonLake Immunotherapeutics, Helix Holdings LLC and the holders signatory thereto (incorporated by reference to Exhibit 10.5 of the Company's Form 8-K, filed with the SEC on April 11, 2022).
10.3	Form of Subscription Agreement (incorporated by reference to Exhibit 10.3 of the Company's Form 8-K, filed with the SEC on October 4, 2021).
10.4	Form of Subscription Agreement (incorporated by reference to Exhibit 10.7 of the Company's Form 8-K, filed with the SEC on April 11, 2022).
10.5	Form of Subscription Agreement (incorporated by reference to Exhibit 10.8 of the Company's Form S-1/A filed with the SEC on May 2, 2022).
10.6	MoonLake Immunotherapeutics 2022 Equity Incentive Plan (incorporated by reference to Exhibit 10.8 of the Company's Form 8-K, filed with the SEC on April 11, 2022).
10.7†#	Clinical and Commercial Manufacturing Agreement, dated April 11, 2022, effective July 1, 2021, by and between MoonLake Immunotherapeutics AG and Richter-Helm Biologics GmbH & Co. KG (incorporated by reference to Exhibit 10.12 of the Company's Form S-1/A, filed with the SEC on May 2, 2022).
10.8†#	License Agreement, dated April 29, 2021, by and between MoonLake Immunotherapeutics AG and MERCK Healthcare KGaA (incorporated by reference to Exhibit 10.9 of the Company's Form S-1/A, filed with the SEC on March 14, 2022).
10.9	Side Letter to License Agreement, dated April 29, 2021, by and between MoonLake Immunotherapeutics AG and MERCK Healthcare KGaA. (incorporated by reference to Exhibit 10.10 of the Company's Form S-1/A, filed with the SEC on March 14, 2022).
10.10†#	Novation, Amended and Restatement of License Agreement, dated June 1, 2023, between MoonLake Immunotherapeutics AG, Research Corporation Technologies, Inc. and Merck KGaA (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 10, 2023).
10.11	Sales Agreement, by and between the Company and Leerink Partners, dated August 31, 2023 (incorporated by reference to Exhibit 1.2 to the Company's Registration Statement on Form S-3 filed with the SEC on August 31, 2023).
10.12#	Loan and Security Agreement, dated March 31, 2025, by and among the Company, MoonLake AG, the Lenders party thereto and Hercules Capital, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 12, 2025).

10.13+	Form of Restricted Stock Award (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 12, 2025).
10.14+	Employment Agreement, dated April 30, 2021, by and between MoonLake Immunotherapeutics AG and Dr. Jorge Santos da Silva (incorporated by reference to Exhibit 10.14 of the Company's Form S-1/A, filed with the SEC on March 8, 2022).
10.15+	Amendment to Employment Agreement, dated September 9, 2021, by and between MoonLake Immunotherapeutics AG and Dr. Jorge Santos da Silva (incorporated by reference to Exhibit 10.15 of the Company's Form S-1/A, filed with the SEC on March 8, 2022).
10.16+	Employment Agreement, dated April 30, 2021, by and between MoonLake Immunotherapeutics AG and Prof. Dr. Kristian Reich (incorporated by reference to Exhibit 10.16 of the Company's Form S-1/A, filed with the SEC on March 8, 2022).
10.17+	Amendment to Employment Agreement, dated November 8, 2021, by and between MoonLake Immunotherapeutics AG and Prof. Dr. Kristian Reich (incorporated by reference to Exhibit 10.17 of the Company's Form S-1/A, filed with the SEC on March 8, 2022).
10.18+	Employment Agreement, dated May 10, 2021, by and between MoonLake Immunotherapeutics AG and Matthias Bodenstedt (incorporated by reference to Exhibit 10.18 of the Company's Form S-1/A, filed with the SEC on March 8, 2022).
10.19+	Amendment to Employment Agreement, dated June 22, 2021, by and between MoonLake Immunotherapeutics AG and Matthias Bodenstedt (incorporated by reference to Exhibit 10.19 of the Company's Form S-1/A, filed with the SEC on March 8, 2022).
10.20†+	Board Member Agreement, dated September 25, 2021, by and between MoonLake Immunotherapeutics AG and Simon Sturge (incorporated by reference to Exhibit 10.23 of the Company's Form S-1/A, filed with the SEC on March 8, 2022).
10.21+	Form of Indemnification Agreement for directors and executive officers (incorporated by reference to Exhibit 10.32 of the Company's Form S-1/A, filed with the SEC on March 8, 2022).
10.22+	Form of Non-Employee Director Stock Option Agreement (incorporated by reference to Exhibit 10.33 of the Company's Form 8-K, filed with the SEC on April 11, 2022).
10.23+	Employee Stock Option Plan of MoonLake Immunotherapeutics AG, dated June 22, 2022 (incorporated by reference to Exhibit 10.4 of the Company's Form S-8, filed with the SEC on September 30, 2022).
10.24+	Employee Share Participation Plan of MoonLake Immunotherapeutics AG, dated June 22, 2022 (incorporated by reference to Exhibit 10.7 of the Company's Form S-8, filed with the SEC on September 30, 2022).
10.25+	Form of Nonqualified Stock Option Agreement (incorporated by reference to Exhibit 10.25 of the Company's Annual Report on Form 10-K, filed with the SEC on March 20, 2023).
10.26+	Amended and Restated Employee Stock Option Plan of MoonLake Immunotherapeutics AG, dated June 15, 2023 (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 10, 2023).
10.27+	Amended and Restated Employee Share Participation Plan of MoonLake Immunotherapeutics AG, dated June 15, 2023 (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 10, 2023).
19.1*	Insider Trading Policy.
21.1	Subsidiaries of MoonLake Immunotherapeutics (incorporated by reference to Exhibit 21.1 of the Company's Annual Report on Form 10-K filed on February 29, 2024).
23.1*	Consent of Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (included on the signature page to this Annual Report on Form 10-K).
31.1*	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rules 13a-14(a) and 15(d)-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial and Accounting Officer Pursuant to Securities Exchange Act Rules 13a-14(a) and 15(d)-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

32.2**	Certification of Principal Financial and Accounting Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Incentive Compensation Clawback Policy (incorporated by reference to Exhibit 97.1 to the Company's Annual Report on Form 10-K filed with the SEC on February 29, 2024).
101.INS*	Inline XBRL Instance Document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.
** Furnished.
† The annexes, schedules, and certain exhibits to this Exhibit have been omitted pursuant to Item 601(a)(5).
+ Indicates a management contract or compensatory plan.
# Portions of the Exhibit have been omitted because they are both (i) customarily and actually treated as private and confidential and (ii) not material.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

MOONLAKE IMMUNOTHERAPEUTICS

		/s/ Dr. Jorge Santos da Silva
Date: February 25, 2026	Name:	Dr. Jorge Santos da Silva
	Title:	Chief Executive Officer (Principal Executive Officer)
		/s/ Matthias Bodenstedt
Date: February 25, 2026	Name:	Matthias Bodenstedt
	Title:	Chief Financial Officer (Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Dr. Jorge Santos da Silva and Matthias Bodenstedt, and each of them, the true and lawful attorneys-in-fact and agents of the undersigned, with full power of substitution and resubstitution, for and in the name, place and stead of the undersigned, to sign in any and all capacities (including, without limitation, the capacities listed below), this Annual Report on Form 10-K, any and all amendments thereto, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, and hereby grants to such attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and anything necessary to be done to enable the registrant to comply with the provisions of the Securities Exchange Act and all the requirements of the Securities and Exchange Commission, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his or her substitute, or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Dr. Jorge Santos da Silva Dr. Jorge Santos da Silva	Chief Executive Officer; Director (Principal Executive Officer)	February 25, 2026
/s/ Matthias Bodenstedt Matthias Bodenstedt	Chief Financial Officer (Principal Financial and Accounting Officer)	February 25, 2026
/s/ Simon Sturge Simon Sturge	Chairperson; Director	February 25, 2026

SIGNATURES

/s/ Spike Loy Spike Loy	Director	February 25, 2026
/s/ Catherine Moukheibir Catherine Moukheibir	Director	February 25, 2026
/s/ Dr. Andrew Phillips Dr. Andrew Phillips	Director	February 25, 2026
/s/ Dr. Ramnik Xavier Dr. Ramnik Xavier	Director	February 25, 2026

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MOONLAKE IMMUNOTHERAPEUTICS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of MoonLake Immunotherapeutics

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of MoonLake Immunotherapeutics and its subsidiaries (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, changes in equity, and cash flows, for each of the three years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2025, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2025 and 2024, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's consolidated financial statements and an opinion on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures to respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are

recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matter

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Baker Tilly US, LLP

Santa Clara, California

February 25, 2026

We have served as the Company’s auditor since 2021.

MOONLAKE IMMUNOTHERAPEUTICS

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)	December 31, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 334,517	$ 180,426
Short-term marketable debt securities	59,451	267,601
Other receivables	4,869	2,844
Prepaid expenses	22,857	23,418
Total current assets	**421,694**	**474,289**
Non-current assets		
Operating lease right-of-use assets	1,566	2,922
Property and equipment, net	577	722
Other non-current assets	596	—
Total non-current assets	**2,739**	**3,644**
Total assets	**$ 424,433**	**$ 477,933**
Liabilities and Equity		
Current liabilities		
Trade and other payables	$ 29,553	$ 8,992
Accrued expenses and other current liabilities	14,691	12,099
Short-term portion of operating lease liabilities	1,234	1,372
Total current liabilities	**45,478**	**22,463**
Non-current liabilities		
Long-term debt	74,100	—
Long-term portion of operating lease liabilities	374	1,458
Pension liability	—	621
Total non-current liabilities	**74,474**	**2,079**
Total liabilities	**119,952**	**24,542**
Commitments and contingencies (Note 16)		
Shareholders' equity		
Class A Ordinary Shares: $0.0001 par value per share; 500,000,000 shares authorized; 71,373,579 shares issued and outstanding as of December 31, 2025, 63,077,431 shares issued and outstanding as of December 31, 2024	7	6
Class C Ordinary Shares: $0.0001 par value per share; 100,000,000 shares authorized; no shares issued and outstanding as of December 31, 2025, 841,269 shares issued and outstanding as of December 31, 2024	—	—
Additional paid-in capital	766,781	677,415
Accumulated deficit	(462,911)	(235,593)
Accumulated other comprehensive income	604	4,997
Total shareholders' equity	**304,481**	**446,825**
Noncontrolling interests	—	6,566
Total equity	**304,481**	**453,391**
Total liabilities and equity	**$ 424,433**	**$ 477,933**

The accompanying Notes are an integral part of these Consolidated Financial Statements.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share data)	Year Ended December 31, 2025	Year Ended December 31, 2024	Year Ended December 31, 2023
Operating expenses			
Research and development	$ (202,862)	$ (112,771)	$ (31,802)
General and administrative	(41,972)	(30,320)	(22,321)
Total operating expenses	**(244,834)**	**(143,091)**	**(54,123)**
Operating loss	**(244,834)**	**(143,091)**	**(54,123)**
Interest expense	(7,248)	—	—
Other income, net	22,372	22,129	10,138
Loss before income tax	**(229,710)**	**(120,962)**	**(43,985)**
Income tax expense	(611)	(282)	(94)
Net loss	**$ (230,321)**	**$ (121,244)**	**$ (44,079)**
Of which: net loss attributable to controlling interests shareholders	*(227,318)*	*(118,936)*	*(36,007)*
Of which: net loss attributable to noncontrolling interests shareholders	*(3,003)*	*(2,308)*	*(8,072)*
Net unrealized gain (loss) on marketable securities and short-term investments	(5,123)	2,686	2,330
Actuarial gain (loss) on employee benefit plans	641	(87)	(336)
Other comprehensive income (loss)	(4,482)	2,599	1,994
Comprehensive loss	**$ (234,803)**	**$ (118,645)**	**$ (42,085)**
Comprehensive loss attributable to controlling interests shareholders	*(231,730)*	*(116,383)*	*(34,511)*
Comprehensive loss attributable to noncontrolling interests	*(3,073)*	*(2,262)*	*(7,574)*
Weighted-average number of Class A Ordinary Shares, basic and diluted	64,463,889	62,870,237	49,122,534
Basic and diluted net loss per share attributable to controlling interests shareholders	**$ (3.53)**	**$ (1.89)**	**$ (0.73)**

The accompanying Notes are an integral part of these Consolidated Financial Statements.

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

(in thousands except share data)	Class A Ordinary Shares		Class C Ordinary Shares		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Shareholders' Equity	Noncontrolling Interests	Total Equity
	Shares	Amount	Shares	Amount						
Balance at January 1, 2023	**38,977,600**	**$ 4**	**13,723,511**	**$ 1**	**$ 129,193**	**$ (80,650)**	**$ 351**	**$ 48,899**	**$ 19,868**	**$ 68,767**
Issuance of Class A Ordinary Shares under the 2023 Offering, net of transaction costs	10,270,818	1	—	—	482,453	—	—	**482,454**	**—**	**482,454**
Capital injection from MoonLake to MoonLake AG	—	—	—	—	(60,062)	—	1	**(60,061)**	**57,310**	**(2,751)**
Conversion of MoonLake Class C Ordinary Shares into Class A Ordinary Shares	11,218,035	1	(11,218,035)	(1)	52,479	—	510	**52,989**	**(52,989)**	**—**
Share-based compensation under the Employee Share Participation Plan, Employee Stock Option Plan, MoonLake Immunotherapeutics 2022 Equity Incentive Plan, and reverse vesting of Restricted Founder Shares	—	—	—	—	5,907	—	—	**5,907**	**1,199**	**7,106**
Refund of stamp duty fees	—	—	—	—	(1)	—	—	**(1)**	**1**	**—**
Net loss for the year ended December 31, 2023	—	—	—	—	—	(36,007)	—	**(36,007)**	**(8,072)**	**(44,079)**
Other comprehensive income	—	—	—	—	—	—	1,496	**1,496**	**498**	**1,994**
Balance at December 31, 2023	**60,466,453**	**$ 6**	**2,505,476**	**$ —**	**$ 609,969**	**$ (116,657)**	**$ 2,358**	**$ 495,676**	**$ 17,815**	**$ 513,491**

The accompanying Notes are an integral part of these Consolidated Financial Statements.

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

(in thousands except share data)	Class A Ordinary Shares		Class C Ordinary Shares		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Shareholders' Equity	Noncontrolling Interests	Total Equity
	Shares	Amount	Shares	Amount						
Balance at January 1, 2024	**60,466,453**	**$ 6**	**2,505,476**	**$ —**	**$ 609,969**	**$ (116,657)**	**$ 2,358**	**$ 495,676**	**$ 17,815**	**$ 513,491**
Issuance of Class A Ordinary Shares, net of transaction costs	914,828	—	—	—	52,540	—	—	52,540	—	52,540
Capital injection from MoonLake to MoonLake AG net of stamp duty fee refund	—	—	—	—	(4,577)	—	—	(4,577)	3,058	(1,519)
Conversion of MoonLake Class C Ordinary Shares into Class A Ordinary Shares	1,647,354	—	(1,647,354)	—	11,873	—	86	11,959	(11,959)	—
Share-based compensation under the Employee Share Participation Plan and MoonLake Immunotherapeutics 2022 Equity Incentive Plan	—	—	—	—	7,255	—	—	7,255	27	7,282
Buyback of unvested MoonLake AG Common Shares by MoonLake AG into treasury following an employee contract termination	—	—	—	—	113	—	1	114	(114)	—
Cancellation of MoonLake Class C Ordinary Shares following an employee contract termination in MoonLake AG	—	—	(16,853)	—	—	—	—	—	—	—
Options exercised under the Moonlake Immunotherapeutics 2022 Equity Incentive Plan	48,796	—	—	—	242	—	—	242	—	242
Net loss for the year ended December 31, 2024	—	—	—	—	—	(118,936)	—	(118,936)	(2,308)	(121,244)
Other comprehensive income	—	—	—	—	—	—	2,552	2,552	47	2,599
Balance at December 31, 2024	**63,077,431**	**$ 6**	**841,269**	**$ —**	**$ 677,415**	**$ (235,593)**	**$ 4,997**	**$ 446,825**	**$ 6,566**	**$ 453,391**

The accompanying Notes are an integral part of these Consolidated Financial Statements.

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

(in thousands except share data)	Class A Ordinary Shares		Class C Ordinary Shares		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Shareholders' Equity	Noncontrolling Interests	Total Equity
	Shares	Amount	Shares	Amount						
Balance at January 1, 2025	**63,077,431**	**$ 6**	**841,269**	**$ —**	**$ 677,415**	**$ (235,593)**	**$ 4,997**	**$ 446,825**	**$ 6,566**	**$ 453,391**
Share-based compensation under the Employee Share Participation Plan and MoonLake Immunotherapeutics 2022 Equity Incentive Plan	—	—	—	—	12,858	—	—	12,858	40	12,898
Conversion of MoonLake Class C Ordinary Shares into Class A Ordinary Shares	841,269	—	(841,269)	—	3,505	—	19	3,524	(3,524)	—
Options exercised and converted under the Employee Stock Option Plan, net of stamp duty fee	93,347	—	—	—	129	—	—	129	(9)	120
Options exercised under the MoonLake Immunotherapeutics 2022 Equity Incentive Plan	27,149	—	—	—	480	—	—	480	—	480
Issuance of Restricted Stock Awards under the MoonLake Immunotherapeutics 2022 Equity Incentive Plan	191,526	—	—	—	—	—	—	—	—	—
Issuance of Class A Ordinary Shares under the 2025 Offering, net of transaction costs	7,142,857	1	—	—	72,394	—	—	72,395	—	72,395
Net loss for the year ended December 31, 2025	—	—	—	—	—	(227,318)	—	(227,318)	(3,003)	(230,321)
Other comprehensive loss	—	—	—	—	—	—	(4,412)	(4,412)	(70)	(4,482)
Balance at December 31, 2025	**71,373,579**	**$ 7**	**—**	**$ —**	**$ 766,781**	**$ (462,911)**	**$ 604**	**$ 304,481**	**$ —**	**$ 304,481**

The accompanying Notes are an integral part of these Consolidated Financial Statements.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)	Year Ended December 31, 2025	Year Ended December 31, 2024	Year Ended December 31, 2023
Cash flow from operating activities			
Net loss	$ (230,321)	$ (121,244)	$ (44,079)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,616	1,385	370
Share-based compensation expense	12,898	7,282	7,106
Net periodic pension benefit (gain) loss for the qualified pension plan	(58)	1	(85)
Other non-cash items	(1,020)	(227)	128
Changes in operating assets and liabilities:			
Other receivables	(2,025)	(1,786)	(840)
Operating lease right-of-use assets	—	(6)	(66)
Prepaid expenses	561	(12,893)	(6,346)
Other non-current assets	(587)	—	—
Trade and other payables	20,560	7,155	1,583
Operating lease liabilities	(1,222)	(1,423)	(222)
Accrued expenses and other current liabilities	2,591	5,169	(327)
Net cash flow used in operating activities	**(196,007)**	**(116,587)**	**(42,778)**
Cash flow from investing activities			
Purchase of short-term marketable debt securities	(265,374)	(350,279)	(175,733)
Proceeds from maturities of short-term marketable debt securities	468,401	145,203	150,833
Purchase of property and equipment	(35)	(520)	(284)
Net cash flow provided by (used in) investing activities	**202,992**	**(205,596)**	**(25,184)**
Cash flow from financing activities			
Proceeds from long-term debt, net of issuance costs	73,022	—	—
Issuance of Class A Ordinary Shares, net of transaction costs	72,395	52,540	482,454
Stamp duty on capital injection from MoonLake to MoonLake AG	—	(1,470)	(2,753)
Proceeds from options exercised under the MoonLake Immunotherapeutics 2022 Equity Incentive Plan	480	242	—
Proceeds from options exercised under Employee Stock Option Plan	100	—	—
Net cash flow provided by financing activities	**145,997**	**51,312**	**479,701**
Effect of movements in exchange rates on cash held	1,109	128	(76)
Net change in cash and cash equivalents	**154,091**	**(270,743)**	**411,663**
Cash and cash equivalents, beginning of period	180,426	451,169	39,506
Cash and cash equivalents, end of period	**$ 334,517**	**$ 180,426**	**$ 451,169**
Supplementary disclosure of cash flow information:			
Cash paid for interest	$ 5,059	$ —	$ —
Non-cash operating lease right-of-use assets obtained in exchange for lease obligations	—	555	3,638

The accompanying Notes are an integral part of these Consolidated Financial Statements.

Note 1 — Overview of the Company

Corporate Information

MoonLake Immunotherapeutics ("the Company" or "MoonLake") is a clinical stage biotechnology company advancing therapies to address significant unmet needs in inflammatory skin and joint diseases. MoonLake Immunotherapeutics is currently a single asset company focused on the development of Sonelokimab ("SLK"), a novel tri-specific IL-17A and IL-17F inhibiting Nanobody that has the potential, based on response levels seen in clinical trials, to drive disease modification in dermatology and rheumatology patients. The Company's Class A Ordinary Shares are listed on the Nasdaq Capital Market (the "Nasdaq") under the trading symbol "MLTX".

The Company, a Cayman Islands exempted company was originally incorporated on August 13, 2020 under the name Helix Acquisition Corp. ("Helix") as a special purpose acquisition company, formed for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization, or similar business combination with one or more businesses. On April 5, 2022 Helix consummated such business combination with MoonLake Immunotherapeutics AG ("MoonLake AG"), a stock-based company incorporated in Switzerland in 2021, pursuant to that certain business combination agreement, dated October 4, 2021 (the "Business Combination Agreement"), by and among Helix, MoonLake AG, the existing equityholders of MoonLake AG set forth on the signature pages to the Business Combination Agreement and the equityholders of MoonLake AG that executed joinders to the Business Combination Agreement (collectively, the "ML Parties"), Helix Holdings LLC, a Cayman Islands limited liability company and the sponsor of Helix, and the representative of the ML Parties (such transactions contemplated by the Business Combination Agreement, collectively, the "Business Combination"). Pursuant to the Business Combination Agreement, Helix changed its name from "Helix Acquisition Corporation" to "MoonLake Immunotherapeutics", and MoonLake AG merged with and into Helix, with MoonLake AG as the surviving company in the Business Combination and, after giving effect to such Business Combination, MoonLake AG became a wholly-owned subsidiary of the Company. For financial accounting and reporting purposes, MoonLake AG was deemed the accounting acquirer and Helix was treated as the accounting acquiree, and the Business Combination was accounted for as a reverse recapitalization, in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Note 2 — Basis of Presentation and Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements include those of the Company and its subsidiaries, MoonLake AG, a Swiss stock corporation (Aktiengesellschaft) registered with the commercial register of the Canton of Zug, Switzerland under the number CHE-433.093.536, MoonLake Immunotherapeutics Ltd., a private limited company incorporated in the United Kingdom, and MNLK Immunotherapeutics, Unipessoal Lda, a private limited company incorporated in Portugal, after elimination of all intercompany accounts and transactions. The accompanying consolidated financial statements and notes hereto have been prepared in conformity with U.S. GAAP. Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

All amounts are presented in U.S. Dollar ("$"), unless otherwise indicated. The term and "CHF" refer to the legal currency of Switzerland, "GBP" refers to the legal currency of the United Kingdom, and "€" and "Euro" refer to the legal currency of Portugal.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses. Items of significance for the Company relate to:

- determining assumptions used in estimating the fair value of share-based compensation;
- estimating the recoverability of the deferred tax asset; and
- estimating the amount of accruals in connection with the completion of clinical trial milestones.

The Company bases its judgments and estimates on various factors and information, which may include, but are not limited to, the Company's forecasts and future plans, current economic conditions and observable market-based transactions of its own shares, the results of which form the basis for making judgments about the carrying value of assets and liabilities and recorded amounts of expenses that are not readily apparent from other sources. To the extent there are material differences between the Company's estimates and the actual results, the Company's future results of operation may be affected.

Segment Information

The Company operates as a single operating segment. The Company's chief operating decision maker ("CODM"), its Chief Executive Officer, manages the Company's operations on a stand-alone basis for the purposes of allocating resources, and assessing financial performance.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. Cash and cash equivalents are recorded at cost, which approximates fair value. The Company considers $nil and $59.7 million of short-term marketable debt securities in the form of eurocommercial papers and certificates of deposit to be cash equivalents as of December 31, 2025 and 2024, respectively.

Marketable Securities and Short-Term Investments

The Company invests in short-term marketable securities in the form of debt securities. At the time of purchase, the Company assesses whether such debt security should be classified as held-to-maturity or available-for-sale debt securities.

Debt securities are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Held-to-maturity debt securities are carried at amortized cost, adjusted for accretion of discounts or amortization of premiums to maturity computed under the effective interest method. Such accretion or amortization is included in "Other income, net". Marketable debt securities not classified as held-to-maturity are classified as available-for-sale and reported at fair value.

Net unrealized gains and losses on available-for-sale debt securities are excluded from the determination of earnings and are instead recognized in the "Accumulated other comprehensive income" component of shareholders' equity until realized. Realized gains and losses on available-for-sale debt securities are computed based upon the historical cost of these securities, using the specific identification method.

Interest income is recognized when earned. Realized gains and losses are included in "Other income, net" and the cost of securities sold is determined using the specific-identification method.

Marketable debt securities are classified as either "Cash and cash equivalents" or "Short-term marketable debt securities" according to their original maturity at the time of acquisition. Changes in unrealized gains and losses

pertaining to cash equivalent securities are added back into the consolidated statements of cash flows as those are excluded from the determination of earnings but impact the cash and cash equivalents position.

The Company estimates credit losses expected over the life of financial assets based on historical experience, current conditions and reasonable and supportable forecasts. There is no material impact to the consolidated financial statements given the investments are highly liquid thereby carrying negligible credit loss risk and are all held with reputable companies with a low risk of default.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash accounts in large financial institutions which, at times, may exceed the CHF 100,000 deposit protection limit in Switzerland, the $250,000 Federal Deposit Insurance Corporation deposit insurance coverage limit in the United States, the GBP 85,000 Financial Services Compensation Scheme deposit protection limit in the United Kingdom, or the €100,000 Fundo de Garantia de Depósitos deposit protection limit in Portugal. The Company believes it is not exposed to significant credit risk due to the financial strength of the depository institutions in which the cash and cash equivalents are held. Additionally, the Company ensures further protection against credit risk by diversifying its cash holdings across a variety of credit institutions, thereby minimizing the potential impact of any adverse events on a single institution. Further, the Company's investment strategy for cash (in excess of current business requirements) is set to invest in short-term marketable debt securities. Management actively monitors credit risk in the investment portfolio. Credit risk exposures are controlled in accordance with policies approved by the board of directors to identify, measure, monitor and control credit risks.

Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

There are three levels of inputs to fair value measurements:

- Level 1, meaning the use of quoted prices for identical instruments in active markets;
- Level 2, meaning the use of quoted prices for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active or are directly or indirectly observable; and
- Level 3, meaning the use of unobservable inputs. Observable market data is used when available.

Transfers between Levels 1, 2 or 3 within the fair value hierarchy are recognized at the end of the reporting period when the respective transaction occurred.

Long-Term Debt

Long-term debt is recognized as the amount of cash proceeds received plus the accreted present value of the End of Term Charge (as defined in the Loan and Security Agreement, as defined in Note 4 — *Debt*), less the unamortized End of Term Charge, debt issuance costs, and debt discount. It is subsequently reported at amortized cost. Interest expense is calculated using the effective interest method and any difference between the proceeds (net of unamortized debt discount, debt issuance costs, End of Term Charge, and accreted present value of End of Term Charge) and the principal amount is recognized through interest expense over the estimated life of the related debt. For the undrawn term loan tranches, allocated issuance costs are recorded as deferred charges - long-term debt, which is included in "Other non-current assets" on the Company’s consolidated balance sheets until drawn. In the case of a milestone event not being met or the tranche availability window expiring undrawn, the deferred asset will be recorded as interest expense on the Company's consolidated statements of operations and comprehensive loss.

Leases

The Company determines if an arrangement is or contains a lease at contract inception. For these arrangements, it is evaluated if the arrangement involves an identified asset that is physically distinct or whether the Company has the right to substantially all of the capacity of an identified asset that is not physically distinct. In arrangements that involve an identified asset, there is also judgment in evaluating if the Company has the right to direct the use of that asset.

MoonLake does not have any finance leases. As of December 31, 2025, the Company has five operating leases related to the office spaces located in (i) Dorfstrasse 29, 6300, Zug, Switzerland (comprised of two leases), (ii) 95 Regent Street, CB2 1AW, Cambridge, England, United Kingdom, and (iii) Rua Manuel Pinto de Azevedo 860, 4150-335, Porto, Portugal (comprised of two leases). The operating leases are recognized over a straight-line basis over the lease term commencing on the date the Company has the right to use the leased property. Right-of-use assets and lease liabilities are measured at the lease commencement date based on the present value of the remaining lease payments over the lease term, determined using the discount rate for the lease at the commencement date. Because the rate implicit in the leases is not readily determinable, the Company uses the incremental borrowing rate as the discount rate, which approximates the interest rate at which the Company could borrow on a collateralized basis with similar terms and payments and in similar economic environments.

Leases with an initial term of 12 months or less and that do not have the option to purchase the underlying asset are not recorded on the consolidated balance sheets, with lease expense for these leases recognized on a straight-line basis over the lease term commencing on the date the Company has the right to use the leased property.

Property and Equipment

Property and equipment, net is stated at cost, net of accumulated depreciation. Depreciation is computed using the straight-line method based on the estimated useful lives of three to five years. As of December 31, 2025, property and equipment, net relates to information technology, office equipment, and leasehold improvements.

Impairment of Long-Lived Assets

The Company reviews all long-lived assets, which consist of operating lease right-of-use assets, and property and equipment, whenever events or changes in circumstance indicate that these assets may not be recoverable. When evaluating long-lived assets, if the Company concludes that the estimated undiscounted cash flows attributable to the assets are less than their carrying value, the Company recognizes an impairment loss based on the excess of the carrying amount of the assets over their respective fair values, which could adversely affect its results of operations. There was no impairment of long-lived assets for the years ended December 31, 2025, 2024, and 2023.

Research and Development Contract Costs and Accruals

Research and development expenses include employee payroll, consulting, contract research, and contract manufacturing costs attributable to research and development activities and manufacturing of pre-launch inventory, which are expensed as incurred.

Upfront payments and milestone payments made for the licensing of technology are expensed as research and development expenses in the period in which it is probable that a liability has been incurred. Advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

The Company has entered into various research and development contracts with companies both inside and outside of the United States. These agreements are generally cancellable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When

evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or trials, including the phase or completion of events, invoices received and contracted costs. Estimates are made in determining the accrued balances at the end of any reporting period based on facts and circumstances known at the time. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Pre-Launch Inventory

Prior to obtaining regulatory approval of a product candidate, the Company may incur production costs to support the commercial launch of such product. Until the date at which regulatory approval has been received or it is considered probable, and the future economic benefit is expected to be realized, all such costs are recorded as research and development expenses as incurred.

A number of factors are considered in incurring such expenses, including the current status in the regulatory approval process, potential impediments to the approval process such as safety or efficacy, anticipated R&D initiatives that could impact the indication in which the compound will be used, viability of commercialization, marketplace trends, and the shelf life of the compound.

Share-Based Compensation

The Company recognizes compensation expense based on estimated fair values for all stock-based payment awards made to eligible employees, members of the board of directors and independent contractors that are expected to vest.

The valuation of stock option awards is determined at the date of grant using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the Company to make assumptions and judgments about the inputs used in the calculations, such as the fair value of the common stock, expected term, expected volatility of the Company's common stock, risk-free interest rate and expected dividend yield. The valuation of restricted stock awards is measured by the fair value of the Company's common stock on the date of the grant.

For all stock options granted, the Company calculated the expected term as the period that share-based awards are expected to be outstanding. The estimate of expected volatility is based on comparative companies' volatility within the Company's industry. The risk-free rate is based on the yield available on United States Treasury zero-coupon issues corresponding to the expected term of the award.

The fair value of the common stock granted under the ESPP (as defined in Note 14 — *Share-Based Compensation*) was historically estimated by management with reference to the market-based transaction with its Series A investors, as there was no public market for the common stock.

Share-based payment arrangements are accounted for under the fair value method. Total compensation is measured at grant date, based on the fair value of the award at that date, and recorded in earnings over the period the employees are required to render service. The Company recognizes compensation cost only for those awards expected to meet the service conditions on a straight-line basis over the requisite service period of the award.

Foreign Currency

The functional currency of the Company and its subsidiaries is the U.S. dollar. Balances and transactions denominated in foreign currencies are converted as follows: monetary assets and liabilities are translated using exchange rates in effect at the balance sheet dates and non-monetary assets and liabilities are translated at historical exchange rates. Income and expenses are translated at the daily exchange rate on the respective transaction date.

Gains or losses from foreign currency transactions are included in the consolidated statements of operations and comprehensive loss in "Other income, net". The Company recognized a net foreign currency transaction gain of $599 thousand for the year ended December 31, 2025, a net foreign currency transaction loss of $42 thousand for the year ended December 31, 2024, and a net foreign currency transaction gain of $151 thousand for the year ended December 31, 2023.

Income Taxes

The Company accounts for income taxes by using the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is recorded to the extent it is more likely than not that all or a portion of the Company's deferred tax assets will not be realized. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date.

Net Loss per Class A Ordinary Shares

Basic net loss per Class A Ordinary Share is calculated using the two-class method under which earnings are allocated to both Class A Ordinary Shares and participating securities. Basic net loss per share is calculated by dividing the net loss attributable to Class A Ordinary Shares by the weighted-average number of Class A Ordinary Shares outstanding for the period. The diluted net loss per Class A Ordinary Share is computed by dividing the net loss using the weighted-average number of Class A Ordinary Shares and, if dilutive, potential Class A Ordinary Shares outstanding during the period.

In periods in which the Company reports a net loss attributable to shareholders of Class A Ordinary Shares, diluted net loss per share attributable to shareholders of Class A Ordinary Shares is the same as basic net loss per share attributable to shareholders of Class A Ordinary Shares, since dilutive Class A Ordinary Shares are not assumed to be outstanding if their effect is anti-dilutive.

Acquisitions

The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first assessing whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. On April 29, 2021, MoonLake AG entered into an in-licensing agreement (the “In-License Agreement”) with Merck Healthcare KGaA, Darmstadt, Germany (“MHKDG”) to acquire the Sonelokimab program (the “SLK Program”) and determined that substantially all of the fair value of the gross assets acquired related to IPR&D of SLK. Therefore, this transaction was accounted for as an asset acquisition. IPR&D represents incomplete technologies that the Company acquires, which at the time of acquisition, are still under development and have no alternative future use. The fair value of such technologies is expensed upon acquisition.

Contingent consideration payments (for example milestone payments due upon the occurrence of a specific event) in asset acquisitions are recognized in the period in which it is probable that a liability has been incurred (unless the contingent consideration meets the definition of a derivative, in which case the amount becomes part of the cost in the asset acquired). Upon recognition of the contingent consideration payment, the amount is expensed if it relates to IPR&D or capitalized if it relates to a developed product which is generally considered to be when clinical trials have been completed and regulatory approval obtained.

Future royalty payments due on net sales will be recognized in cost of goods sold when net sales are recognized.

Pensions

The Company accounts for pension assets and liabilities, which requires the recognition of the funded status of pension plans in the Company's consolidated balance sheets. The liability in respect to defined benefit pension plans is the projected benefit obligation calculated annually by independent actuaries using the projected unit credit method. The projected benefit obligation represents the actuarial present value of the estimated future payments required to settle the obligation that is attributable to employee services rendered before that date. Service costs for such pension plans, represented in the net periodic pension benefit cost, are included in the personnel expenses of the various functions where the employees are engaged. The other components of net benefit cost are included in the consolidated statements of operations and comprehensive loss separately from the service cost component, in "Other income, net." Plan assets are recorded at their fair value.

Gains or losses arising from plan curtailments or settlements are accounted for at the time they occur. Any net pension asset is limited to the present value of the future economic benefits available to the Company in the form of refunds from the plan or expected reductions in future contributions to the plan. Actuarial gains and losses arising from differences between the actual and the expected return on plan assets are recognized in "Accumulated other comprehensive income".

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes - Improvements to Income Taxes Disclosure*, which amends guidance on to enhance the transparency and decision usefulness of income tax disclosures by disaggregating information about a reporting entity's effective tax rate reconciliation as well as additional information on income taxes paid. It is effective for fiscal years beginning after December 15, 2024. The Company adopted a prospective application of ASU 2023-09 during the year ended December 31, 2025. Refer to Note 15 — *Income Taxes* for the inclusion of new disclosures required.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosure*, which requires a public entity to disclose additional information about specific expense categories in the notes to financial statements on an annual and interim basis. It is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. In January 2025, the FASB issued ASU 2025-01 to clarify that all public entities, including non-calendar year-end entities, should adopt the disclosure requirements of ASU 2024-03. The Company is currently evaluating the impact this will have on its consolidated financial statements and related disclosures.

Prior Period Reclassification

The amortization expense in the consolidated statements of cash flows in prior periods has been reclassified to conform with the current period presentation. The amortization expense was reclassified from "Other non-cash items" to "Depreciation and amortization" for the year ended December 31, 2023. The change did not have any impact on the net cash flow used in operating activities.

Note 3 — Risks and Liquidity

Going Concern, Liquidity and Capital Resources

MoonLake is subject to risks common to companies in the biopharmaceutical industry, and the Company believes that changes in any of the following areas could have a material adverse effect on the Company's future financial position or

results of operations: ability to obtain future financing, regulatory approval and market acceptance of, and reimbursement for, product candidates, performance of third-party contract research organizations and manufacturers upon which the Company relies, protection of the Company's intellectual property, litigation or claims against the Company based on intellectual property, patent, product, regulatory, clinical or other factors, and the Company's ability to attract and retain employees necessary to support its growth.

The Company is dependent on third-party manufacturers to supply products for research and development activities in its programs and for eventual commercialization. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply the Company with its requirements for the active pharmaceutical ingredients and formulated drugs related to these programs. These programs could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

The Company's ability to generate revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of SLK in one or more indications, which is expected to take a number of years. The Company expects to continue to incur substantial expense and operating losses for at least the next two years as the Company continues the development of SLK and prepares for commercial launches. It is expected that operating losses will fluctuate notably from year to year depending on the timing of the Company's planned clinical development programs, efforts to achieve regulatory approval, and planned marketing and sales expenditures leading up to a commercial launch.

The Company incurred a loss of $230.3 million for the year ended December 31, 2025. As of December 31, 2025, the Company’s current assets exceeded its current liabilities by $376.2 million.

As of December 31, 2025, the Company had $334.5 million of cash and cash equivalents. Based on the Company's current operating plan and the Loan and Security Agreement as defined in Note 4 — *Debt*, management believes that the Company has sufficient capital to fund its operations and capital expenditures into the second half of 2027.

Note 4 – Debt

On March 31, 2025 (the “Closing Date”), MoonLake as a guarantor entered into a loan and security agreement (the “Loan and Security Agreement”) with its subsidiary, MoonLake AG, as borrower, the lenders party thereto (the “Lenders”), and Hercules Capital, Inc., as the administrative and collateral agent for itself and the Lenders. The Loan and Security Agreement provides a non-dilutive senior secured term loan facility (the “Credit Facility”) of up to an aggregate principal amount of $500.0 million. The Credit Facility matures on April 1, 2030 and bears interest at an annual rate equal to the greater of (i) prime rate as reported in The Wall Street Journal plus 1.45% and (ii) 8.45%, subject to a 0.25% reduction upon achievement of the U.S. Food and Drug Administration's (“FDA”) approval of a Biologics License Application (“BLA”) for SLK.

The Credit Facility comprises:

a. A first tranche (the “Tranche 1 Loan”) in an aggregate principal amount of $75.0 million fully funded on the Closing Date,
b. Subject to MoonLake’s announcement that the VELA-1 and VELA-2 Phase 3 studies of SLK in adult patients with moderate to severe hidradenitis suppurativa each achieved their protocol-specified primary endpoint with SLK having demonstrated an acceptable safety profile (the “Tranche 2 Milestone”), a second tranche with additional term loans in an aggregate principal amount of up to $125.0 million, available on the Tranche 2 Milestone achievement date through the earlier of (i) 30 days following such date and (ii) December 31, 2025,
c. Subject to MoonLake's announcement that the IZAR-1 and IZAR-2 Phase 3 studies of SLK in patients with active psoriatic arthritis each achieved their protocol-specified primary endpoint with SLK having demonstrated an acceptable safety profile (the “Tranche 3 Milestone”), a third tranche (the “Tranche 3 Loan”)

with additional term loans in an aggregate principal amount of up to $50.0 million, available on the Tranche 3 Milestone achievement date through the earlier of (i) 60 days following such date and (ii) September 15, 2026,

d. Subject to the Company's achievement of the Tranche 2 Milestone and Tranche 3 Milestone and the FDA's acceptance of the Company's submission of a BLA for SLK (collectively, the "Tranche 4 Milestone"), a fourth tranche with additional term loans in an aggregate principal amount of up to $50.0 million, available on the Tranche 4 Milestone achievement date through the earlier of (i) 60 days following such date and (ii) March 15, 2027, and

e. Subject to approval by the Lenders' in their discretion, a fifth tranche (the "Tranche 5 Loan") of additional term loans in an aggregate principal amount of up to $200.0 million.

On September 28, 2025, the Company announced the primary endpoint results of the VELA-1 and VELA-2 Phase 3 studies. While VELA-1 met the primary endpoint, a higher-than-expected placebo response at week 16 precluded VELA-2 from meeting the pre-specified primary endpoint and, as a result, the Company did not achieve the Tranche 2 and Tranche 4 Milestones. As of December 31, 2025, the Company had $250.0 million of remaining undrawn tranches, representing the aggregate principal amount available to be drawn under the Credit Facility.

As of December 31, 2025, the Company's carrying value of long-term debt and recognized deferred charges on the consolidated balance sheet consists of the following:

(in thousands)

Non-current liabilities	**December 31, 2025**
Principal amount	$ 75,000
Accreted present value of End of Term Charge	3,618
Unamortized End of Term Charge	(2,837)
Unamortized debt issuance cost	(958)
Unamortized debt discount	(723)
Carrying value	**$ 74,100**
Non-current assets	
Deferred charges - long-term debt	$ 587
Total	**$ 587**

The effective interest rate is 10.41% and the Company recognized interest expense of $7.2 million on the Loan and Security Agreement for the year ended December 31, 2025. A portion of the debt issuance costs related to the undrawn third and fifth tranches were recognized as deferred charges until drawn. The debt issuance costs related to the second and fourth tranches have been recognized as interest expense in the current period.

The Company may prepay advances in whole at any time subject to a prepayment charge. Upon repayment of all term loans on or after April 1, 2027, the Company is further required to pay an additional charge equal to 6.95% for the Tranche 1 Loan and any draws under the Tranche 3 Loan; 4.25% for any draw under the Tranche 5 Loan, and if repayment occurs prior to 24 months, the charge applied will be 4.25% ("End of Term Charge"). As of December 31, 2025, the End of Term Charge is accrued at 6.95% of the Tranche 1 Loan balance and is recorded at present value as an addition to the long-term debt in non-current liabilities whereas the unamortized portion is recorded as contra non-current liabilities. The unamortized contra-liability will be amortized and the present value will be accreted up to the future value over the loan term as interest expense. The Tranche 1 Loan has a maturity requirement of $75.0 million due in 2030, with no other principal payments due for each of the five years following the date of the latest consolidated balance sheets presented. Additional fees will be payable in connection with the Credit Facility upon drawing of future tranches.

The Loan and Security Agreement allows for the Company to satisfy a portion of the cash interest payments by capitalizing such interest payments as payment-in-kind ("PIK"). No PIK interest relating to the term loan has been recorded and included in the consolidated balance sheet as of December 31, 2025.

The Loan and Security Agreement contains customary covenants, such as financial covenants and certain events of default after which loans under the Credit Facility may be due and payable immediately. The Company was in compliance with all covenants as of December 31, 2025.

All obligations under the Loan and Security Agreement will be secured on a first-priority basis, subject to certain exceptions, by security interests in substantially all assets of the Company and material subsidiaries of the Company, including its intellectual property, and will be guaranteed by material subsidiaries of the Company, including foreign subsidiaries, subject to certain exceptions.

Refer to Note 18 — *Subsequent Events* for further discussion on the amendment to the Loan and Security Agreement subsequent to the year ended December 31, 2025.

Note 5 — Fair Value Measurements

The following table presents information about the Company's short-term marketable debt securities measured at fair value on a recurring basis and indicate the level in the fair value hierarchy in which the Company classifies the fair value measurement:

(in thousands)	December 31, 2025		December 31, 2024	
	Level 2	**Total**	**Level 2**	**Total**
Eurocommercial Papers	$ —	**$ —**	$ 207,701	**$ 207,701**
Certificates of Deposit	59,451	**59,451**	119,583	**119,583**
Total	**$ 59,451**	**$ 59,451**	**$ 327,284**	**$ 327,284**

Cash and accounts payable approximate their fair values as of December 31, 2025 and 2024, due to their short-term nature. Pension plan assets fair value is determined based on Level 2 inputs. The fair value of the long-term debt is estimated using the net present value of the payments, discounted at an interest rate that is consistent with a market interest rate, which is a Level 2 input as it is not actively traded. As of December 31, 2025, long-term debt of $74.1 million is reported at amortized cost which approximates the fair value.

Note 6 — Investments

The fair value and amortized cost of investments in short-term marketable debt securities by major security type as of December 31, 2025 and 2024 are as follows:

(in thousands)	December 31, 2025			
	Amortized cost	**Gross unrealized gains**	**Gross unrealized losses**	**Fair value**
Certificates of Deposit	59,166	285	—	59,451
Total	**$ 59,166**	**$ 285**	**$ —**	**$ 59,451**
Of which classified within short-term marketable debt securities	59,166	285	—	59,451

(in thousands)	December 31, 2024			
	Amortized cost	**Gross unrealized gains**	**Gross unrealized losses**	**Fair value**
Eurocommercial Papers	$ 204,572	$ 3,129	$ —	$ 207,701
Certificates of Deposit	117,305	2,278	—	119,583
Total	**$ 321,877**	**$ 5,407**	**$ —**	**$ 327,284**
Of which classified within cash and cash equivalents	59,311	372	—	59,683
Of which classified within short-term marketable debt securities	262,566	5,035	—	267,601

The following table presents the changes in fair values of the Company's short-term marketable debt securities, classified as Level 2 financial assets, and recognized in "Accumulated other comprehensive income" for the years ended December 31, 2025, 2024 and 2023, respectively:

(in thousands)	Year Ended December 31, 2025	Year Ended December 31, 2024	Year Ended December 31, 2023
Beginning balance	$ 5,407	$ 2,721	$ 391
Other comprehensive income before reclassifications	10,299	16,433	8,751
Amounts reclassified from accumulated other comprehensive income	(15,422)	(13,747)	(6,421)
Ending balance	**$ 284**	**$ 5,407**	**$ 2,721**

As of December 31, 2025, the Company's marketable debt securities maturities are all due within one year.

Note 7 — Prepaid Expenses

(in thousands)	December 31, 2025	December 31, 2024
Non-clinical research and clinical development services	$ 17,362	$ 14,136
Supply and manufacturing services	3,494	7,716
Insurance	886	1,113
Other prepayments	1,115	453
Total	**$ 22,857**	**$ 23,418**

Note 8 — Trade and Other Payables

(in thousands)	December 31, 2025	December 31, 2024
Research and development services	$ 16,381	$ 5,081
Supply and manufacturing fees payable	12,045	3,597
Consulting and advisory services	672	39
Legal advisory services	90	93
Other payables	365	182
Total	**$ 29,553**	**$ 8,992**

Note 9 — Accrued Expenses and Other Current Liabilities

(in thousands)	December 31, 2025	December 31, 2024
Supply and manufacturing services	$ 6,618	$ 4,474
Research and development services and license fees	4,225	2,022
Bonuses and related employee compensation expenses	2,324	4,237
Tax liabilities	1,094	642
Consultant and other fees	266	586
Legal fees	164	138
Total	**$ 14,691**	**$ 12,099**

Note 10 — Leases

In August 2021, the Company entered into an open-ended office lease agreement, effective November 1, 2021, to lease approximately 2,300 square feet of space on the last two floors of the building located at Dorfstrasse 29, 6300 Zug, Switzerland. In December 2023, the contract was extended, leading to a new estimated effective duration of the lease period of 3 years, with expected expiration in January 2027.

On October 9, 2023, the Company entered into an office lease agreement, effective as of October 9, 2023, to lease approximately 3,900 square feet of office space on the fifth floor of the building located at Rua Manuel Pinto de

Azevedo 860, 4150-335, Porto, Portugal. This lease has a 3-year initial term, with two extendable periods of 3 years each. The Company expects to exercise the first available option and extend this lease through October 2029.

On October 13, 2023, the Company entered into an office lease agreement, effective as of October 16, 2023, to lease approximately 6,000 square feet of office space on the first floor of the building located at 95 Regent Street, CB2 1AW, Cambridge, England, United Kingdom. This lease has a 3-year term agreement and is set to expire in October 2026.

On December 12, 2023, the Company entered into an open-ended office lease agreement, effective as of January 15, 2024, to lease approximately 1,700 square feet of additional office space at its existing corporate headquarters located at Dorfstrasse 29, 6300 Zug, Switzerland. The Company estimated the duration of the lease at inception and determined a 3-year term.

On August 14, 2024, the Company entered into an office lease agreement, effective as of September 8, 2024, to lease approximately 2,000 square feet of additional office space at its existing office located at Rua Manuel Pinto de Azevedo 860, 4150-335, Porto, Portugal. This lease has a 2-year initial term, with two extendable periods of 3 years each. The Company currently expects that this lease will be extended until October 2029.

The weighted average remaining lease term and weighted average discount rate for the operating leases as of December 31, 2025 and 2024 were as follows:

	December 31, 2025	December 31, 2024
Weighted average remaining lease term	22 months	29 months
Weighted average discount rate	4.6 %	4.7 %

The future minimum annual lease payments under these operating leases as of December 31, 2025 are as follows:

(in thousands)

Fiscal Year		Amount
2026	$	1,272
2027		147
2028		147
2029		100
Thereafter		—
Total lease payments		**1,666**
Less imputed interest		(58)
Total lease liabilities		**1,608**
Less: Short-term portion of operating lease liabilities		(1,234)
Long-term portion of operating lease liabilities	**$**	**374**

Operating cash outflows for amounts included in the measurement of lease liabilities were $1,555 thousand, $1,475 thousand and $422 thousand for the years ended December 31, 2025, 2024 and 2023, respectively.

The Company recorded the following lease and variable lease expenses for the years ended December 31, 2025, 2024 and 2023:

(in thousands)	Year Ended December 31, 2025	Year Ended December 31, 2024	Year Ended December 31, 2023
Operating lease expense	$ 1,460	$ 1,424	$ 400
Variable lease expense [(1)]	54	16	—
Total lease expense	**$ 1,514**	**$ 1,440**	**$ 400**

(1) Variable lease expense resulting from increased lease payments linked to changes in the reference index.

Note 11 — Employee Benefit Plans

The Company operates a defined benefit pension plan in Switzerland ("the Plan") and a defined contribution pension plan in the United Kingdom, in accordance with local regulations and practices. As of December 31, 2025, the Plan covers the Company's employees in Switzerland with benefits in the event of death, disability, retirement, or termination of employment.

A summary of the changes in projected benefit obligations ("PBO") and plan assets is presented below:

(in thousands)	Year Ended December 31, 2025	Year Ended December 31, 2024	Year Ended December 31, 2023
Beginning PBO	$ 2,921	$ 2,494	$ 1,322
Service cost	331	281	123
Interest cost	33	33	31
Contributions by plan participants	342	260	200
Actuarial (gain) losses	(430)	41	488
Benefits paid	891	11	230
Foreign currency exchange rates changes	469	(199)	208
Plan amendment	—	—	(108)
Ending PBO	**$ 4,557**	**$ 2,921**	**$ 2,494**

(in thousands)	Year Ended December 31, 2025	Year Ended December 31, 2024	Year Ended December 31, 2023
Beginning fair value of plan assets	$ 2,300	$ 1,911	$ 1,040
Expected return on plan assets	81	60	37
Return on plan assets above (below) expected return	197	(47)	49
Contributions by the employer	342	260	200
Contributions by plan participants	342	260	200
Benefits paid	891	11	230
Foreign currency exchange rates changes	413	(155)	155
Ending fair value of plan assets	**$ 4,566**	**$ 2,300**	**$ 1,911**

Amounts recorded on the consolidated balance sheets:

(in thousands)	December 31, 2025	December 31, 2024
Fair value of plan assets	$ 4,566	$ 2,301
Present value of projected benefit obligation	(4,557)	(2,921)
Funded status	**$ 9**	**$ (620)**

Amounts recorded in "Accumulated other comprehensive income":

(in thousands)	Year Ended December 31, 2025	Year Ended December 31, 2024	Year Ended December 31, 2023
Actuarial (gain) loss beginning of year	$ 322	$ 235	$ (102)
Actuarial (gain) loss of current year	(639)	87	444
Amortization	(13)	(10)	—
Prior service (cost) credit recognized in current year	11	10	(107)
Total	**$ (319)**	**$ 322**	**$ 235**

Weighted average assumptions used to calculate the projected benefit obligation are summarized in the table below:

	December 31, 2025	December 31, 2024
Discount rate	1.35% p.a.	1.00% p.a.
Expected return on plan assets	3.20% p.a.	2.70% p.a.
Inflation	0.70% p.a.	1.00% p.a.
Long-term expected rate of salary increase	1.20% p.a.	1.50% p.a.

Service cost of $331 thousand, $281 thousand, and $123 thousand was recognized in the net periodic benefit cost for the years ended December 31, 2025, 2024, and 2023, respectively.

The allocation of plan assets is presented below:

	December 31, 2025	December 31, 2024
Equities	38.00 %	34.00 %
Bonds	22.00 %	32.00 %
Mortgages	5.00 %	4.00 %
Liquidity	1.00 %	1.00 %
Real estate	24.00%	26.00%
Alternative investments	7.00%	3.00%
Infrastructure	3.00%	—%

The fair value of plan assets is determined based on Level 2 inputs. As all members of the Plan are active, no future expected benefit payments are currently being made and are not foreseen to occur within the next ten years. For fiscal year 2026, the Company presently anticipates contributing an estimated amount of $342 thousand to fund the Plan.

Note 12 — Shareholders' Equity

Class A Ordinary Shares

As of December 31, 2025, there were 71,373,579 Class A Ordinary Shares issued and outstanding. The Company is authorized to issue up to 500,000,000 Class A Ordinary Shares, par value $0.0001 per share. Holders of Class A Ordinary Shares are entitled to one vote for each share.

Class C Ordinary Shares

As of December 31, 2025, there were no Class C Ordinary Shares issued and outstanding. The Company is authorized to issue up to 100,000,000 Class C Ordinary Shares, with a par value $0.0001 per share. Each Class C Ordinary Share entitles the holders thereof to one vote per share, but carries no economic rights.

At the closing of the Business Combination, MoonLake, MoonLake AG, and the ML Parties entered into a Restated and Amended Shareholders' Agreement (the "A&R Shareholders' Agreement"). With the intent to approximate the rights, obligations and restrictions that an ML Party would enjoy if it were a holder of Class A Ordinary Shares, the A&R Shareholders' Agreement (i) imposed certain transfer and other restrictions on the ML Parties, (ii) provided for the waiver of certain statutory rights and (iii) established certain mechanics whereby MoonLake and each of the ML Parties were able to effect the conversion of MoonLake AG Common Shares and Class C Ordinary Shares into a number of Class A Ordinary Shares as defined by the Business Combination Agreement equal to 33.638698 (the "Exchange Ratio"). During the year ended December 31, 2023, pursuant to the A&R Shareholders' Agreement, 333,486 MoonLake AG Common Shares and 11,218,035 Class C Ordinary Shares were converted into 11,218,035 Class A Ordinary Shares. During the year ended December 31, 2024, pursuant to the A&R Shareholders' Agreement, 48,972 MoonLake AG Common Shares and 1,647,354 Class C Ordinary Shares were converted into 1,647,354 Class A Ordinary Shares. During the year ended December 31, 2025, pursuant to the A&R Shareholders' Agreement, 25,009 MoonLake AG Common Shares and 841,269 Class C Ordinary Shares were converted into 841,269 Class A Ordinary Shares. As of December 31, 2025, all remaining issued and outstanding Class C Ordinary Shares had been converted into Class A Ordinary Shares. The A&R Shareholders' Agreement automatically terminated with the last conversion on December 19, 2025. The foregoing description of the A&R Shareholders' Agreement is not complete and is qualified in its entirety by reference to, and should be read in connection with, the full text of the A&R Shareholders' Agreement filed as an exhibit on the Company's Current Report on Form 8-K filed with the SEC on April 11, 2022.

Equity Offerings

At-the-Market Offering

On May 11, 2023, the Company entered into a Sales Agreement (the "May 2023 Sales Agreement") with Leerink Partners LLC (formerly known as SVB Securities LLC) ("Leerink Partners"), through which the Company could issue and sell up to $200.0 million of its Class A Ordinary Shares (the "May 2023 ATM Shares"), through Leerink Partners as its sales agent. The May 2023 ATM Shares to be sold under the May 2023 Sales Agreement, if any, would be issued and sold pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-271546), which was declared effective by the SEC on May 9, 2023, and a prospectus supplement thereto filed with the SEC on May 11, 2023.

On June 27, 2023, the Company reduced the maximum aggregate offering amount of its Class A Ordinary Shares that could be issued and sold under the May 2023 Sales Agreement to $0 and no longer intends to sell Class A Ordinary Shares under the May 2023 Sales Agreement unless the Company files a further prospectus supplement indicating an amount of shares proposed to be sold.

On August 31, 2023, the Company entered into a Sales Agreement with Leerink Partners (the "August 2023 Sales Agreement" and, together with the May 2023 Sales Agreement, the "Sales Agreements"), through which the Company could issue and sell up to $350.0 million of its Class A Ordinary Shares (the "August 2023 ATM Shares"), through Leerink Partners as its sales agent. The August 2023 ATM Shares to be sold under the August 2023 Sales Agreement, if any, would be issued and sold pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-274286), which was declared effective by the SEC on September 11, 2023, and a prospectus supplement thereto filed with the SEC on August 31, 2023. As of December 31, 2025, there was $265.0 million remaining for future sales under the August 2023 ATM Sales Agreement.

For the year ended December 31, 2024, the Company sold 914,828 Class A Ordinary Shares through the Sales Agreements for net proceeds of $52.5 million after deducting sales agent's commissions and transaction costs. For the three months and year ended December 31, 2025, there were no sales under the August 2023 Sales Agreement.

Public Offerings of Class A Ordinary Shares

On June 27, 2023, the Company entered into an underwriting agreement with Leerink Partners and Guggenheim Securities LLC as the representatives of the underwriters named therein, to issue and sell 8,000,000 Class A Ordinary Shares at a public offering price of $50.00 per share (the "2023 Offering"). In addition, the Company granted the underwriters an option for a period of 30 days to purchase up to an additional 1,200,000 Class A Ordinary Shares at the public offering price less the underwriting discounts and commissions (the "Option"), and such Option was exercised in full by the underwriters. The 2023 Offering closed on June 30, 2023, and net proceeds, including proceeds from the exercise in full by the underwriters of the Option, were $436.7 million, after deducting the underwriting discounts, commissions, and offering expenses in the amount of $23.3 million.

Following the completion of the 2023 Offering, the Company opted to direct a substantial portion of the net proceeds to MoonLake AG. This was executed as a two-step process: (i) the Company acquired the remaining 22,756 MoonLake AG Common Shares held in treasury through a share purchase and assignment agreement formally executed on July 09, 2023 ($38.9 million) and (ii) the Company contributed additional funds to MoonLake AG's capital reserves through a cash contribution agreement formally executed on July 10, 2023 ($275 million). A stamp duty tax of $2.8 million was levied on the aforementioned capital contribution which the Company has classified as cash flows from financing activities in order to correctly mirror the underlying nature of the transaction.

On March 8, 2024, the Company executed a similar transaction as a two-step process: (i) the Company acquired 501 MoonLake AG Common Shares held in treasury through a share purchase and assignment agreement ($0.8 million) and (ii) the Company contributed an additional $150.0 million of funds to MoonLake AG's capital reserves through a cash contribution. A stamp duty tax of $1.5 million, net of refund received, was levied on the capital contribution which the Company has classified as cash flows from financing activities in order to correctly mirror the underlying nature of the transaction. The aforementioned increase in treasury shares occurred during the three months ended March 31, 2024 as a result of an employee termination entitling MoonLake AG to repurchase such employee's unvested shares (501 MoonLake AG Common Shares and 16,853 Class C Ordinary Shares) previously awarded as part of a share-based compensation program. Since the shares were subsequently sold to MoonLake, the corresponding Class C Ordinary Shares were canceled.

On November 5, 2025, the Company entered into an underwriting agreement with Leerink Partners as the underwriter, to issue and sell 7,142,857 Class A Ordinary Shares at a public offering price of $10.50 per share (the "2025 Offering"). The 2025 Offering closed on November 6, 2025, and net proceeds were $72.4 million, after deducting the underwriting discounts, commissions, and offering expenses in the amount of $2.6 million.

Options Exercised under the Equity Incentive Plan

In the years ended December 31, 2025 and 2024, certain participants exercised their stock options under the Equity Incentive Plan (as defined below in Note 14 — *Share-Based Compensation*) for an aggregate of 27,149 and 48,796 Class A Ordinary Shares and total cash consideration of $480 thousand and $242 thousand, respectively.

There were no options exercised in the year ended December 31, 2023.

Note 13 — Net Loss per Share

The following table sets forth the net loss per share calculations for the years ended December 31, 2025, 2024, and 2023:

(in thousands, except share and per share data)	Year Ended December 31, 2025	Year Ended December 31, 2024	Year Ended December 31, 2023
Numerator			
Net loss attributable to controlling interests shareholders	$ (227,318)	$ (118,936)	$ (36,007)
Denominator			
Total weighted average number of outstanding shares	64,463,889	62,870,237	49,122,534
Net loss per share – basic and diluted	**$ (3.53)**	**$ (1.89)**	**$ (0.73)**

There were 2,348,038, 972,476, and 312,400 common stock equivalents outstanding in the form of stock options and restricted stock awards under the Equity Incentive Plan (as defined below in Note 14 — *Share-Based Compensation*) as of December 31, 2025, 2024, and 2023, respectively, that have been excluded from the calculation of net loss per share – diluted as their effect would be anti-dilutive.

Class C Ordinary Shares have been excluded from the weighted average number of outstanding shares used to calculate the net loss per share – basic and diluted as they do not carry economic rights.

Note 14 — Share-Based Compensation

As of December 31, 2025, the Company had the following share-based compensation arrangements:

a. Restricted Founder Shares (as defined below) – created in April 2021 by MoonLake AG (fully vested as of April 2023);
b. The Employee Share Participation Plan (“ESPP”) – created in July 2021 by MoonLake AG;
c. The Employee Stock Option Plan (“ESOP”) – created in July 2021 by MoonLake AG (fully vested as of January 2024);
d. MoonLake Immunotherapeutics 2022 Equity Incentive Plan ("Equity Incentive Plan") – created in April 2022 by MoonLake.

The purpose of the arrangements is to attract and retain the best available personnel and to provide participants with additional incentive to increase their efforts on behalf and in the best interest of the Company and its subsidiaries. The reference to “Common Shares” refers to shares in MoonLake AG.

MoonLake AG's compensation plans are settled with its Common Shares and with a number of Class C Ordinary Shares of the Company, determined by multiplying the number of Common Shares by the Exchange Ratio. The owners of

Common Shares have the right to exchange their Common Shares for a number of Class A Ordinary Shares derived using the Exchange Ratio. In the event MoonLake AG shareholders elect to exchange their Common Shares, such MoonLake AG shareholder forfeits a number of Class C Ordinary Shares equal to the number of Class A Ordinary Shares issued (refer to Note 12 — *Shareholders' Equity - Class C Ordinary Shares*).

As of January 1, 2024, the Company executed the conversion of the majority of the outstanding ESOP awards into an equivalent number of Equity Incentive Plan option awards that are settled with Class A Ordinary Shares, thereby eliminating the intermediary right to the exchange step noted above. From an accounting perspective, there is no underlying modification to the economic, control or legal rights of the awards, including vesting terms and conditions, exercise price and accounting classification. This is purely an administrative change as opposed to an accounting modification whereby the plan issuer is amended from MoonLake AG to MoonLake Immunotherapeutics. Consequently, there is no incremental fair value generated following the conversion and therefore no incremental expense recorded. Any remaining unvested compensation expense will be recorded over the remaining vesting period of the original awards, thereby resulting in no change to the consolidated financial statements if the conversion had not occurred.

As a result of this administrative conversion, the two plans which remain active as of December 31, 2025 are the ESPP and Equity Incentive Plan, whereas the Restricted Founder Shares and ESOP are fully vested as of April 2023 and January 2024, respectively.

For the years ended December 31, 2025, 2024, and 2023, the Company has recognized an increase in equity in the consolidated balance sheets due to share-based compensation expense in the consolidated statements of operations and comprehensive loss of $12.9 million, $7.3 million, and $7.1 million, respectively. The share-based compensation expense was mainly driven by the aforementioned two active share-based compensation plans and programs:

(in thousands)

Compensation Plan	**Year Ended December 31, 2025**	**Year Ended December 31, 2024**	**Year Ended December 31, 2023**
MoonLake AG Restricted Founder Shares	$ —	$ —	$ 1,574
ESPP	2,940	2,933	3,353
ESOP	(18)	—	974
Equity Incentive Plan	9,976	4,349	1,205
Total share-based compensation expense	**$ 12,898**	**$ 7,282**	**$ 7,106**
Of which: included in research and development expense	*3,938*	*1,971*	*1,525*
Of which: included in general and administrative expense	*8,960*	*5,311*	*5,581*

The Company expects that all future employee awards will be made under the Equity Incentive Plan. As of December 31, 2025, 1,836,618 Class A Ordinary Shares from the authorized pool of 4,353,948 Class A Ordinary Shares remain available for future grants, and 2,156,512 Class A Ordinary Shares are reserved for issuance upon exercise of stock options granted under the Equity Incentive Plan.

Restricted Founder Shares 2021-2023 - MoonLake AG

On April 28, 2021, the shareholders' agreement between the co-founders, the Series A investors and MoonLake AG imposed a reverse vesting condition on 90% of the total 110,000 Common Shares (the equivalent of 3,700,257 Class C Ordinary Shares) held by each of the three co-founders. Therefore, 99,000 Common Shares (the equivalent of 3,330,231

Class C Ordinary Shares) held by each of the co-founders were subject to these restrictions and considered unvested (the "Restricted Founder Shares"). The Restricted Founder Shares vested on the 28th of each month at a rate of 4.166% over a period of two years until April 28, 2023. In the event of a termination of the contractual relationship of the relevant co-founder before the end of the vesting period, MoonLake AG in first priority, or any third-party designated by it, and the other shareholders in second priority pro rata to their shareholdings, had an option to purchase all or a pro rata portion of the leaver shares that remained unvested on the effective day of the termination at nominal value of CHF 0.10.

Employee Share Participation Plan 2021-2026 - MoonLake AG

The ESPP grants will vest 25% on each anniversary of the grant date. In the event of a termination of contractual relationship between the Company and the entitled employee, the awards can be deemed forfeited by MoonLake AG if certain conditions are met. Awards feature an accelerated vesting condition linked to a "Change of Control", defined as any transfer of shares that results in the proposed acquirer holding more than 50% of the then issued share capital of MoonLake AG or the Company, as the case may be, where all the outstanding awards (whether currently outstanding or granted in the future) will be deemed fully vested.

ESPP	Number of Shares	Weighted-Average Grant Date Fair Value
Awards unvested as of January 1, 2025	**319,769**	**$ 10.00**
Awards vested for the year ended December 31, 2025	(293,867)	10.00
Awards unvested as of December 31, 2025	**25,902**	**$ 10.00**

As of December 31, 2025, MoonLake AG had $0.1 million of total unrecognized compensation expense related to the ESPP that will be recognized over the weighted average period of 0.05 years. All ESPP awards, including those unvested, have been converted to Class A Ordinary Shares.

Employee Stock Option Plan 2021-2025 - MoonLake AG

The ESOP grants vested 25% on each anniversary of the grant date. In the event of a termination of the contractual relationship between the Company and the entitled employee, options could be forfeited by MoonLake AG if certain conditions were met. The awards featured an accelerated vesting condition linked to a "Change of Control", defined as any transfer of shares that resulted in the proposed acquirer holding more than 50% of the then issued share capital of MoonLake AG or the Company, as the case may be, where all the outstanding awards (whether currently outstanding or granted in the future) would have been deemed fully vested.

ESOP	Number of Options	Weighted-Average Exercise Price	Aggregate Intrinsic Value (in thousands)	Weighted-Average Remaining Contractual Term (in years)
Awards outstanding as of January 1, 2025	**98,393**	**$ 1.50**	**$ 5,180**	**6.73**
Awards exercised for the year ended December 31, 2025	(93,347)	1.30	n/a	n/a
Awards forfeited for the year ended December 31, 2025	(5,046)	5.25	n/a	n/a
Awards outstanding as of December 31, 2025	**—**	**$ —**	**$ —**	**$ —**

Weighted average assumptions for the awards issued during the year ended December 31, 2023[4]	
Estimated fair value of the option on the grant date using Black-Scholes model ($)	25.53
Exercise price ($)	37.11
Expected term of the award on the grant date (years) [1]	6
Expected volatility of the share price [2]	75%
Risk-free interest rate [3]	4%
Expected dividend rate	—%

[1] The expected term represents the period that share-based awards are expected to be outstanding.
[2] The expected volatility was derived from the historical stock volatilities of comparable peer public companies within the Company's industry.
[3] The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the measurement date with maturities approximately equal to the expected term.
[4] The issued awards include awards that were converted from the ESOP to the EIP as of January 1, 2024.

MoonLake Immunotherapeutics 2022 Equity Incentive Plan

On April 5, 2022 (the "Effective Date"), the Company created the Equity Incentive Plan to promote and closely align the interests of employees, officers, non-employee directors and other service providers of MoonLake Immunotherapeutics and its shareholders by providing share-based compensation and other performance-based compensation.

The Equity Incentive Plan provides for the grant of options, stock appreciation rights, restricted stock units, restricted stock, and other share-based awards and for incentive bonuses, which may be paid in cash, Common Shares or a combination thereof, as determined by the compensation committee of the board of directors or such other committee as designated by the board of directors to administer the Equity Incentive Plan. The Equity Incentive Plan shall remain available for the grant of awards until the 10th anniversary of the Effective Date.

Equity Incentive Plan (Options)	**Number of Options**	**Weighted-Average Exercise Price**	**Aggregate Intrinsic Value (in thousands)**	**Weighted-Average Remaining Contractual Term (in years)**
Awards outstanding as of January 1, 2025	**972,476**	**$ 24.94**	**$ 28,588**	**8.18**
Awards granted for the year ended December 31, 2025	1,358,127	26.44	n/a	n/a
Awards exercised for the year ended December 31, 2025	(27,149)	17.68	n/a	n/a
Awards forfeited for the year ended December 31, 2025	(146,942)	42.87	n/a	n/a
Awards outstanding as of December 31, 2025	**2,156,512**	**$ 24.76**	**$ 3,700**	**8.52**
Awards exercisable as of December 31, 2025	**622,487**	**$ 16.77**	**$ 3,222**	**6.31**

The aggregate intrinsic value represents the difference between the exercise price and the selling price received by option holders upon the exercise of stock options during the period.

The total intrinsic value of options exercised was $0.9 million and $2.3 million for the years ended December 31, 2025 and 2024, respectively. No options were exercised for the year ended December 31, 2023.

As of December 31, 2025, the Company had $23.6 million of total unrecognized compensation expense related to options under the Equity Incentive Plan that will be recognized over the weighted average period of 2.58 years.

Weighted average assumptions for the awards issued during	Year Ended December 31, 2025	Year Ended December 31, 2024[4]	Year ended December 31, 2023
Estimated fair value of the option on the grant date using Black-Scholes model ($)	18.08	31.82	25.58
Exercise price ($)	26.44	46.36	37.22
Expected term of the award on the grant date (years) [1]	6	6	6
Expected volatility of the share price [2]	75%	75%	75%
Risk-free interest rate [3]	4.0%	4.3%	4%
Expected dividend rate	—%	—%	—%

[1] The expected term represents the period that share-based awards are expected to be outstanding.
[2] The expected volatility was derived from the historical stock volatilities of comparable peer public companies within the Company's industry.
[3] The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the measurement date with maturities approximately equal to the expected term.
[4] The issued awards exclude awards that were converted from the ESOP to the EIP as of January 1, 2024.

Equity Incentive Plan (Restricted Stock Awards)	Number of Shares	Weighted-Average Grant Date Fair Value
Awards unvested as of January 1, 2025	**—**	**$ —**
Awards granted for the year ended December 31, 2025	191,526	41.77
Awards unvested as of December 31, 2025	**191,526**	**$ 41.77**

Weighted average assumptions for the awards issued during the nine months ended December 31, 2025	
Estimated fair value of Common Shares on the grant date ($)	41.77

As of December 31, 2025, the Company had $6.3 million of total unrecognized compensation expense related to restricted stock awards under the Equity Incentive Plan that will be recognized over the weighted average period of 3.17 years.

Note 15 — Income Taxes

The Company's effective tax rate ("ETR") was (0.3)%, (0.2)%, and (0.3)% for the years ended December 31, 2025, 2024, and 2023, respectively. The Company is not aware of any items that would cause the quarterly or period-to-date ETR to be significantly different from the Company's annual ETR. The difference between the income tax provision that would be derived by applying the statutory rate to the Company's loss before income taxes and the income tax provision recorded was primarily attributable to the change in the valuation allowance. The Company continues to incur losses for the Cayman Island and Swiss entity and its ability to utilize the deferred tax asset related to the tax losses is not considered more likely than not.

The Company's main operating affiliate, MoonLake AG, is subject to taxation in the Canton of Zug, Switzerland. For the years ended December 31, 2025, 2024, and 2023, the Company did not incur any significant income tax expense or benefit, as the Company incurred tax losses and provided a full valuation allowance.

The components of loss before income tax were as follows:

(in thousands)	Year Ended December 31, 2025	Year Ended December 31, 2024	Year Ended December 31, 2023
Switzerland	$ (229,118)	$ (120,417)	$ (43,470)
Foreign	(592)	(545)	(515)
Total	**$ (229,710)**	**$ (120,962)**	**$ (43,985)**

The reconciliation of taxes at the federal statutory rate to the Company's provision for income taxes is as follows:

	Year Ended December 31, 2025	
(in thousands, except percentages)	Amount	Percent
Statutory federal income tax rate[1]	$ (19,525)	8.5 %
State and local income tax, net of federal income tax effect[2]	455	(0.2)%
Changes in valuation allowance	19,238	(8.4)%
Nontaxable or nondeductible expense	217	(0.1)%
Other adjustments	226	(0.1)%
Effective tax rate	**$ 611**	**(0.3)%**

[1] The statutory income tax rate utilized is the federal (national) Switzerland tax rate which is the Company's country of domicile.
[2] Cantonal & local taxes in the Canton of Zug comprise 100% of this category.

Below is a tabular rate reconciliation previously disclosed for the years ended December 31, 2024 and 2023:

	Year Ended December 31, 2024	Year Ended December 31, 2023
Statutory income tax rate	11.8 %	11.8 %
Effect of income taxed at different rates	(0.3)%	(0.4)%
Changes in prior year estimates	— %	(0.5)%
Utilization of unrecognized losses	— %	0.6 %
Changes in valuation allowance	(11.3)%	0.5 %
Nondeductible expense	(0.5)%	(12.3)%
Total	**(0.2)%**	**(0.3)%**

Significant components of the Company's deferred tax assets (liabilities) were:

(in thousands)	December 31, 2025	December 31, 2024
Intangible assets	$ 4,437	$ 4,491
Defined benefit plan	—	74
Lease liabilities	37	64
Net operating loss carry forward	47,241	20,373
Total deferred tax assets	**51,715**	**25,002**
Operating lease right-of-use assets	(37)	(70)
Defined benefit plan	(1)	—
Total deferred tax liabilities	**(38)**	**(70)**
Total deferred tax assets (net)	**51,677**	**24,932**
Valuation allowance	(51,677)	(24,932)
Total deferred tax (net)	**$ —**	**$ —**

As of December 31, 2025, the Company's net deferred tax assets before valuation allowance were $51.7 million. In assessing the realizability of its deferred tax assets, the Company considers whether it is more likely than not that some portion or all of its deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. The Company considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based on the weight of all evidence, the Company has determined that it is not more likely than not that the net deferred tax assets will be realized. Therefore, a valuation allowance of $51.7 million has been recorded against the deferred tax assets.

As of December 31, 2025, MoonLake AG had net operating losses of approximately $403.5 million of which $12.6 million will expire in 2028, $44.0 million will expire in 2029, $115.3 million will expire in 2031, and $231.6 million will expire in 2032.

The Company's net operating losses will not be subject to any limitation due to change in ownership according to Swiss Income Tax Law.

The Company has no unrecognized tax benefits and does not expect that uncertain tax benefits will change significantly in the next twelve months.

Cash paid for income taxes, net of refunds, during the year ended December 31, 2025 was $799 thousand, of which, $598 thousand was paid to the United Kingdom and $201 thousand was paid to Portugal.

Cash paid for income taxes, net of refunds, during the year ended December 31, 2024 and 2023 was $147 thousand and $42 thousand, respectively.

Note 16 — Commitments and Contingencies

Commitments

The Company has entered into agreements as of December 31, 2025 primarily regarding the clinical and non-clinical development services with contract research organizations ("CROs"), as well as supply and logistics services with contract manufacturing organizations, for the advancement of SLK. As of December 31, 2025, the total committed expense under these agreements amounted to $204.9 million.

The Company's In-License Agreement with MHKDG includes contractual milestone payments related to the achievement of pre-specified research, development, regulatory and commercialization events and indemnification

provisions, which are common in such agreements. Pursuant to the agreements, the Company is obligated to make research and development and regulatory milestone payments upon the occurrence of certain events. Subject to the terms of the license, additional milestone payments of up to €299.6 million ($351.7 million using a December 31, 2025 exchange rate) are potentially payable upon satisfying specific milestones related to regulatory filing acceptance, first commercial sales, and aggregate annual net sales. The milestone payments are payable in cash. Milestone payments due prior to obtaining regulatory approval will be recorded as research and development expense upon determination that a milestone payment is probable to occur. Milestone payments due after obtaining regulatory approval will be capitalized when and if incurred. The Company will use commercially reasonable efforts to cause the milestones to occur. However, if the Company reasonably determines that a technical failure or commercial failure has occurred with respect to all or a part of the SLK Program, the Company, at its sole discretion, can terminate all or part of the SLK Program. As of December 31, 2025, the Company made a total of €7.5 million ($8.1 million using the then applicable exchange rate) in additional milestone payments.

In addition, on May 12, 2023, MoonLake AG entered into an agreement with Research Cooperation Technologies, Inc. (“RCT”) and MHKDG, effective as of June 1, 2023, pursuant to which the Company was granted a royalty-bearing, nonexclusive, sublicensable right and license under RCT’s patents and know-how related to a manufacturing process using an underlying yeast strain, Pichia pastoris, to develop, manufacture, use, sell, offer for sale, and import and otherwise commercialize SLK on a world-wide basis, subject to certain restrictions. This agreement replaces the Company’s sublicense for similar rights under the In-License Agreement. In the aggregate, the Company is required to pay royalties within the range of low to mid-teen percent of net sales under the aforementioned agreements with MHKDG and RCT.

Royalties will be recognized in the consolidated statements of operations and comprehensive loss when net sales are recognized.

Note 17 — Segment Information

The Company operates as a single operating segment, focusing exclusively on the research, development, and eventual commercialization of its product. As the entire Company is centered around these activities, all consolidated parts of the Company are reviewed and analyzed as part of one segment.

As of December 31, 2025, the Company's single operating segment had not generated revenue from any programs or services. The accounting policies of the segment are the same as those described in the Note 2 — *Basis of Presentation and Significant Accounting Policies* section. The measure of segment assets is reported on the consolidated balance sheets as total assets. The measure of segment profit or loss is reported on the consolidated statement of operations and comprehensive loss as net loss. The CODM uses this as a starting point alongside significant non-cash items and working capital changes to evaluate cash burn and determine financial sustainability, cost management patterns and overall business viability as the clinical trials progress. The CODM also uses this to manage operations and ensure the most efficient use of Company resources against current budgets, alignment with strategic goals and preparation of future forecasts.

Significant Segment Expenses

The measure of significant segment expenses is reported in the accompanying consolidated statements of operations and comprehensive loss as "Research and development" and "General and administrative" for the years ended December 31, 2025, 2024, and 2023, respectively.

Non-cash share-based compensation is reported in Note 14 — *Share-Based Compensation* for the years ended December 31, 2025, 2024, and 2023. Non-cash depreciation and amortization for the years ended December 31, 2025, 2024, and 2023 was $2.6 million, $1.4 million, and $0.4 million, respectively.

Geographical Data

Long-lived assets, consisting of property and equipment, net, and operating lease right-of-use assets by geographical area as of December 31, 2025 and 2024 are as follows:

(in thousands)

Country	December 31, 2025	December 31, 2024
Switzerland	$ 322	$ 610
United Kingdom	804	1,777
Portugal	1,017	1,257
Total	**$ 2,143**	**$ 3,644**

Note 18 — Subsequent Events

The Company has evaluated events subsequent to the balance sheet date through the date the financial statements were issued and determined that the following subsequent event requires disclosure in the financial statements.

On February 20, 2026 (the "Amendment Date"), the Company executed a first amendment to the Loan and Security Agreement (the "Amendment"), pursuant to which the parties agreed to, among other things, revise available tranches, milestone dates, and financial covenants, resulting in $25.0 million drawn as a second tranche upon execution of the Amendment, and up to $400.0 million remaining available as future tranches.

Additional information about the Amendment is set forth in the Company's Current Report on Form 8-K filed with the U.S. Securities and Exchange Commission on February 23, 2026.

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Dorfstrasse 29, Zug, Switzerland 6300

NOTICE OF THE 2026 ANNUAL GENERAL MEETING OF SHAREHOLDERS
TO BE HELD ON JUNE 4, 2026

To the Shareholders of MoonLake Immunotherapeutics:

NOTICE IS HEREBY GIVEN, that MoonLake Immunotherapeutics (the ''Company'') will hold its 2026 Annual General Meeting of Shareholders (the ''Annual Meeting'') on Thursday, June 4, 2026, at 8:00 a.m. Eastern Time at the offices of Gibson, Dunn & Crutcher LLP, located at 200 Park Avenue, New York, New York 10166. The Annual Meeting will be held for the following purposes, as more fully described in the accompanying proxy statement (the ''Proxy Statement''):

(1) To elect the Class I director nominee named in the Proxy Statement to serve until the 2029 Annual General Meeting of Shareholders and until his successor is duly elected and qualified;

(2) To ratify, by ordinary resolution, the selection of Baker Tilly US, LLP as the Company's independent registered public accounting firm for the year ending December 31, 2026;

(3) To approve, on a non-binding, advisory basis, the compensation of the Company's named executive officers;

(4) To approve an amendment and restatement of the Company's 2022 Equity Incentive Plan; and

(5) To transact any other matters that may properly come before the Annual Meeting or any adjournments or postponements thereof.

The Board of Directors has fixed April 9, 2026 as the record date. Only shareholders of record at the close of business on that date will be entitled to notice of, and to attend and vote at the Annual Meeting or any adjournment or postponement thereof.

By Order of the Board of Directors,

/s/ Dr. Jorge Santos da Silva
Dr. Jorge Santos da Silva
Chief Executive Officer

Zug, Switzerland
April 21, 2026

Whether or not you expect to attend the Annual Meeting, please vote as promptly as possible in order to ensure your representation at the Annual Meeting. You may vote online or, if you requested printed copies of the proxy materials, by telephone or by using the proxy card or voting instruction form provided with the printed proxy materials.

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LEGAL MATTERS

Important Notice Regarding the Availability of Proxy Materials for the 2026 Annual General Meeting of Shareholders to Be Held on June 4, 2026. The Proxy Statement and Annual Report for the year ended December 31, 2025 are available at *www.proxyvote.com*.

Forward-Looking Statements. The Proxy Statement may contain ‘‘forward-looking statements’’ within the meaning of the ‘‘safe harbor’’ provisions of the Private Securities Litigation Reform Act of 1995, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements other than statements of historical fact included in the Proxy Statement, including statements about the Company’s Board of Directors, corporate governance practices, executive compensation program and equity compensation utilization, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as ‘‘may’’, ‘‘might’’, ‘‘will’’, ‘‘objective’’, ‘‘intend’’, ‘‘should’’, ‘‘could’’, ‘‘can’’, ‘‘would’’, ‘‘expect’’, ‘‘believe’’, ‘‘design’’, ‘‘estimate’’, ‘‘predict’’, ‘‘potential’’, ‘‘plan’’, or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results or outcomes to differ materially from the forward-looking statements expressed or implied in the Proxy Statement. Such risks, uncertainties and other factors include those risks described in ‘‘Risk Factors’’ and ‘‘Management’s Discussion and Analysis of Financial Condition and Results of Operations’’ in the Company’s most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (‘‘SEC’’) and other subsequent documents we file with the SEC. The Company expressly disclaims any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

Website References. Website references throughout this document are inactive textual references and provided for convenience only, and the content on the referenced websites is not incorporated herein by reference and does not constitute a part of the Proxy Statement.

Use of Trademarks. MoonLake is the trademark of MoonLake Immunotherapeutics. Other names and brands may be claimed as the property of others.

Dorfstrasse 29, Zug, Switzerland 6300

PROXY STATEMENT

FOR THE 2026 ANNUAL GENERAL MEETING OF SHAREHOLDERS

QUESTIONS AND ANSWERS ABOUT THE PROXY MATERIALS AND VOTING

What Is the Purpose of These Proxy Materials?

We are making these proxy materials available to you in connection with the solicitation of proxies by the Board of Directors (the ''Board'') of MoonLake Immunotherapeutics (''we'', ''us'', ''our'' or the ''Company'') for use at the 2026 Annual General Meeting of Shareholders (the ''Annual Meeting'') to be held on June 4, 2026 at 8:00 a.m. Eastern Time, or at any other time following adjournment or postponement thereof. You are invited to attend the Annual Meeting at the offices of Gibson, Dunn & Crutcher LLP, located at 200 Park Avenue, New York, New York 10166 and to vote on the proposals described in this Proxy Statement. The proxy materials are first being made available to our shareholders on or about April 21, 2026.

Why Did I Receive a Notice of Internet Availability?

Pursuant to U.S. Securities and Exchange Commission (''SEC'') rules, we are furnishing the proxy materials to our shareholders primarily via the Internet instead of mailing printed copies. This process allows us to expedite our shareholders' receipt of proxy materials, lower the costs of printing and mailing the proxy materials and reduce the environmental impact of our Annual Meeting. If you received a Notice of Internet Availability of Proxy Materials (the ''Notice''), you will not receive a printed copy of the proxy materials unless you request one. The Notice provides instructions on how to access the proxy materials for the Annual Meeting via the Internet, how to request a printed set of proxy materials and how to vote your shares.

Who Can Vote?

Only shareholders of record at the close of business on April 9, 2026 (the ''Record Date'') are entitled to notice of the Annual Meeting and to vote on the proposals described in this Proxy Statement. At the close of business on the Record Date, 72,852,170 shares of our Class A Ordinary Shares were issued and outstanding. Each Class A Ordinary Share is entitled to one vote on each proposal to be voted on at the Annual Meeting.

What Is the Difference between Holding Shares as a Registered Shareholder and as a Beneficial Owner?

Registered Shareholder: Shares Registered in Your Name

If your shares are registered directly in your name with our transfer agent, Continental Stock Transfer & Trust Company, you are considered to be, with respect to those shares, the registered shareholder, and these proxy materials are being sent directly to you by us.

Beneficial Owner: Shares Registered in the Name of a Broker, Fiduciary or Custodian

If your shares are held by a broker, fiduciary or custodian, you are considered the beneficial owner of shares held in ''street name'', and these proxy materials are being forwarded to you from that broker, fiduciary or custodian.

What Am I Voting on?

The proposals to be voted on at the Annual Meeting are as follows:

(1) Election of the Class I director nominee to serve until the 2029 Annual General Meeting of Shareholders (''Proposal 1'');

(2) Ratification, by ordinary resolution, of the selection of Baker Tilly US, LLP as the Company's independent auditor for 2026 (''Proposal 2'');

(3) Approval of, on a non-binding, advisory basis, the compensation of the Company's named executive officers ("Proposal 3"); and

(4) Approval of an amendment and restatement of the Company's 2022 Equity Incentive Plan ("Proposal 4").

How Does the Board Recommend That I Vote?

The Board recommends that you vote your shares "**FOR**" the director nominee in Proposal 1 and "**FOR**" Proposals 2, 3 and 4.

What If Another Matter Is Properly Brought before the Annual Meeting?

As of the date of filing this Proxy Statement, the Board knows of no other matters that will be presented for consideration at the Annual Meeting. If any other matters are properly brought before the Annual Meeting, it is the intention of the persons named as proxies in the proxy card to vote on such matters in accordance with their best judgment.

What Does It Mean If I Receive More Than One Set of Proxy Materials?

If you receive more than one set of proxy materials, your shares may be registered in more than one name or held in different accounts. Please cast your vote with respect to each set of proxy materials that you receive to ensure that all of your shares are voted.

How Do I Vote?

Even if you plan to attend the Annual Meeting, we recommend that you also submit your vote as early as possible in advance so that your vote will be counted if you later decide not to, or are unable to, attend the Annual Meeting.

Registered Shareholder: Shares Registered in Your Name

If you are the registered shareholder, you may vote your shares in person at the Annual Meeting or by proxy in advance of the Annual Meeting by Internet (at *www.proxyvote.com*) or, if you requested paper copies of the proxy materials, by completing and mailing a proxy card or by telephone (at 800-690-6903).

Beneficial Owner: Shares Registered in the Name of a Broker, Fiduciary or Custodian

If you are the beneficial owner, you may direct your broker, fiduciary or custodian how to vote in advance of the Annual Meeting by following the instructions they provide or, if you want to vote your shares in person at the Annual Meeting, you should contact your bank, broker or other nominee (preferably at least five days before the Annual Meeting) and obtain a "legal proxy".

What Happens If I Do Not Vote?

Registered Shareholder: Shares Registered in Your Name

If you are the registered shareholder and do not vote in one of the ways described above, your shares will not be voted at the Annual Meeting and will not be counted toward the quorum requirement.

Beneficial Owner: Shares Registered in the Name of a Broker, Fiduciary or Custodian

If you are the beneficial owner and do not direct your broker, fiduciary or custodian how to vote your shares, your broker, fiduciary or custodian will only be able to vote your shares with respect to proposals considered to be "routine". Your broker, fiduciary or custodian is not entitled to vote your shares with respect to "non-routine" proposals, which we refer to as a "broker non-vote". Whether a proposal is considered routine or non-routine is subject to stock exchange rules and final determination by the stock exchange. Even with respect to routine matters, some brokers are choosing not to exercise discretionary voting authority. As a result, we urge you to direct your broker, fiduciary or custodian how to vote your shares on all proposals to ensure that your vote is counted.

What If I Sign and Return a Proxy Card or Otherwise Vote but Do Not Indicate Specific Choices?

Registered Shareholder: Shares Registered in Your Name

The shares represented by each signed and returned proxy will be voted at the Annual Meeting by the persons named as proxies in the proxy card in accordance with the instructions indicated on the proxy card. However, if you are the registered shareholder and you sign and return your proxy card without giving specific instructions, the persons named as proxies in the proxy card will vote your shares in accordance with the recommendations of the Board. Your shares will be counted toward the quorum requirement.

Beneficial Owner: Shares Registered in the Name of a Broker, Fiduciary or Custodian

If you are the beneficial owner and do not direct your broker, fiduciary or custodian how to vote your shares, your broker, fiduciary or custodian will only be able to vote your shares with respect to proposals considered to be ''routine''. Your broker, fiduciary or custodian is not entitled to vote your shares with respect to ''non-routine'' proposals, resulting in a broker non-vote with respect to such proposals.

Can I Change My Vote after I Submit My Proxy?

Registered Shareholder: Shares Registered in Your Name

If you are the registered shareholder, you may revoke your proxy at any time before the final vote at the Annual Meeting in any one of the following ways:

(1) You may complete and submit a new proxy card, but it must bear a later date than the original proxy card;

(2) You may submit new proxy instructions via telephone or the Internet;

(3) You may send a timely written notice that you are revoking your proxy to our Corporate Secretary at the address set forth on the first page of this Proxy Statement; or

(4) You may vote in person at the Annual Meeting. However, your attendance at the Annual Meeting will not, by itself, revoke your proxy.

Your last submitted vote is the one that will be counted.

Beneficial Owner: Shares Registered in the Name of a Broker, Fiduciary or Custodian

If you are the beneficial owner, you must follow the instructions you receive from your broker, fiduciary or custodian with respect to changing your vote.

What Is the Quorum Requirement?

The holders of a majority of the shares outstanding must be present in person or represented by proxy at the Annual Meeting to constitute a quorum. A quorum is required to transact business at the Annual Meeting.

Your shares will be counted toward the quorum only if you submit a valid proxy (or a valid proxy is submitted on your behalf by your broker, fiduciary or custodian) or if you attend the Annual Meeting. Abstentions and broker non-votes will be counted toward the quorum requirement. If there is no quorum within 30 minutes of the meeting start time, unless otherwise determined by the Board of Directors, the Annual Meeting will be adjourned to the same day in the next week at the same time and place and, if there is no quorum within 30 minutes of the adjourned meeting start time, the shares present in person or represented by proxy at the adjourned meeting shall constitute a quorum.

How Many Votes Are Required to Approve Each Proposal and How Are Votes Counted?

Votes will be counted by Broadridge Financial Solutions, the Inspector of Elections appointed for the Annual Meeting.

Proposal 1: Election of Director

At the Annual Meeting, the director will be elected by a plurality of the votes cast. This means that the nominee who receives the highest number of votes cast ''**FOR**'' is elected as the Class I director. Broker non-votes, if any, and votes that are withheld will not be counted as votes cast on the matter and will have no effect on the outcome of the election. Shareholders do not have cumulative voting rights for the election of directors.

Other Proposals

A simple majority of the votes cast at the Annual Meeting is required to approve Proposals 2, 3 and 4. Broker non-votes, if any, and abstentions will not be counted as votes cast on these matters and will have no effect on the outcome of these matters.

Who May Attend and Participate in the Annual Meeting?

Only shareholders as of the Record Date are entitled to attend the Annual Meeting in person. Attendees should bring the appropriate materials described below in order to be admitted to the meeting.

Natural Persons. If you are a registered shareholder, your name will be on a list, and you will be able to gain entry with a government-issued photo identification, such as a driver's license, state-issued ID card or passport. If you are the beneficial owner, in order to gain entry you must present a government-issued photo identification and proof of beneficial share ownership as of the Record Date that includes the same name that is on your government-issued photo identification. Acceptable forms of proof of beneficial share ownership include your Notice, a copy of your proxy card or voting instruction form, if you received one, or an account or brokerage statement showing share ownership as of the Record Date.

Entities. If you are a director, officer, trustee or other legal representative of an entity that owns shares of the Company, you must present a government-issued photo identification, evidence that you are authorized to act on behalf of the entity at the Annual Meeting and, if the entity is a beneficial owner, proof of the entity's beneficial share ownership as of the Record Date.

Non-Shareholders. If you are not a shareholder and are not the representative of an entity that owns shares of the Company, you will be entitled to admission only if you are a proxy holder attending in lieu of a shareholder. To gain entry, you must present a government-issued photo identification and either a valid proxy from a registered shareholder authorizing you to vote the shareholder's shares or, if you are a proxy holder for a beneficial shareholder, a valid legal proxy from the record holder or the bank, brokerage firm or other nominee that holds shares on behalf of the beneficial shareholder.

The offices of Gibson, Dunn & Crutcher LLP are located at 200 Park Avenue, New York, New York 10166, adjacent to Grand Central Terminal on East 42nd Street and accessible via Metro-North Railroad and various New York City subway lines. All shareholders are directed to the building's main security desk located on the mezzanine level. Upon presentation of identification and the materials described above, shareholders will be directed to the Gibson, Dunn & Crutcher LLP reception on the 47th floor.

No cameras, video or recording equipment will be permitted at the Annual Meeting. Many cellular phones have built-in digital cameras, and while these phones may be brought into the Annual Meeting, the camera function may not be used at any time. Additional information regarding the rules and procedures for participating in the Annual Meeting will be set forth in our meeting rules of conduct, which will be available to shareholders during the meeting.

Who Is Paying for This Proxy Solicitation?

We will pay the costs associated with the solicitation of proxies, including the preparation, assembly, printing and mailing of the proxy materials. We may also reimburse brokers, fiduciaries or custodians for the cost of forwarding proxy materials to beneficial owners of shares held in ''street name''.

Our employees, officers and directors may solicit proxies in person or via telephone or the Internet. We will not pay additional compensation for any of these services.

How Can I Find out the Voting Results?

We expect to announce preliminary voting results at the Annual Meeting. Final voting results will be published in a Current Report on Form 8-K to be filed with the SEC within four business days after the Annual Meeting.

PROPOSAL 1: ELECTION OF DIRECTOR

The number of directors constituting the Board is currently set at five. Pursuant to the terms of our Memorandum and Articles of Association (“MAA”), at the Annual Meeting, the shareholders will vote to elect the Class I director nominee named in this Proxy Statement to serve until the 2029 Annual General Meeting of Shareholders and until his successor is duly elected and qualified or until his earlier death, resignation or removal. Our Board has nominated Spike Loy for election to our Board. Mr. Loy was most recently elected by shareholders at the 2023 Annual General Meeting of Shareholders. Our director nominee has indicated that he is willing and able to serve as director. However, if he becomes unable or, for good cause, unwilling to serve, proxies may be voted for the election of such other person as shall be designated by our Board, or the Board may decrease the size of the Board.

Information Regarding the Director Nominee and Continuing Directors

Our Board is divided into three classes, with members of each class holding office for staggered three-year terms. There is currently one Class I director, who is up for election at this meeting for a term expiring at the 2029 Annual General Meeting of Shareholders; two Class II directors, whose terms expire at the 2027 Annual General Meeting of Shareholders; and two Class III directors, whose terms expire at the 2028 Annual General Meeting of Shareholders.

Biographical and other information regarding our director nominee and directors continuing in office, including the primary skills and experiences considered by our Nominating and Corporate Governance Committee (the “Nominating Committee”) in determining to recommend them as nominees, is set forth below.

Name	Class	Age (as of April 21)	Position
Dr. Jorge Santos da Silva	III	49	Chief Executive Officer; Interim Chair of the Board
Spike Loy[1][2][3]	I	45	Lead Independent Director
Catherine Moukheibir[1][2]	II	66	Independent Director
Dr. Andrew Phillips[1][2][3]	III	55	Independent Director
Dr. Ramnik Xavier	II	64	Independent Director

(1) Member of the Audit Committee

(2) Member of the Compensation Committee

(3) Member of the Nominating Committee

Class I Director Nominee

Spike Loy has served as a director of our Company since April 2022 and was appointed Lead Independent Director of the Board in February 2026. Mr. Loy has also served as a director of our subsidiary, MoonLake AG, since May 2021. Mr. Loy is a Managing Director at BVF Partners L.P., a private investment firm, where he has served since August 2009. Mr. Loy previously served as a director of GH Research PLC (Nasdaq: GHRS), a biopharmaceutical company, from October 2020 to March 2022, and as a director of multiple private biopharmaceutical companies. Mr. Loy holds a J.D. from Harvard Law School and a B.A. in Human Biology, with a minor in Economics, from Stanford University.

We believe Mr. Loy is qualified to serve on our Board because of his experience serving as a director of biopharmaceutical companies and as a manager of funds specializing in the area of life sciences.

Class II Directors Continuing in Office

Catherine Moukheibir has served as a director of our Company since April 2022. Ms. Moukheibir is a professional non-executive director specializing in life sciences. In this capacity, she has served as chair of the audit committees of various companies, including Ironwood Pharmaceuticals (Nasdaq: IRWD) since 2019. She also serves on the boards of private companies, including Esteve Healthcare S.A. since 2024, CMR Surgical since 2021, Noema Pharma since 2022 and Synthon B.V. where she serves as Chair. She previously served on the boards of various biotechnology companies, including Oxford Biomedica plc (OTCMKTS: OXBDF), Biotalys (EBAR: BTLS), Ablynx (acquired by Sanofi in 2019), Kymab (acquired by Sanofi in 2021), Zealand Pharma (CPH: ZEAL), Creabilis (acquired by Sienna Biopharmaceuticals in 2016), GenKyoTex (acquired by Calliditas Therapeutics in 2020) and Orphazyme (now known as Strategic Partners A/S). Over the last 20 years, Ms. Moukheibir has held a number of executive-level finance positions at numerous biotechnology companies, including as Director of Capital Markets at Zeltia Group, from 2001-2007; Chief Financial Officer at Movetis, from 2008 to 2010; Executive Vice President of Finance and Strategy

at Innate Pharma (Nasdaq: IPHA), from 2011-2016; and Chairman, then Chief Executive Officer of MedDay Pharmaceuticals from 2016-2021. Ms. Moukheibir began her career in management consulting in Boston and London and then worked in investment banking, where she served as an Executive Director in equity capital markets, first at Citi then at Morgan Stanley in London between 1997 and 2001. Ms. Moukheibir also served for five years on the advisory board of the business school at Imperial College (London). She earned an M.A. in Economics and an M.B.A. from Yale University.

We believe Ms. Moukheibir is qualified to serve on our Board because of her financial expertise, experience on the boards of directors of life sciences companies in the United States and Europe and experience in a variety of roles in executive management, management consulting and investment banking.

Dr. Ramnik Xavier has served as a director of our Company since April 2022. Since 2018, Dr. Xavier has served as a core institute member of the Broad Institute of MIT and Harvard, where he also serves as Director of the Klarman Cell Observatory. Dr. Xavier has served as Director of the Broad Institute's Immunology Program since 2019 and Co-Director of the Broad's Infectious Disease and Microbiome Program since 2016. Since 2013, Dr. Xavier has served as a Professor of Medicine at Harvard Medical School, where he is currently the Kurt J. Isselbacher Professor of Medicine. In addition, since 2018 he has served as Director of the Center for Computational and Integrative Biology and as a member in the Department of Molecular Biology at Massachusetts General Hospital. He has also served as co-director of the Center for Microbiome Informatics and Therapeutics at MIT since 2014. Dr. Xavier holds an M.B. Ch.B. (Hons.) from the Godfrey Huggins School of Medicine, University of Zimbabwe and a Ph.D. from the University of Groningen (Netherlands).

We believe Dr. Xavier is qualified to serve on our Board because of his extensive biomedical research experience and research specializations in the characterization of genetic variants, chemical biology approaches to cellular disease and computational approaches to diseases and treatments.

Class III Directors Continuing in Office

Dr. Jorge Santos da Silva has served as Chief Executive Officer and a director of our Company since April 2022, and he has served as Interim Chair of the Board since February 2026. He co-founded MoonLake AG and served as its Chief Executive Officer from July 2021 until April 2022. Dr. Santos da Silva also serves as a professor and Board Advisor at the School of Medicine at the Minho University (Portugal). Prior to co-founding MoonLake AG, Dr. Santos da Silva was at McKinsey & Company, Inc., a consulting firm, from September 2007 to June 2021, where he served as Senior Partner and led the Pharmaceutical & Medical Products Practice, the Biotech group and the Biosimilars group and advised international biopharmaceutical and biotechnology companies on corporate and business-unit strategy, commercial operating models, research and development, organizational design, mergers and acquisitions and joint ventures. Dr. Santos da Silva was a Postdoctoral Fellow at Cold Spring Harbor Laboratory and holds a Ph.D. in Neuronal Cell Biology from the University of Turin (Italy) and a B.Sc. in Molecular Biology from the University of Glasgow, Institute of Biological and Life Sciences (United Kingdom). He also participated in a work placement in neurobiology at the European Molecular Biology Laboratory, Heidelberg (Germany).

We believe Dr. Santos da Silva is qualified to serve on our Board because of his extensive management and operational experience in the life sciences sector, as well as his academic and research experience in the life sciences.

Dr. Andrew Phillips has served as a director of our Company since April 2022. Dr. Phillips has served as the Chief Executive Officer and President of Aleksia Therapeutics, Inc., a biotechnology company, since August 2022, where he previously served as interim Chief Executive Officer; and as the Chief Executive Officer and President of Nexo Therapeutics, Inc., a biotechnology company, since November 2022. Previously, he served as the Chief Executive Officer of Blossom Bioscience Ltd., a biotechnology company, from June 2021 to December 2023. Prior to Blossom, he served as a Managing Director at Cormorant Asset Management, an investment manager, from August 2020 to July 2022. He served as Chief Financial Officer of Helix from April 2021 until April 2022. Dr. Phillips currently serves as a director OnKure, Inc. (Nasdaq: OKUR), a biopharmaceutical company. He also serves as a director at various private biotechnology companies. Dr. Phillips previously served as a director at the following biotechnology companies: Enliven Therapeutics (Nasdaq: ELVN), from February 2023 to January 2026, Elevation Oncology, Inc. (formerly, Nasdaq: ELEV), from November 2020 through June 2021, and Immuneering Corp. (Nasdaq: IMRX) from December 2020 through July 2021. From January 2016 to March 2020, Dr. Phillips was with C4 Therapeutics, Inc. (Nasdaq: CCCC), a clinical-stage biopharmaceutical company focused on therapeutics for the treatment of cancer and other diseases, where he served as Chief Executive Officer from May 2018 to March 2020, President from September 2016 to May 2018 and Chief Scientific Officer from January 2016 to May 2018. From July 2014 to

January 2016, he served as Senior Director, Center for Development of Therapeutics at the Broad Institute, a biomedical and genomic research organization. From June 2010 to January 2015, Dr. Phillips was a Professor of Chemistry at Yale University, and from July 2001 to June 2010 he was Assistant Professor, Associate Professor, and Professor of Chemistry and Biochemistry at the University of Colorado. He holds a B.Sc. in Biochemistry and a Ph.D. in Chemistry from the University of Canterbury (New Zealand).

We believe Dr. Phillips is qualified to serve on our Board because of his experience serving as an executive officer of biopharmaceutical companies and as a manager of funds specializing in the area of life sciences, in addition to his extensive academic and leadership positions in the area of life sciences.

Board Recommendation

The Board recommends a vote "**FOR**" the election of the Class I director nominee set forth above.

PROPOSAL 2: RATIFICATION OF INDEPENDENT AUDITOR SELECTION

Our Audit Committee has selected Baker Tilly US, LLP (''Baker Tilly'') as the Company's independent registered public accounting firm for the year ending December 31, 2026. In this Proposal 2, we are asking shareholders to vote to ratify this selection. Representatives of Baker Tilly are expected to attend the Annual Meeting. They will have the opportunity to make a statement, if they desire to do so, and are expected to be available to respond to appropriate questions from shareholders.

Shareholder ratification of the selection of Baker Tilly as the Company's independent auditor is not required by applicable law or our MAA. However, we are seeking shareholder ratification as a matter of good corporate practice. If our shareholders fail to ratify the selection, the committee will reconsider its selection. Even if the selection is ratified, the committee, in its discretion, may direct the selection of a different independent auditor at any time during the year if it determines that such a change would be in the best interests of the Company and our shareholders.

Baker Tilly has served as our independent auditor since June 2022 and previously provided services to MoonLake AG. The following table summarizes the audit fees billed and expected to be billed by Baker Tilly for the indicated fiscal years and the fees billed by Baker Tilly for all other services rendered during the indicated fiscal years. All services associated with such fees were pre-approved by our Audit Committee in accordance with the ''Pre-Approval Policies and Procedures'' described below.

	Year Ended December 31,	
Fee Category	**2025**	**2024**
Audit Fees[(1)]	$1,046,410	$973,450
Audit-Related Fees[(2)]	—	—
Tax Fees[(3)]	—	—
All Other Fees[(4)]	—	—
Total Fees	**$1,046,410**	**$973,450**

(1) Audit Fees include fees for professional services rendered for the audit of year-end financial statements, reviews of quarterly financial statements and services that are normally provided by our independent registered public accounting firm in connection with statutory and regulatory filings.

(2) Audit-Related Fees include fees billed for assurance and related services that are reasonably related to performance of the audit or review of our year-end financial statements and are not reported under ''Audit Fees''. These services include attest services that are not required by statute or regulation and consultation concerning financial accounting and reporting standards.

(3) Tax Fees include fees consist of fees billed for professional services relating to tax compliance, tax planning and tax advice.

(4) All Other Fees consist of fees billed for all other services, including annual licensing fees for accounting database subscriptions.

In addition, in 2025, MoonLake AG incurred $28,686 (CHF 23,100) in audit fees for services provided by OBT AG pertaining to the audit of the statutory financial statements of MoonLake AG for the period ended December 31, 2025. In 2024, MoonLake AG incurred $31,427 (CHF 26,500) in audit fees for services provided by OBT AG pertaining to the audit of the statutory financial statements of MoonLake AG for the period ended December 31, 2024.

Pre-Approval Policies and Procedures

Our Audit Committee has adopted procedures requiring the pre-approval of all audit and permissible non-audit services performed by our independent registered public accounting firm. In its pre-approval and review of non-audit service fees, the Audit Committee considers, among other factors, the possible effect of the performance of such services on the auditors' independence.

These procedures generally approve the performance of specific services subject to a cost limit for all such services. This general approval is reviewed, and if necessary modified, at least annually. The committee may pre-approve certain other audit-related or other non-audit services it believes would not impair the independence of the auditor and are consistent with SEC and Public Company Accounting Oversight Board (''PCAOB'') rules on auditor independence. The committee does not delegate its responsibility to approve services performed by our auditor to any member of management. The committee has delegated authority to the committee chair to pre-approve any audit or non-audit service to be provided to us by our auditor provided that the fees for such services do not exceed $100,000. Any approval of services by the committee chair pursuant to this delegated authority must be reported to the committee at its next regularly scheduled meeting.

Report of the Audit Committee

The Audit Committee has reviewed and discussed the audited financial statements for the year ended December 31, 2025 with the Company's management and with Baker Tilly, the Company's independent registered public accounting firm. The Audit Committee has discussed with Baker Tilly the matters required to be discussed by the applicable standards of the PCAOB and the SEC. The Audit Committee has also received the written disclosures and the letter from Baker Tilly pursuant to applicable PCAOB requirements regarding its communications with the Audit Committee concerning independence, and the Audit Committee has discussed with Baker Tilly its independence. Based on the foregoing, the Audit Committee recommended to the Board that the audited financial statements be included in the Company's Annual Report on Form 10-K for the year ended December 31, 2025 for filing with the SEC.

This report is provided by the following directors, who serve on the Audit Committee:

Catherine Moukheibir (Chair)
Spike Loy
Dr. Andrew Phillips

Board Recommendation

The Board recommends a vote "**FOR**" the ratification, by ordinary resolution, of the selection of Baker Tilly to serve as our independent auditor

PROPOSAL 3: ADVISORY VOTE ON EXECUTIVE COMPENSATION

Our Board is asking you to approve, on a non-binding, advisory basis, the compensation of our named executive officers, as disclosed in this Proxy Statement. This item, which is provided pursuant to Section 14A of the Securities Exchange Act of 1934, as amended (the ''Exchange Act''), is commonly referred to as a ''say-on-pay'' resolution.

This say-on-pay proposal gives our shareholders the opportunity to express their views on our named executive officers' compensation as a whole. This vote is not intended to address any specific element of compensation but rather the overall compensation of our named executive officers and our compensation philosophy, policies and practices described in this Proxy Statement. Please read the ''Executive Compensation'' section, including the Compensation Discussion and Analysis and the compensation tables and accompanying narrative disclosure, for information about our executive compensation program, including details of our 2025 compensation for our named executive officers. Our Compensation Committee believes that these policies and practices are effective in implementing our compensation philosophy and achieving our compensation program goals.

As an advisory vote, the outcome of the vote on this proposal is not binding. However, our Compensation Committee, which is responsible for designing and administering our executive compensation program, will consider the outcome of this vote when making future executive compensation decisions. Unless our Board modifies its policy on the frequency of holding say-on-pay votes, the next say-on-pay vote will occur at our 2027 Annual General Meeting of Shareholders.

Board Recommendation

The Board recommends a vote ''**FOR**'' the approval, on a non-binding, advisory basis, of our named executive officers' compensation.

PROPOSAL 4: APPROVAL OF AN AMENDMENT AND RESTATEMENT OF THE COMPANY'S 2022 EQUITY INCENTIVE PLAN

The Company's shareholders are being asked to approve an amendment and restatement of the MoonLake Immunotherapeutics 2022 Equity Incentive Plan (the ''Incentive Plan''). The Incentive Plan originally became effective on April 5, 2022, and, in order to continue to provide employees, officers, non-employee directors and other service providers with stock-based incentives, the Board adopted the amendment and restatement of the Incentive Plan on April 17, 2026, subject to its approval by the Company's shareholders, to increase the number of Class A Ordinary Shares available for stock-based awards by 5,000,000 shares, remove liberal share recycling provisions, incorporate a one-year minimum vesting requirement, revise the non-employee director compensation limits set forth therein, specify the treatment of outstanding awards in the event of a change in control, extend the term of the Incentive Plan to June 4, 2036, and make certain other administrative changes. If the Company shareholders approve the amendment and restatement of the Incentive Plan, it will become effective upon the date of the 2026 Annual Meeting.

We believe that employees, officers, non-employee directors, and other key service providers should have a significant stake in the Company under programs that link compensation to shareholder return. As a result, equity compensation is considered to be an integral part of the Company's compensation program. The Board approved the amendment and restatement of the Incentive Plan because there are limited remaining shares available for grant and the Company does not have any other plans under which equity awards can be granted to existing employees. If shareholders do not approve this proposal, we will continue to have the authority to grant awards under the Incentive Plan, but the proposed 5,000,000 share increase will not be effective, which could result in a serious disruption of our compensation programs and will limit our ability to provide retention incentives to our executives and other employees. Equity awards are a significant component of total compensation for our executive officers and other employees and are vital to our ability to attract and retain outstanding and highly skilled individuals in the extremely competitive labor markets in which we compete. If shareholders do not approve the proposal, we would need to grant cash and other non-equity rewards to these individuals. We believe that such alternative forms of compensation do not align employee interests with those of shareholders as efficiently as equity-based awards, and we think it is important to provide compensation that continues to effectively align employees with shareholders and provides a total compensation package that is competitive with other companies. We strongly believe that the approval of this proposal is instrumental to our continued success, and that the additional 5,000,000 shares requested will be sufficient to fund future equity grants under the Incentive Plan for approximately the next 3 to 5 years.

When approving the amendment and restatement of the Incentive Plan, the Board considered the potential dilution of the amended and restated Incentive Plan to the shareholders of the Company. If the amendment and restatement of the Incentive Plan is approved, then the Company's total potential dilution from the new shares available for issuance thereunder would represent approximately 6.2% as of April 1, 2026. The Board considered this potential dilution level in the context of competitive data from its peer group and the Company's expected growth needs, and believes that the resulting dilution levels are reasonable and in the best interests of shareholders.

Existing Equity Plan Information

The Company does not maintain any other equity plans. The following table includes aggregated information regarding awards outstanding as of April 1, 2026 under the Incentive Plan and the proposed number of additional shares under the Incentive Plan:

Outstanding Stock Option Awards	2,522,420
Weighted Average Exercise Price	$14.78
Weighted Average Remaining Term	8.81 years
Outstanding Full Value Awards	497,942
Number of Shares Available for Grant Under Incentive Plan (prior to the proposed amendment and restatement)	1,046,782
Total Class A Ordinary Shares Outstanding	72,605,691
Number of Additional Shares Requested for Incentive Plan	5,000,000

Summary of the Incentive Plan

The following description of the amended and restated Incentive Plan is qualified in its entirety by reference to the plan document, a copy of which is attached as Appendix A and incorporated into this revised proxy statement by reference. Shareholders and potential investors are urged to read the Incentive Plan in its entirety. Any capitalized terms which are used in this summary description but not defined here or elsewhere in this revised proxy statement have the meanings assigned to them in the Incentive Plan.

Purpose of the Incentive Plan

We have adopted the Incentive Plan. The purpose of the Incentive Plan is to promote and closely align the interests of our employees, officers, non-employee directors, and other service providers and our shareholders by providing share-based compensation and other performance-based compensation. The objectives of the Incentive Plan are to attract and retain the best available personnel for positions of substantial responsibility and to motivate participants to optimize the profitability and growth of the Company through incentives that are consistent with our goals and that link the personal interests of participants to those of our shareholders. The Incentive Plan allows for the grant of stock options, both incentive and ''non-qualified'' stock options; SARs, alone or in conjunction with other awards; restricted stock and RSUs; incentive bonuses, which may be paid in cash, shares, or a combination thereof; and other stock-based awards. We refer to these collectively herein as ''Awards''.

Administration

The Incentive Plan is administered by the Compensation Committee, or such other committee as may be designated by the Company's Board to administer the plan, which we refer to herein as the ''Administrator''. The Administrator has broad authority, subject to the provisions of the Incentive Plan, to administer and interpret the Incentive Plan and Awards granted thereunder. All decisions and actions of the Administrator will be final.

Eligibility

Any current or prospective employee, officer, non-employee director or other service provider of the Company or any of its subsidiaries may be selected by the Administrator to receive an award under the Incentive Plan; provided, however, that incentive stock options may only be granted to employees of the Company or any of its ''subsidiary corporations'' within the meaning of Section 424 of the Code. As of April 1, 2026, approximately 125 employees and 4 non-employee directors were eligible to participate in the Incentive Plan. While consultants are generally considered eligible under the Incentive Plan to preserve our flexibility, we have never granted equity awards under the Incentive Plan to any consultants and do not currently have plans to do so in the near future.

Stock Subject to Incentive Plan

The maximum number of Class A Ordinary Shares that may be issued under the Incentive Plan is equal to 9,353,948 (the ''Share Pool''), all of which may be issued pursuant to the exercise of incentive stock options. The Share Pool is subject to certain adjustments in the event of a change in our capitalization. Class A Ordinary Shares issued under the Incentive Plan may be either authorized and unissued shares or previously issued shares acquired by us. On termination or expiration of an Award under the Incentive Plan, in whole or in part, the number of Class A Ordinary Shares subject to such Award but not issued thereunder or that are otherwise forfeited back to the Company will again become available for grant under the Incentive Plan. Notwithstanding the foregoing, shares subject to Awards under the Incentive Plan may not again be made available for issuance under the Plan if such shares are shares that were subject to a stock-settled SAR and were not issued upon the net settlement or net exercise of such SAR, shares that have been delivered (either actually or by attestation) to, or retained or withheld by, the Company in payment or satisfaction of any exercise price, purchase price or tax withholding obligation of an Award, or shares that have been repurchased on the open market with the proceeds of an option exercise.

Limits on Non-Employee Director Compensation

Under the Incentive Plan, the aggregate dollar value of all cash and equity-based compensation (whether granted under the Incentive Plan or otherwise) to our non-employee directors for services in such capacity shall not exceed $750,000 during any calendar year. However, during the calendar year in which a non-employee director first joins the Company's Board or during any calendar year in which a non-employee director serves as chairperson or lead director, such aggregate limit shall instead be $1,000,000.

Minimum Vesting Requirements

Awards granted under the Incentive Plan may not become exercisable, vest or be settled, in whole or in part, prior to the one (1) year anniversary of the date of grant except (i) with respect to an Award that is granted in connection with a merger or other acquisition as a substitute or replacement award for awards held by grantees of the acquired business and (ii) with respect to an Award granted to a non-employee director that vests on the earlier of the one-year anniversary of the date of grant and the next annual meeting of shareholders which is at least 50 weeks after the immediately preceding year's annual meeting; provided, that up to 5% of the aggregate number of shares authorized for issuance under the Incentive Plan may be issued pursuant to Awards subject to any, or no, vesting conditions, as the Administrator determines appropriate; and, provided, further, that the foregoing restriction does not apply to the Administrator's discretion to provide for accelerated exercisability or vesting of any Award, including in cases of retirement, death, disability, or a change in control, in the terms of the Award or otherwise.

Types of Awards

Stock Options

All stock options granted under the Incentive Plan will be evidenced by a written agreement with the participant, which provides, among other things, whether the option is intended to be an incentive stock option or a non-qualified stock option, the number of shares subject to the option, the exercise price, exercisability (or vesting), the term of the option, which may not generally exceed ten years, and other terms and conditions. Subject to the express provisions of the Incentive Plan, options generally may be exercised over such period, in installments or otherwise, as the Administrator may determine. The exercise price for any stock option granted may not generally be less than the fair market value of the Class A Ordinary Shares subject to that option on the grant date. The exercise price may be paid in cash or such other method as determined by the Administrator, including an irrevocable commitment by a broker to pay over such amount from a sale of the shares issuable under an option, the delivery of previously owned shares or withholding of shares deliverable upon exercise. Other than in connection with a change in our capitalization, we will not, without shareholder approval, reduce the exercise price of a previously awarded option, and at any time when the exercise price of a previously awarded option is above the fair market value of a Class A Ordinary Share, we will not, without shareholder approval, cancel and re-grant or exchange such option for cash or a new Award with a lower (or no) exercise price. Participants will not have voting rights nor the right to receive dividends or dividend equivalents in respect of an award of options or any Class A Ordinary Shares subject to such an award until the participant has become the holder of record of such Class A Ordinary Shares.

Stock Appreciation Rights

SARs may be granted alone or in conjunction with all or part of a stock option. Upon exercising a SAR, the participant is entitled to receive the amount by which the fair market value of the Class A Ordinary Shares at the time of exercise exceeds the exercise price of the SAR. This amount is payable in Class A Ordinary Shares, cash, restricted stock, or a combination thereof, at the Administrator's discretion. Participants will not have voting rights nor the right to receive dividends or dividend equivalents in respect of an award of SARs or any Class A Ordinary Shares subject to such an award until the participant has become the holder of record of such Class A Ordinary Shares.

Restricted Stock and RSUs

Awards of restricted stock consist of shares that are transferred to the participant subject to restrictions that may result in forfeiture if specified conditions are not satisfied. RSUs result in the transfer of shares or cash to the participant only after specified conditions are satisfied. The Administrator will determine the restrictions and conditions applicable to each Award of restricted stock or RSUs, which may include performance vesting conditions. In no event will dividends or dividend equivalents be paid during the performance period with respect to unearned awards of restricted stock or RSUs that are subject to performance-based vesting criteria. Dividends or dividend equivalents accrued on such shares will become payable no earlier than the date the performance-based vesting criteria have been achieved and the underlying shares of restricted stock or RSUs have been earned.

Other Stock-Based Awards

Other stock-based awards are Awards denominated in or payable in, valued in whole or in part by reference to, or otherwise based on or related to, the value of shares. In no event will dividends or dividend equivalents be paid during the performance period with respect to unearned other stock-based awards that are subject to

performance-based vesting criteria. Dividends or dividend equivalents accrued on such shares will become payable no earlier than the date the performance-based vesting criteria have been achieved and the underlying shares relating to such award have been earned.

Incentive Bonuses

Each incentive bonus will confer upon the participant the opportunity to earn a future payment tied to the level of achievement with respect to one or more performance criteria established for a specified performance period. The Administrator will establish the performance criteria and level of achievement versus these criteria that will determine the threshold, target, and maximum amount payable under an incentive bonus, which criteria may be based on financial performance and/or personal performance evaluations. Payment of the amount due under an incentive bonus may be made in cash or shares, as determined by the Administrator.

Performance Criteria

The Administrator may specify certain performance criteria which must be satisfied before Awards will be granted or will vest. The performance goals may vary from participant to participant, group to group, and period to period.

Change in Control

In the event of a change in control, immediately prior to the change in control, all Awards will be treated as follows: (A) in the case of a stock option or SAR, the participant will have the ability to exercise such stock option or SAR, including any portion of the stock option or SAR not previously exercisable, (B) in the case of any Award the vesting of which is in whole or in part subject to performance criteria or an incentive bonus, all conditions to the grant, issuance, retention, vesting or transferability of, or any other restrictions applicable to, such Award will immediately lapse and the participant will have the right to receive a payment based on the greater of target level achievement or actual performance through the date of the change in control, and (C) in the case of outstanding restricted stock, restricted stock units or other share-based Awards (other than those referenced in subsection (B)), all conditions to the grant, issuance, retention, vesting or transferability of, or any other restrictions applicable to, such Award will immediately lapse.

The Administrator may provide for the cancellation and cash settlement of all outstanding Awards upon such change in control.

Transferability

Awards generally may not be sold, transferred for value, pledged, assigned or otherwise alienated or hypothecated by a participant other than by will or the laws of descent and distribution, and each option or SAR may be exercisable only by the participant during his or her lifetime.

Amendment and Termination; Term

The Company's Board has the right to amend, alter, suspend or terminate the Incentive Plan at any time, provided certain enumerated material amendments may not be made without shareholder approval. No amendment or alteration to the Incentive Plan or an Award or Award agreement will be made that would materially impair the rights of the holder, without such holder's consent; however, no consent will be required if the Administrator determines in its sole discretion and prior to the date of any change in control that such amendment or alteration either is required or advisable in order for the Company, the Incentive Plan, or such Award to satisfy any law or regulation or to meet the requirements of or avoid adverse financial accounting consequences under any accounting standard, or is not reasonably likely to significantly diminish the benefits provided under such Award, or that any such diminishment has been adequately compensated. Unless earlier terminated by the Board, the Incentive Plan will remain available for the grant of Awards until June 4, 2036, but previously granted Awards may continue beyond that date in accordance with their terms. Notwithstanding the foregoing, incentive stock options may not be granted after the tenth anniversary of the Board's approval of the Incentive Plan.

Certain U.S. Federal Income Tax Consequences

The following discussion of the federal income tax consequences of the Incentive Plan is intended to be a summary of applicable federal law as currently in effect. It should not be taken as tax advice by participants, who are urged to consult their individual tax advisors.

Stock Options. Incentive Stock Options (''ISOs'') and Non-qualified stock options (''NQSOs'') are treated differently for federal income tax purposes. ISOs are intended to comply with the requirements of Section 422 of the Code. NQSOs do not comply with such requirements. An optionee is not taxed on the grant or exercise of an ISO. The difference between the exercise price and the fair market value of the shares on the exercise date will, however, be a preference item for purposes of the alternative minimum tax. If an optionee holds the shares acquired upon exercise of an ISO for at least two years following the option grant date and at least one year following exercise, the optionee's gain, if any, upon a subsequent disposition of such shares is long term capital gain. The measure of the gain is the difference between the proceeds received on disposition and the optionee's basis in the shares (which generally equals the exercise price). If an optionee disposes of stock acquired pursuant to the exercise of an ISO before satisfying these holding periods, the optionee will recognize both ordinary income and capital gain in the year of disposition. The Company is not entitled to an income tax deduction on the grant or exercise of an ISO or on the optionee's disposition of the shares after satisfying the holding period requirement described above. If the holding periods are not satisfied, the Company will be entitled to a deduction in the year the optionee disposes of the shares in an amount equal to the ordinary income recognized by the optionee.

In order for an option to qualify for ISO tax treatment, the grant of the option must satisfy various other conditions more fully described in the Code. The Company does not guarantee that any option will qualify for ISO tax treatment even if the option is intended to qualify for such treatment. In the event an option intended to be an ISO fails to so qualify, it will be taxed as an NQSO as described below.

An optionee is not taxed on the grant of an NQSO. On exercise, the optionee recognizes ordinary income equal to the difference between the exercise price and the fair market value of the shares acquired on the date of exercise. The Company is entitled to an income tax deduction in the year of exercise in the amount recognized by the optionee as ordinary income. The optionee's gain (or loss) on a subsequent disposition of the shares is long term capital gain (or loss) if the shares are held for at least one year following exercise. The Company does not receive a deduction for this gain.

SARs. An optionee is not taxed on the grant of a SAR. On exercise, the optionee recognizes ordinary income equal to the cash or the fair market value of any shares received. The Company is entitled to an income tax deduction in the year of exercise in the amount recognized by the optionee as ordinary income.

Restricted Stock and Restricted Stock Units. Generally, grantees of restricted stock or restricted stock units do not recognize income at the time of the grant. When the award vests or is paid, grantees generally recognize ordinary income in an amount equal to the fair market value of the stock or units at such time, and the Company will receive a corresponding deduction. However, no later than 30 days after a participant receives an award of restricted stock, the participant may elect to recognize taxable ordinary income in an amount equal to the fair market value of the shares at the time of receipt (i.e., grant). Provided that the election is made in a timely manner, when the restrictions on the shares lapse, the participant will not recognize any additional income. If the participant forfeits the shares to the Company (e.g., upon the participant's termination prior to vesting), the participant may not claim a deduction with respect to the income recognized as a result of the election.

Cash Awards. A participant will have taxable income at the time a cash award becomes payable, and, if the participant has timely elected deferral to a later date, such later date. At that time, the participant will recognize ordinary income equal to the value of the amount then payable.

Company Deduction and Section 162(m). In general, Section 162(m) of the Code limits a publicly traded company's federal income tax deduction for compensation in excess of $1 million paid to its Chief Executive Officer, Chief Financial Officer and the next three highest-paid executive officers. As such, we expect that we will be unable to deduct all compensation in excess of $1 million paid to our Chief Executive Officer, Chief Financial Officer and the next three highest-paid executive officers.

Withholding Taxes. The Company will generally be required to withhold applicable taxes with respect to any ordinary income recognized by a participant in connection with awards made under the Incentive Plan. Whether or not such withholding is required, the Company will make such information reports to the Internal Revenue Service as may be required with respect to any income (whether or not that of an employee) attributable to transactions involving awards.

Plan Benefits; Market Value of Securities

The benefits that will be awarded or paid in the future under the Incentive Plan are not currently determinable as awards under the Incentive Plan are within the discretion of the Administrator, and the Administrator has not determined future awards or who might receive them. However, each non-employee director is expected to receive an annual award of share options on the date of the Annual Meeting with a grant date fair value equal to approximately $290,000. The following table shows information regarding the awards granted under the Incentive Plan as of April 1, 2026 to the persons and groups identified below. The closing market price of our Class A Ordinary Shares as reflected on Nasdaq on April 1, 2026 was $16.52.

Name and Position	Number of Options Granted (#)	Number of Shares Subject to Stock Awards (#)
Dr. Jorge Santos da Silva, Chief Executive Officer and Interim Chair of the Board	520,342	95,763
Matthias Bodenstedt, Chief Financial Officer	—	450,059
Dr. Kristian Reich, Chief Scientific Officer	659,615	—
All current executive officers as a group (3 persons)	1,179,957	545,822
All current directors who are not executive officers as a group (4 persons)	237,668	—
Each other nominee for election as a director	—	—
Each associate of any such directors, executive officers, or nominee	—	—
Each other person who received or is to receive 5% of such options, warrants, or rights	—	—
All current employees, including all current officers who are not executive officers, as a group	1,655,813	—

Registration

If our shareholders approve the Incentive Plan, we intend to file a Registration Statement on Form S-8 with the SEC to register the additional shares available for issuance under the plan following the Annual Meeting during the second or third fiscal quarter.

Board Recommendation

The Board recommends a vote **"FOR"** the approval of an amendment and restatement of the Incentive Plan.

CORPORATE GOVERNANCE

Our business affairs are managed under the direction of our Board. Our Board has adopted a set of Principles of Corporate Governance as a framework for the governance of the Company, which is posted on our website located at *ir.moonlaketx.com*, under ''Corporate Governance''.

Our Governance Structure and Philosophy

Our governance practices reflect the environment in which we operate and are designed to support our mission to advance therapies to address significant unmet needs in inflammatory skin and joint diseases. We are a pre-revenue single-asset clinical-stage biotechnology company in an evolving industry. We are focused on the development of Sonelokimab (''SLK''), a novel tri-specific IL-17A and IL-17F inhibiting Nanobody, that we exclusively licensed from Merck Healthcare KGaA, Darmstadt, Germany (''MHKDG'') and that has the potential, based on response levels seen in clinical trials, to drive disease modification in dermatology and rheumatology patients. We are working towards submitting our first Biologics License Application (''BLA'') for SLK in the second half of 2026.

Like other companies in the biotechnology industry, we face extreme share price and volume fluctuations that are often unrelated or disproportionate to our operating performance. With these business environment considerations in mind, the Board put in place our current governance structure to enable the management team to act with deliberation and to focus on delivering long-term value to shareholders and protect minority investors from the interests of potentially short-sighted investors who may seek to act opportunistically and not in the best interests of the Company or shareholders generally. This structure includes the following elements:

- **Classified board**: our directors serve three-year terms, with approximately 1/3 of the Board (instead of the entire Board) elected at each annual general meeting. This helps to provide stability and continuity, permitting directors to develop and share institutional knowledge and focus on the long term, and encourages shareholders to engage directly with the Board and management team regarding significant corporation transactions.
- **Supermajority voting**: the voting standard for most items at a general meeting is a simple majority vote, but a 2/3 supermajority vote is needed to, among other things, amend our MAA and to remove directors. This helps protect against a small group of shareholders acting to amend our governing documents or to remove directors for reasons that may not be in the best interests of all shareholders.
- **Plurality voting for directors**: our directors are elected by a plurality of votes cast (instead of a simple majority of votes cast), meaning the nominees with the most votes are elected. This helps avoid potential disruption to the Board and management team as a result of a ''failed election''.
- **Shareholders cannot call general meetings**: shareholders can propose business at each annual general meeting (in accordance with our advance notice provisions of our MAA and Rule 14a-8), but cannot call a shareholder vote in between annual general meetings. This helps avoid unnecessary diversion of Board and management time (potentially at the request of a limited number of shareholders acting to further short-term special interests) from executing on our long-term strategy.

Recognizing that the Company's operating environment continues to evolve and that governance practices should not be static as a matter of course, the Board annually evaluates our governance structure to confirm it remains in the best interests of the Company and shareholders and values input from our shareholders on this topic.

Board Composition

Director Nomination Process

The Nominating Committee is responsible for, among other things, overseeing succession planning for directors and building a qualified board to oversee management's execution of the Company's strategy and safeguard the long-term interests of shareholders. In this regard, the committee is charged with developing and recommending Board membership criteria to the Board for approval, evaluating the composition of the Board annually to assess the skills and experience that are currently represented on the Board and the skills and experience that the Board may find valuable in the future, and identifying, evaluating and recommending potential director candidates.

In identifying potential candidates for Board membership, the Nominating Committee considers recommendations from directors, shareholders, management and others, including, from time to time, third-party

search firms to assist it in locating qualified candidates. Once potential director candidates are identified, the committee, with the assistance of management, undertakes a vetting process that considers each candidate's background, independence and fit with the Board's priorities. As part of this vetting process, the committee, as well as other members of the Board and the CEO, may conduct interviews with the candidates. If the committee determines that a potential candidate meets the needs of the Board and has the desired qualifications, it recommends the candidate to the full Board for appointment or nomination and to the shareholders for election at the annual general meeting.

Criteria for Board Membership

In assessing potential candidates for Board membership and in assessing Board composition, the Nominating Committee considers a wide range of factors and generally seeks to balance the following skills, experiences and backgrounds on the Board:

- **Biotechnology & Related Industry Experience**: experience within the biotechnology, pharmaceuticals, medical technologies or healthcare industries, particularly, experience with biologics and immunology therapeutic areas (e.g., dermatology or rheumatology) or experience in clinical development, operations or research and development.
- **Corporate Governance**: experience, whether currently or in the past, serving on other public company boards of directors.
- **Diverse Perspectives**: contributes to a diversity of skills, experiences, perspectives and backgrounds on the Board.
- **Finance & Accounting**: experience or expertise in finance, accounting, investment analysis, financial reporting processes and capital markets.
- **Sales & Marketing**: experience overseeing or driving product sales, marketing and commercialization, particularly in the biotechnology and pharmaceuticals industries and in the context of payor or reimbursed and regulated markets.
- **Science & Research**: scientific knowledge related to biotechnology and related industry experience, and experience in related research and clinical development.
- **Senior Leadership**: experience serving in a leadership role of an organization, including driving strategy execution, organizational growth and managing human capital.

The Nominating Committee generally believes it is important for all Board members to possess the highest personal and professional ethics, integrity and values, an inquisitive and objective perspective, a sense for priorities and balance, the ability and willingness to devote sufficient time and attention to Board matters, and a willingness to represent the long-term interests of all our shareholders.

In addition to the factors discussed above, the Board and the Nominating Committee actively seek to achieve a diversity of viewpoints, occupations, perspectives and backgrounds on the Board. The Nominating Committee assesses its effectiveness in balancing these considerations in connection with its annual evaluation of the composition of the Board. For example, our current Board of five directors includes one director (20%) who self-identifies as female and one director (20%) who self-identifies as racially/ethnically diverse.

Shareholder Recommendations for Directors

It is the Nominating Committee's policy to consider written recommendations from shareholders for director candidates. The committee considers candidates recommended by our shareholders in the same manner as a candidate recommended by other sources. Any such recommendations should be submitted to the committee as described under ''Shareholder Communications'' and should include the same information required under our MAA for nominating a director, as described under ''Shareholder Proposals and Director Nominations for Next Year's Annual General Meeting''.

Director Time Commitments

While Board members benefit from service on the boards of other companies and such service is encouraged, under the Board's Principles of Corporate Governance, directors are expected to limit the number of other boards on which they serve so as not to interfere with their service as a director of the Company. Directors are expected to advise the Chairperson of the Nominating Committee before accepting a seat on the board of another company.

Board Leadership Structure

Our Principles of Corporate Governance provide our Board with the flexibility to combine or separate the positions of Chair of the Board and CEO. Our Board believes that there is no single, generally accepted board leadership structure that is appropriate across all circumstances, and that the right structure may vary as circumstances change. As such, the Board periodically reviews its leadership structure to evaluate whether the structure remains appropriate for the Company, and may modify this structure from time to time as and when appropriate to best address the Company's unique circumstances and advance the best interests of all shareholders. At any time when the Chair of the Board is not independent, the independent directors of the Board will designate an independent director to serve as Lead Independent Director.

Currently, Dr. Santos da Silva, our CEO, also serves as our Interim Chair of the Board, and the independent directors have selected Mr. Loy to serve as our Lead Independent Director. The Board believes that this is the appropriate board leadership structure for us at this time. Combining the roles of CEO and Chair of the Board on an interim basis provides unified leadership during this time of transition whereby the person responsible for driving strategy and agenda setting at the Board level is also responsible for executing on that strategy as CEO, while our Lead Independent Director, combined with a Board that is completely independent except for the CEO, provides independent Board oversight of management.

The Lead Independent Director's responsibilities include: (a) presiding at meetings of the Board at which the Chair of the Board is not present, including executive sessions of the independent directors; (b) consulting on information sent to the Board; (c) consulting on the agenda and schedule for Board meetings so that there is sufficient time for discussion of all agenda items; (d) serving as liaison between the Chair of the Board and the independent directors; (e) being available for consultation and communication with major shareholders upon request; and (f) performing such other duties as the Board may determine from time to time. The Lead Independent Director also has the authority to call executive sessions of the independent directors.

The independent directors have the opportunity to meet in executive sessions without management present at every regular Board meeting and at such other times as may be determined by the Lead Independent Director. The purpose of these executive sessions is to encourage and enhance communication among the independent directors.

The Board believes that its programs for overseeing risk, as described under ''Board Risk Oversight'', would be effective under a variety of leadership frameworks. Accordingly, the Board's risk oversight function did not significantly impact its selection of the current leadership structure.

Director Independence

Nasdaq listing rules require a majority of a listed company's board of directors to be comprised of independent directors who, in the opinion of the board of directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Subject to specified exceptions, each member of a listed company's audit, compensation and nominating committees must be independent, and audit and compensation committee members must satisfy additional independence criteria under the Exchange Act.

Our Board undertook a review of its composition and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, our Board has determined that Mr. Loy, Drs. Phillips and Xavier, and Ms. Moukheibir qualify as ''independent directors'' as defined by the Nasdaq listing rules. Dr. Santos da Silva is not deemed to be independent under Nasdaq listing rules by virtue of his employment with the Company. Former director Simon Sturge was independent under Nasdaq listing rules during the period he served on our Board.

Our Board also determined that each of the directors currently serving on the Audit Committee and the Compensation Committee satisfy the additional independence criteria applicable to directors on such committees under Nasdaq listing rules and the rules and regulations established by the SEC.

Board Committees

Our Board has a separately designated Audit Committee, Compensation Committee and Nominating Committee, each of which has the composition and responsibilities described below. Members serve on these committees until their resignation or until otherwise determined by our Board. Each of these committees is empowered to retain outside advisors as it deems appropriate, regularly reports its activities to the full Board and has a written charter, which is posted on our website located at *ir.moonlaketx.com*, under ''Corporate Governance''.

Name	Audit Committee	Compensation Committee	Nominating Committee
Dr. Jorge Santos da Silva			
Spike Loy	X	X	X
Catherine Moukheibir	Chair	X	
Dr. Andrew Phillips	X	Chair	Chair
Dr. Ramnik Xavier			
# of Meetings in 2025	4	3	3

Audit Committee. The primary responsibilities of our Audit Committee are to oversee the accounting and financial reporting processes of the Company, including the audits of the Company's financial statements, the integrity of the financial statements and the annual review of the performance, effectiveness and independence of the outside auditor. This includes reviewing the financial information provided to shareholders and others and the adequacy and effectiveness of the Company's internal controls. The committee also makes recommendations to the Board as to whether financial statements should be included in the Company's Annual Report on Form 10-K.

Ms. Moukheibir qualifies as an ''audit committee financial expert'', as that term is defined in the rules and regulations established by the SEC, and all members of the Audit Committee are ''financially literate'' under Nasdaq listing rules.

Compensation Committee. The primary responsibilities of our Compensation Committee are to periodically review and approve the compensation and other benefits for our senior officers and directors. This includes reviewing and approving corporate goals and objectives relevant to the compensation of our senior officers, evaluating the performance of these officers in light of the goals and objectives and setting the officers' compensation based on those evaluations. The committee also administers and makes recommendations to the Board regarding equity incentive plans that are subject to the Board's approval and approves the grant of equity awards under the plans.

The Compensation Committee may delegate its authority to one or more subcommittees. The committee may also delegate authority to review and approve the compensation of our employees to certain of our executive officers. Even where the committee does not delegate authority, our executive officers will typically make recommendations to the committee regarding compensation to be paid to our employees and the size of equity awards under our equity incentive plans but will not be present during voting or deliberations on their own compensation. The committee has the authority to engage outside advisors, such as compensation consultants, to assist it in carrying out its responsibilities. The committee engaged Deloitte AG (''Deloitte'') in 2025 to provide advice regarding the amount and form of executive and director compensation.

Compensation Committee Interlocks and Insider Participation. None of the members of our Compensation Committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board or compensation committee of any entity that has one or more executive officers serving on our Board or Compensation Committee.

Nominating Committee. The primary responsibilities of our Nominating Committee are to engage in succession planning for the Board, develop and recommend to the Board criteria for identifying and evaluating qualified director candidates and make recommendations to the Board regarding candidates for election or reelection to the Board at each annual shareholders' meeting. In addition, the committee is responsible for overseeing our corporate governance practices and making recommendations to the Board concerning corporate governance matters. The committee is also responsible for making recommendations to the Board concerning the structure, composition and functioning of the Board and its committees.

Board Risk Oversight

We believe that risk management is an important part of establishing and executing on the Company's business strategy. Our Board, as a whole and at the committee level, focuses its oversight on the most significant risks facing the Company and on the Company's processes to identify, prioritize, assess, manage and mitigate those risks. The committees oversee specific risks within their purview, as follows:

- **The Audit Committee** has overall responsibility for overseeing the Company's practices with respect to risk assessment and management. Additionally, the committee is responsible for overseeing management of risks related to our accounting and financial reporting processes, and information technology and cybersecurity.
- **The Compensation Committee** is responsible for overseeing management of risks related to our compensation policies and programs.
- **The Nominating Committee** is responsible for overseeing management of risks related to director succession planning and corporate governance practices.

Our Board and its committees receive regular reports from members of the Company's senior management on areas of material risk to the Company, including strategic, operational, financial, legal and regulatory risks. While our Board has an oversight role, management is principally tasked with direct responsibility for assessing and managing risks, including implementing processes and controls to mitigate their effects on the Company.

Other Corporate Governance Practices and Policies

Director Attendance

The Board met eleven times during the year ended December 31, 2025. Each member of the Board attended at least 75% of the aggregate number of meetings of the Board and the committees on which he or she served during the period in which he or she was on the Board or committee.

Directors are encouraged to attend the annual general meeting of shareholders. All of our directors then serving on the Board attended our 2025 Annual General Meeting of Shareholders.

Shareholder Communications

Shareholders and other interested parties may communicate with our Board or a particular director by sending a letter addressed to the Board or a particular director to our Corporate Secretary at the address set forth on the first page of this Proxy Statement. These communications will be compiled and reviewed by our Corporate Secretary, who will determine whether the communication is appropriate for presentation to the Board or the particular director. The purpose of this screening is to allow the Board to avoid having to consider irrelevant or inappropriate communications (such as advertisements, solicitations and hostile communications).

To enable the Company to speak with a single voice, as a general matter, senior management serves as the primary spokesperson for the Company and is responsible for communicating with various constituencies, including shareholders, on behalf of the Company. Directors may participate in discussions with shareholders and other constituencies on issues where Board-level involvement is appropriate. In addition, the Board is kept informed by Company management of the Company's shareholder engagement efforts.

Code of Business Conduct and Ethics

The Board has adopted a Code of Business Conduct and Ethics (the ''Conduct and Ethics Code'') that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer. Among other things, the Conduct and Ethics Code establishes certain guidelines and principles relating to (i) compliance with laws and regulations, (ii) conflicts of interest, (iii) corporate opportunities, (iv) gifts, (v) confidentiality, (vi) protection and use of Company assets, (vii) record keeping, (viii) environmental, health and safety, (ix) discrimination and harassment, (x) prohibition against payments to government personnel and (xi) insider information and securities trading, as well as establishes internal reporting and compliance procedures.

A copy of the Conduct and Ethics Code is available on our website at *ir.moonlaketx.com*, under ''Corporate Governance''. We intend to disclose future amendments to certain provisions of the Conduct and Ethics Code, and waivers of the Conduct and Ethics Code granted to executive officers and directors, on our website within four business days following the date of the amendment or waiver to the extent required by applicable rules. Our Board is responsible for applying and interpreting the code in situations where questions are presented to it.

Director Compensation

Our Board has adopted a director compensation program pursuant to which members of our Board who are not employees or officers of our Company or our affiliates receive cash retainers, payable quarterly in advance. The cash retainers payable in respect of fiscal year 2025 are as follows:

- Annual cash retainer of $40,000;
- Cash retainer of $35,000 for service as the Chairperson of the Board;
- Cash retainer of $17,500 for service as chairperson and $7,500 for service other than as chairperson of the Audit Committee;
- Cash retainer of $12,000 for service as chairperson and $5,000 for service other than as chairperson of the Compensation Committee;
- Cash retainer of $8,000 for service as chairperson and $4,000 for service other than as chairperson of the Nominating Committee; and
- Cash retainer of $35,000 for service on non-Board committees of the Company, including the Scientific Advisory Board.

In addition, in 2025, each of our non-employee directors received a grant of 6,682 share options on June 5, 2025 under the Incentive Plan that vest in full on the earlier of (i) the one-year anniversary of the date of grant and (ii) the next annual general meeting of shareholders, subject to continued service through such date.

Members of our Board are also eligible to receive reimbursement for reasonable travel and miscellaneous expenses incurred in attending meetings and activities of our Board and its committees. Additionally, directors who are (or were) also members of the board of directors of MoonLake AG (Messrs. Sturge and Loy and Dr. Phillips) are reimbursed for business expenses reasonably incurred in connection with such services.

2025 Non-Employee Director Compensation

The following table summarizes information concerning the compensation awarded to, earned by and paid to the non-employee directors for services rendered to the Company for the year ended December 31, 2025.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)[1][2]	Total ($)
Simon Sturge[3]	$90,500	$224,349	$314,849
Spike Loy[4]	$52,500	$224,349	$276,849
Catherine Moukheibir	$62,500	$224,349	$286,849
Dr. Andrew Phillips	$56,000	$224,349	$280,349
Dr. Ramnik Xavier	$75,000	$224,349	$299,349

(1) Amounts shown under the "Options Awards" column are calculated using the Black-Scholes option valuation model. While the amounts shown are computed in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 718, the actual value, if any, that a non-employee director may realize from the options are contingent upon the excess of the share price over the exercise price, if any, on the date the award is exercised. For a discussion of the assumptions made in the valuation of options granted in 2025, see Note 14 — "Share-based Compensation" of our audited consolidated financial statements as of and for the period ended December 31, 2025 in our Annual Report on Form 10-K for further information.

(2) The following table provides information on the aggregate number of outstanding share option awards for each non-employee director as of December 31, 2025.

Name	Aggregate Number of Outstanding Options (#)
Simon Sturge[3]	70,667
Spike Loy[4]	25,667
Catherine Moukheibir	47,167
Dr. Andrew Phillips	70,667
Dr. Ramnik Xavier	70,667

(3) Mr. Sturge resigned from the Board effective as of February 28, 2026.

(4) Pursuant to a certain agreement entered into between Mr. Loy and BVF Partners L.P. ("Partners"), Mr. Loy is obligated to transfer to Partners the economic benefit, if any, received upon the sale of the shares issuable upon the exercise of his options.

EXECUTIVE OFFICERS

Biographical and other information regarding our executive officers is set forth below. There are no family relationships among any of our directors or executive officers.

Name	Age (as of April 21)	Position
Dr. Jorge Santos da Silva[(1)]	49	Chief Executive Officer; Interim Chair of the Board
Matthias Bodenstedt.	38	Chief Financial Officer
Dr. Kristian Reich	60	Chief Scientific Officer

(1) For Dr. Santos da Silva's biographical information, see ''Information Regarding the Director Nominee and Continuing Directors'' above.

Matthias Bodenstedt has served as Chief Financial Officer of our Company since April 2022. He previously served as the Chief Financial Officer of MoonLake AG from July 2021 until April 2022. He has served as a director of our subsidiaries, MoonLake Immunotherapeutics Ltd. (''MoonLake Ltd.'') and MNLK Immunotherapeutics Unipessoal Lda since September 2021 and November 2023, respectively. Prior to joining our Company, from October 2011 to June 2021, Mr. Bodenstedt was a Partner at McKinsey & Company, Inc., a consulting firm, in Germany and Switzerland, where he advised a diverse set of clients, ranging from pre-revenue biotechnology companies to large global pharmaceutical companies. Mr. Bodenstedt has experience in financing, mergers and acquisitions, business development and licensing, portfolio strategy, and go-to-market strategy and execution. Mr. Bodenstedt holds an M.B.A. from Columbia Business School (New York), an M.Phil. in Finance from the University of Cambridge (United Kingdom), and B.Sc. in Industrial Engineering from the University of Hannover (Germany).

Dr. Kristian Reich has served as Chief Scientific Officer of our Company since April 2022. He is a co-founder of MoonLake AG and served as its Chief Scientific Officer from May 2021 until April 2022. Dr. Reich has more than 25 years of experience as a global clinical leader in dermatology and immunology, with more than 300 peer-reviewed publications in mucosal and skin immunology. He received the Herbert-Herxheimer Research Prize from the German Society for Allergology and Clinical Immunology and the Stars of the Academy Award for achievements in psoriasis from the American Academy of Dermatology. Dr. Reich has served as a Guest-Professor for Translational Research in Inflammatory Skin Diseases at the University Medical Center Hamburg-Eppendorf, Germany, since April 2019. From 2005 to 2015, he served as managing partner at the Dermatologikum Hamburg, a private outpatient dermatology clinic, and he has served as a self-employed partner at the Dermatologikum Berlin, a private outpatient dermatology clinic, since 2013. Between 1996 and 2005, he held several clinical and teaching positions at the Department of Dermatology, Georg-August-University Goettingen, Germany, including most recently serving as University Professor and Vice Director of the Department of Dermatology. Dr. Reich is an independent medical director and founder of JeruCON Beratungsgesellschaft mbH Hamburg, where he is a self-employed consultant. Since 2016, Dr. Reich also serves as a medical advisor for TFS HealthScience, a contract research organization. Dr. Reich is also a member of the board of directors of Derma2go AG (Zürich, Switzerland), a privately held teledermatology company, Dermagnostix GmbH (Freiburg, Germany), a privately-held diagnostic medical device company and ProDerma Foundation (Hamburg, Germany), a charitable foundation focusing on dermatological research. Dr. Reich was accredited in Dermatology and Venerology in 2000 and in Allergology in 2003. He received his Dr. med. (M.D. equivalent) from the Technical University Munich (Germany) and his Venia legendi (Ph.D. equivalent) in Dermatology and Venerology from the Georg-August-University (Germany).

EXECUTIVE COMPENSATION

COMPENSATION DISCUSSION AND ANALYSIS

In this Compensation Discussion and Analysis (“CD&A”), we provide an overview of our compensation philosophy and each element of our executive compensation program with regard to the compensation awarded to, earned by, or paid to our named executive officers (the “NEOs”) during our fiscal year ended December 31, 2025.

For the fiscal year ended December 31, 2025, our NEOs, which consisted of all of our executive officers during the year, were:

Name	Position
Dr. Jorge Santos da Silva	Chief Executive Officer; Interim Chair of the Board
Matthias Bodenstedt	Chief Financial Officer
Dr. Kristian Reich	Chief Scientific Officer

Business Highlights

In 2025, we further progressed with the development of SLK, started preparations for the filing of a BLA with the Food and Drug Administration (“FDA”) in the United States, and advanced preparatory work for an anticipated first commercial launch in 2027. Business highlights included:

- Completed enrollment and reported primary endpoint results of the Phase 3 VELA trials in hidradenitis suppurativa, and successfully conducted a subsequent Type B interaction with the FDA to validate the path to BLA;
- Initiated an open label extension study for the VELA trials;
- Completed enrollment and reported results of the Phase 2 LEDA trial in palmoplantar pustulosis;
- Continued enrollment of the Phase 3 IZAR-1 and IZAR-2 trials in psoriatic arthritis;
- Completed enrollment of the Phase 2 S-OLARIS trial in axial spondyloarthritis;
- Initiated the Phase 2 P-OLARIS trial in seronegative spondyloarthritis;
- Completed pharmacokinetic and human factor studies supporting the use of an autoinjector for the commercial launch of SLK;
- Raised $75 million in additional capital to support the continued development of SLK, including the planned initiation of a Phase 3 clinical trial in palmoplantar pustulosis;
- Entered into a debt facility with Hercules Capital, securing access of up to $500 million in non-dilutive funds;
- Started stockpiling of drug substance of SLK to serve as launch inventory; and
- Grew the Company from approximately 100 to 120 employees and initiated a trainee program to secure and invest in future talent.

Shareholder Advisory Vote on Executive Compensation

Each year, our shareholders are provided the opportunity to cast an advisory vote on the compensation of our named executive officers, or the “say-on-pay” vote, and the Compensation Committee considers the outcome of the prior year’s say-on-pay vote when making decisions relating to the compensation of our named executive officers and our executive compensation programs. We received 99% support for our say-on-pay proposal at our 2025 Annual Meeting, representing overall support of our executive compensation programs. We did not make any changes to our executive compensation programs as a result of the say-on-pay vote.

Compensation Highlights

Our Compensation Committee believes that executive compensation should be directly linked to short-term and long-term performance. A few of the key decisions made by the Compensation Committee aligned with such philosophy are as follows:

No base salary adjustments: Base salaries for our named executive officers remained the same in 2025.

No annual bonuses: Notwithstanding that corporate performance goals were achieved, our named executive officers voluntarily agreed to waive their cash bonus payouts for 2025.

Annual equity awards: In 2025, our named executive officers received either shares of restricted stock or options with time-based vesting requirements.

Compensation Philosophy and Objectives

Our executive officer compensation program focuses on attracting, retaining and rewarding executive officers in order to promote our long-term success. In setting compensation levels and designing the elements of our program, we seek to establish overall compensation levels that are internally equitable and competitive with the talent market. We regularly review our executive officer compensation program with the goal of motivating our executive team to achieve our strategic goals and aligning them with the interests of our shareholders.

The Compensation Committee has historically compensated executive officers with three primary compensation components: a base salary, an annual bonus opportunity and, at times, equity-based compensation. The Compensation Committee believes that cash compensation in the form of base salary and an annual bonus opportunity provides our executive officers with short-term rewards for success in achieving annual goals and objectives, and that long-term compensation through the grant of equity awards aligns the objectives of management with those of our shareholders with respect to long-term performance and success of the Company.

In setting compensation levels for our executive officers, the Compensation Committee considers a variety of factors, including peer group survey data, tenure, role, responsibilities, performance and competitive market practices. Compensation paid to our named executive officers is delivered primarily through at-risk pay, based on both short-term and long-term incentives.

In addition to our compensation elements, the following compensation program features are designed to align our executive team's interests with shareholder interests and market best practices.

Best Practice Highlights

- **Use of Independent Compensation Consultant.** The Compensation Committee receives objective advice from its independent compensation consultant.
- **Modest Perquisites.** NEOs receive only modest perquisites.
- **Clawback Policy.** The Board has adopted a clawback policy applicable to all incentive payments and performance-based equity awards granted to executive officers.
- **Peer Group Analysis.** The Company reviews total direct compensation (base salary, annual cash incentive and long-term incentive payments) and the mix of the compensation components for the named executive officers relative to the peer group as one of the factors in determining if compensation is adequate to attract and retain executive officers.
- **No Hedging.** The Company has adopted a policy prohibiting hedging and pledging of Company shares by directors and executive officers.
- **No Excise Tax Gross-Ups.** Our named executive officers are not entitled to any such gross-up.

Process for Setting Compensation

Our Board and Compensation Committee review compensation practices and philosophy annually for all employees, including our executives. In setting executive base salaries and bonuses and granting equity incentive awards, they consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our shareholders and our desire to incentivize a long-term commitment to our Company. While we do not establish compensation levels based solely on benchmarking, pay practices at other companies are an important factor that the Compensation Committee considers in assessing the reasonableness of compensation and ensuring that our compensation practices are competitive in the marketplace, based on independent third-party benchmark analytics to inform the mix of compensation of base salary, bonus and long-term incentives.

Our Compensation Committee is responsible for approving all executive compensation matters. Our Compensation Committee typically reviews and discusses management's proposed compensation with the CEO for all executives other than the CEO. Based on those discussions and its discretion, taking into account the factors noted above, the Compensation Committee then determines the compensation for each executive officer. In 2025, the Compensation Committee retained the services of Deloitte as its external compensation consultant, and the Compensation Committee considered Deloitte's input on certain compensation matters as it deemed appropriate. Pursuant to the factors set forth in Item 407 of Regulation S-K of the Exchange Act, the Compensation Committee has reviewed the independence of Deloitte and conducted a conflicts of interest assessment (taking into consideration factors specified in the Nasdaq listing standards) and has concluded that Deloitte is independent and its work for the Compensation Committee has not raised any conflicts of interest. The Company also engaged Deloitte or its affiliates during fiscal year 2025 to provide services unrelated to executive compensation. These engagements, which were approved by management and of which the Compensation Committee was aware, primarily consisted of accounting-related services. Fees invoiced by Deloitte and its affiliates for services related to executive compensation totaled approximately $43,000 and for additional services totaled approximately $2.9 million during fiscal year 2025.

Use of a Peer Group

While we do not establish compensation levels based solely on benchmarking, pay practices at other companies are an important factor that the Compensation Committee considers in assessing the reasonableness of compensation and ensuring that our compensation practices are competitive in the marketplace. Market data is one element considered by the Compensation Committee when making executive compensation decisions, but the Compensation Committee does not set compensation levels based solely on market data. Rather, the Compensation Committee reviews the 25th, 50th and 75th percentiles of relevant market data as one frame of reference in making its executive compensation decisions. Final executive compensation decisions reflect a variety of factors, including each executive's experience, performance rating, the relative importance of the executive's role within the organization, as well as where each executive's pay level falls relative to the market data.

In order to evaluate the level of compensation for our named executive officers for 2025, our Compensation Committee, using information provided by Deloitte, established a peer group of publicly traded companies in the biopharmaceutical and biotechnology industries based on a balance of the following criteria:

- companies with comparable market capitalizations (i.e., in the range of $1 billion to $7 billion); and
- companies with headcounts between 30 to 704 employees.

Our 2025 peer group is comprised of the following companies in the biopharmaceutical and biotechnology industries:

Immunovant	Bicycle Therapeutics
Apellis Pharmaceuticals*	Crinetics Pharmaceuticals*
Apogee Therapeutics*	Vera Therapeutics
Verona Pharma	Pharvaris
Summit Therapeutics	Celldex Therapeutics*
Protagonist Therapeutics	Akero Therapeutics*
Spyre Therapeutics*	Kiniksa Pharmaceuticals*
Arcus Biosciences*	

Due to M&A activity and other companies moving outside of a comparable market capitalization range, we added the eight companies marked with an asterisk in the table above and removed four companies (Acelyrin, Inc., Dice Therapeutics, Inc., Rapt Therapeutics, Inc., and Aclaris Therapeutics, Inc.) from our prior year's peer group.

Key Elements of Compensation

Base Salary

Each named executive officer's base salary is a fixed component of annual compensation for performing specific duties and functions, and has been established by our Compensation Committee taking into account each individual's role, responsibilities, skills and experience. Base salaries for our named executive officers are reviewed annually by our Compensation Committee and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experiences. The table below sets forth the base salaries of our NEOs as of December 31, 2025, which are the same as the base salaries in 2024. Amounts were converted to U.S. Dollars ("USD") from Swiss Francs ("CHF") using the exchange rate applicable as of December 31, 2025 (1.266 USD to 1 CHF).

Name	2025 Base Salary
Dr. Jorge Santos da Silva	$797,848
Matthias Bodenstedt	$631,630
Dr. Kristian Reich	$797,848

Annual Bonus

Our Compensation Committee may approve annual bonuses for our named executive officers based on a review of Company performance and each named executive officer's achievement of goals and objectives for the year.

All executive officers are assigned annual bonus targets, expressed as a percent of base salary, based on each executive officer's accountability, scope of responsibilities, and potential impact on performance, as well as peer group competitive data for similarly situated positions. The table below sets forth the target bonus for each NEO, which are the same as the target bonus opportunities in 2024:

Name	2025 Target Bonus (% of Base Salary)
Dr. Jorge Santos da Silva	55%
Matthias Bodenstedt	50%
Dr. Kristian Reich	55%

Each of our named executive officers is eligible to receive a bonus based on the achievement of reasonable financial and business objectives approved by, in the case of Dr. Santos da Silva, the Board (with input from the Compensation Committee) or, in the case of Mr. Bodenstedt and Dr. Reich, the Compensation Committee (with input from Dr. Santos da Silva). The performance objectives for the named executive officers for fiscal year 2025 were (i) building the Company and its profile with key stakeholders, (ii) delivering the SLK development programs across indications, (iii) securing financial stability, and (iv) building the foundations for pre-market activities for a successful launch of SLK in 2027. Each of Drs. Santos da Silva and Reich and Mr. Bodenstedt voluntarily agreed to waive any cash bonus payouts for 2025 notwithstanding that corporate performance goals were deemed achieved. As a result, the Compensation Committee approved the payout of $0 for each named executive officer.

Long-Term Incentive Compensation

In February 2025, each of the named executive officers received an equity award in the form of either restricted stock awards or stock options, depending on the employee's election with a grant date fair value targeted at $4 million (95,763 shares of restricted stock in the case of Dr. Santos da Silva and Mr. Bodenstedt and 139,273 stock options with an exercise price of $41.77 in the case of Dr. Reich). Similarly, in January 2026, each of the named executive officers received an equity award in the form of either restricted stock awards or stock options, depending on the employee's election with a grant date fair value targeted at $4 million (354,296 shares of restricted stock in the case of Mr. Bodenstedt and 520,342 stock options with an exercise price of $11.29 in the case of Drs. Santos da Silva and Reich). The equity awards vest over a four-year period in equal annual installments on each anniversary of the grant date, subject, in each case, to continued service through each such vesting date.

Other Elements of Compensation

Benefits and Perquisites

Each named executive officer is eligible to receive retirement, survivors and disability insurance, as well as accident insurance, according to Swiss law requirements. In addition, MoonLake AG has taken out daily sickness benefits insurance, and is contributing 50% of the premiums with the other 50% contributed by the employees, for Dr. Santos da Silva and Mr. Bodenstedt, providing salary continuation payments in the amount of 80% of the insured salary, which is capped at CHF 300,000, after a 30 day waiting period for a maximum of 730 days. Due to being subject to social security outside of Switzerland, Dr. Reich is not eligible for the selected insurance plan. In addition, the officers are eligible for reimbursement for justified expenses incurred in the course of their work for MoonLake AG due to travel and other expenses. The named executive officers also received housing allowances during fiscal year 2025.

MoonLake AG operates a defined benefit pension plan (the ''MoonLake AG Swiss Plan'') in accordance with local Swiss regulations and practices. It covers all of MoonLake AG's employees that are subject to Swiss social security, including the named executive officers (other than Dr. Reich) and provides benefits in the event of death, disability, or retirement. MoonLake AG makes contributions to a retirement arrangement governed by German law on behalf of Dr. Reich. Dr. Reich's retirement arrangement program is a defined contribution type structure whereby MoonLake AG makes contributions to a German government regulated pension plan.

Employment and Severance Terms

MoonLake AG entered into employment agreements with each of Drs. Santos da Silva and Reich on April 30, 2021, as subsequently amended on September 21, 2021 for Dr. Santos da Silva and on November 8, 2021 for Dr. Reich, and with Mr. Bodenstedt on May 10, 2021, as subsequently amended on June 22, 2021 (the ''Executive Employment Agreements'', and each an ''Executive Employment Agreement''). The Executive Employment Agreements are based on the same general form, and the material terms of the agreement are summarized below. The Executive Employment Agreements are governed by Swiss law.

The terms of the Executive Employment Agreements with each of Dr. Santos da Silva and Mr. Bodenstedt commenced on July 1, 2021. The term of the Executive Employment Agreement with Dr. Reich commenced on May 17, 2021. The initial terms of these agreements ran through May 1, 2023, except for Mr. Bodenstedt's agreement, which provides for an indefinite term. Under the agreements with Drs. Santos da Silva and Reich, either the executive or MoonLake AG could have terminated the Executive Employment Agreement at the end of such initial term by providing six months' notice. Since no such notice was provided under such agreements, the terms of the Executive Employment Agreements were extended for an indefinite period, and employment will be terminable by either party by providing six months' notice. The Executive Employment Agreement with Mr. Bodenstedt provides for termination of his employment by either party by providing six months' notice beginning on August 31, 2022.

The Executive Employment Agreements provided for initial levels of annual base salary and target bonus opportunity, which were subsequently increased. The Executive Employment Agreements also contain provisions relating to certain payments upon a termination of employment as described in further detail under the section titled ''Potential Payments Upon Termination or Change of Control''. It is the Compensation Committee's belief that the Executive Employment Agreements are necessary from a competitive perspective and contribute to the stability of the management team.

Other Policies

Clawback Policy

We have adopted an Incentive Compensation Clawback Policy, which is intended to comply with the requirements of Nasdaq Listing Standard 5608 implementing Rule 10D-1 under the Exchange Act. In the event the Company is required to prepare an accounting restatement of the Company's financial statements due to material non-compliance with any financial reporting requirement under the federal securities laws, the Company will recover, on a reasonably prompt basis, the excess incentive-based compensation received by any covered executive during the prior three fiscal years that exceeds the amount that the executive otherwise would have received had the incentive-based compensation been determined based on the restated financial statements.

Insider Trading Policies and Prohibitions on Hedging and Pledging

We have adopted insider trading policies and procedures governing the purchase, sale and other transactions in Company securities by the Company's directors, officers, employees, consultants and contractors, as well as the

Company itself, that we believe are reasonably designed to promote compliance with insider trading laws, rules and regulations and Nasdaq listing standards. Our directors and executive officers also are prohibited from engaging in pledging transactions.

Our insider trading policy prohibits our directors, officers, employees, consultants and contractors from engaging in (a) short-term trading; (b) short sales; (c) transactions involving publicly traded options or other derivatives, such as trading in puts or calls with respect to Company securities; and (d) hedging transactions.

Practices on Timing of Equity Awards

We aim to grant annual equity awards on the first day of the calendar year or as soon as practical thereafter. Notwithstanding the foregoing, in 2025, equity awards to our executive officers were not granted until February 27 due to certain administrative procedures that had to be completed to operationalize the new annual award scheme. We do not have any program, plan or practice to time award dates of stock option grants to our executive officers in coordination with the release of material nonpublic information. Equity awards may occasionally be granted following a significant change in job responsibilities or to meet special retention or performance objectives. During 2025, the Compensation Committee did not time the disclosure of material nonpublic information for the purpose of affecting the value of executive compensation. During 2025, a named executive officer was awarded stock options with an effective grant date during the period beginning four business days before the filing or furnishing of a Form 10-Q, Form 10-K or Form 8-K, and ending one business day after the filing or furnishing of such reports, as summarized in the table below:

Name	Grant Date	Number of Securities Underlying the Award	Exercise Price of the Award ($/Sh)	Grant Date Fair Value of the Award	Percentage Change in the Closing Market Price of the Securities Underlying the Award Between the Trading Day Ending Immediately Prior to the Disclosure of Material Nonpublic Information and the Trading Day Beginning Immediately Following the Disclosure of Material Nonpublic Information
Dr. Kristian Reich.	February27,2025	139,273	$41.77	$4,000,021	2.55%

Risk Management

For fiscal year 2025, the Company conducted its annual review of executive and non-executive compensation programs, with particular emphasis on incentive compensation plans and programs. Based on this review, the Company evaluated the primary components of its compensation plans and practices to identify whether those components, either alone or in combination, properly balanced compensation opportunities and risk. Furthermore, the Compensation Committee retains its own independent compensation consultant to provide input on executive pay matters, meets regularly, and approves all performance goals, award vehicles, and pay opportunity levels for named executive officers. As a result of this evaluation, the Company concluded that risks arising from the Company's compensation policies and practices are not reasonably likely to have a material adverse impact on the Company.

Report of the Compensation Committee

The Compensation Committee has reviewed and discussed with management the Compensation Discussion and Analysis required by Item 402(b) of Regulation S-K. Based on this review and discussion, the Compensation Committee recommended to the Board of Directors that the foregoing Compensation Discussion and Analysis be included in this Proxy Statement and incorporated by reference in our Annual Report on Form 10-K for the year ended December 31, 2025.

This report is provided by the following directors, who serve on the Compensation Committee:

Dr. Andrew Phillips (Chair)
Catherine Moukheibir
Spike Loy

2025 Summary Compensation Table

The following table summarizes the compensation awarded to, earned by or paid to our NEOs for 2025, 2024 and 2023.

Name and Principal Position	Year	Salary ($)[1]	Bonus ($)[2]	Stock Awards ($)[3]	Option Awards ($)[3]	Change in Pension Value and Nonqualified Deferred Compensation Earnings ($)[4]	All Other Compensation ($)[5]	Total ($)
Dr. Jorge Santos da Silva	2025	762,386	—	4,000,021	—	155,880	24,922	4,943,209
Chief Executive Officer	2024	698,245	574,254	—	—	109,913	23,626	1,406,038
and Interim Chair of the Board	2023	586,333	589,819	—	—	—	22,063	1,198,215
Matthias Bodenstedt.	2025	603,555	—	4,000,021	—	66,023	22,977	4,692,576
Chief Financial Officer	2024	552,777	413,289	—	—	44,687	21,802	1,032,555
	2023	446,837	424,491	—	—	—	20,269	891,597
Dr. Kristian Reich	2025	762,386	—	—	4,000,021	—	33,086	4,795,493
Chief Scientific Officer	2024	698,245	574,254	—	—	—	30,440	1,302,939
	2023	586,333	589,819	—	—	—	54,752	1,230,904

(1) Represents all amounts earned as salary during the applicable fiscal year. For fiscal year 2025, the salary amounts have been converted to USD from CHF using the exchange rate applicable on the last day of each calendar month (January 31, 2025: 1.099 USD to 1 CHF; February 28, 2025: 1.109 USD to 1 CHF; March 31, 2025: 1.135 USD to 1 CHF; April 30, 2025: 1.213 USD to 1 CHF; May 31, 2025: 1.215 USD to 1 CHF; June 30, 2025: 1.254 USD to 1 CHF; July 31, 2025: 1.241 USD to 1 CHF; August 31, 2025: 1.247 USD to 1 CHF; September 30, 2025: 1.255 USD to 1 CHF; October 31, 2025: 1.246 USD to 1 CHF; November 30, 2025: 1.242 USD to 1 CHF; December 31, 2025: 1.266 USD to 1 CHF). For fiscal year 2024, the salary amounts have been converted to USD from CHF using the exchange rate applicable on the last day of each calendar month (January 31, 2024: 1.160 USD to 1 CHF; February 29, 2024: 1.136 USD to 1 CHF; March 31, 2024: 1.112 USD to 1 CHF; April 30, 2024: 1.095 USD to 1 CHF; May 31, 2024: 1.105 USD to 1 CHF; June 30, 2024: 1.114 USD to 1 CHF; July 31, 2024: 1.132 USD to 1 CHF; August 31, 2024: 1.186 USD to 1 CHF; September 30, 2024: 1.186 USD to 1 CHF; October 31, 2024: 1.152 USD to 1 CHF; November 30, 2024: 1.135 USD to 1 CHF; December 31, 2024: 1.105 USD to 1 CHF). For fiscal year 2023, the salary amounts have been converted to USD from CHF using the exchange rate applicable on the last day of each calendar month (January 31, 2023: 1.085 USD to 1 CHF; February 28, 2023: 1.067 USD to 1 CHF; March 31, 2023: 1.088 USD to 1 CHF; April 30, 2023: 1.117 USD to 1 CHF; May 31, 2023: 1.104 USD to 1 CHF; June 30, 2023: 1.111 USD to 1 CHF; July 31, 2023: 1.149 USD to 1 CHF; August 31, 2023: 1.135 USD to 1 CHF; September 30, 2023: 1.096 USD to 1 CHF; October 31, 2023: 1.106 USD to 1 CHF; November 30, 2023: 1.143 USD to 1 CHF; December 31, 2023: 1.192 USD to 1 CHF).

(2) Represents amounts earned based on the achievement of performance goals determined in accordance with each officer's employment agreement. For fiscal year 2024, the bonus amounts have been converted to USD from CHF using the exchange rate of 1.105 USD to 1 CHF as of December 31, 2024. For fiscal year 2023, the bonus amounts have been converted to USD from CHF using the exchange rate of 1.192 USD to 1 CHF as of December 31, 2023.

(3) For 2024 and 2023, no new equity awards were granted to the named executive officers. In 2025, Dr. Santos da Silva and Mr. Bodenstedt were granted time-based restricted shares and Dr. Reich was granted time-based stock options. Amounts reported reflect the grant date fair values as calculated in accordance with FASB ASC Topic 718. For stock awards, the grant date fair value is calculated by multiplying the number of shares granted by the closing share price on the date of grant. For option awards, the grant date fair value is calculated using the Black-Scholes option valuation model. For a discussion of the assumptions made in the valuation of options granted in 2025, see Note 14 — ''Share-based Compensation'' of our audited consolidated financial statements as of and for the period ended December 31, 2025 in our Annual Report on Form 10-K for further information.

(4) The amounts reported in this column represent the aggregate change in the actuarial present value of the named executive officers' accumulated benefits under all defined benefit and actuarial pension plans in fiscal 2025. For fiscal year 2025, the amounts in this column have been converted to USD from CHF using the exchange rate of 1.266 USD to 1 CHF as of December 31, 2025. For fiscal year 2024, the amounts in this column have been converted to USD from CHF using the exchange rate of 1.105 USD to 1 CHF as of December 31, 2024. The Company qualified as a ''smaller reporting company'' for the year ending December 31, 2023 and was not required to disclose amounts in this column for that period.

(5) The amounts reported for all of the named executive officers for 2025 include amounts paid as a housing allowance ($23,924 for Dr. Santos da Silva, $21,979 for Mr. Bodenstedt and $27,120 for Dr. Reich) and, for Dr. Santos da Silva and Mr. Bodenstedt, $998 in Company contributions to voluntary sick leave insurance premiums. For Dr. Reich, the amount reported for 2025 further includes $5,966 in Company contributions to a German government regulated pension plan. For fiscal years 2025, 2024 and 2023, these amounts have been converted to USD from CHF using the exchange rate applicable on the last day of each calendar month as described in footnote (1) above.

2025 Grants of Plan-Based Awards Table

The following table sets forth the grants of plan-based awards made to our NEOs during 2025.

Name	Grant Date	All Other Share Awards: Number of Shares or Units (#)	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards ($/Sh)	Grant Date Fair Value of Stock and Option Awards ($)
Dr. Jorge Santos da Silva	2/27/2025	95,763	—	—	4,000,021
Matthias Bodenstedt	2/27/2025	95,763	—	—	4,000,021
Dr. Kristian Reich	2/27/2025	—	139,273	41.77	4,000,021

Outstanding Equity Awards at 2025 Fiscal Year End Table

The following table sets forth information regarding outstanding equity awards at the end of 2025 for each of our NEOs.

		Option Awards				Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Option Awards Exercisable (#)	Number of Securities Underlying Unexercised Option Awards Unexercisable (#)	Option Award Exercise Price ($)	Option Award Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)[1]
Dr. Jorge Santos da Silva	01/18/2022[2]	—	—	—	—	7,401	97,545
	02/27/2025[3]	—	—	—	—	95,763	1,262,156
Matthias Bodenstedt	01/18/2022[2]	—	—	—	—	11,101	146,311
	02/27/2025[3]	—	—	—	—	95,763	1,262,156
Dr. Kristian Reich	01/18/2022[2]	—	—	—	—	7,401	97,545
	02/27/2025[3]	—	139,273	$41.77	02/27/2035	—	—

(1) Based on the closing price of $13.18 on December 31, 2025, which was the last trading day of 2025.

(2) Represents the remaining unvested portion of 10,000, 15,000 and 10,000 shares of MoonLake AG, respectively, for Drs. Santos da Silva and Reich and Mr. Bodenstedt purchased under the Employee Share Participation Plan at a purchase price equal to the nominal value per share of CHF 0.10 that were subsequently converted into Class A Ordinary Shares of MoonLake Immunotherapeutics based on the exchange ratio of 1 share of MoonLake AG into 33.638698 MoonLake Immunotherapeutics Class A Ordinary Shares. Subject to the executive's continued employment through each applicable vesting date, these shares vest in accordance with the following vesting schedule: (i) 25% of the shares vested on January 18, 2023 and (ii) 2.08% of the shares vest each month thereafter until fully vested. Until such shares fully vest, MoonLake AG may repurchase such shares at a repurchase price equal to such nominal value in the event the employment of the respective officer terminates.

(3) Represents an award of restricted stock or stock options, as applicable, that vest in four equal annual installments on February 27, 2026, 2027, 2028, and 2029, subject, in each case, to continued service through each applicable date.

Option Exercises and Stock Vested Table

The following table sets forth information regarding the stock awards vested for our named executive officers during fiscal 2025. None of our named executive officers exercised any stock options during 2025.

	Stock Awards	
Name	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting ($)
Dr. Jorge Santos da Silva	83,962	3,075,325
Matthias Bodenstedt	125,943	4,612,988
Dr. Kristian Reich	83,962	3,075,325

Fiscal Year 2025 Pension Benefits

The following table sets forth the pension benefits of the named executive officers as of December 31, 2025.

Name	Plan Name	Number of Years of Credited Service (#)	Present Value of Accumulated Benefit ($)	Payments During Last Fiscal Year ($)
Dr. Jorge Santos da Silva	MoonLake AG Swiss Plan	4.5	797,148	—
Matthias Bodenstedt.	MoonLake AG Swiss Plan	4.5	377,642	—

MoonLake AG Swiss Plan

The MoonLake AG Swiss Plan complies with Swiss tax requirements applicable to broad-based pension plans. Normal retirement age under the MoonLake AG Swiss Plan is 65, for men, and 64, for women. All benefits are immediately vested.

Under the MoonLake AG Swiss Plan, 15% of pensionable salary is contributed as retirement credit with additional contributions for death and disability benefits. MoonLake AG makes 50% of the contributions, and the covered employee makes 50% of the contributions. For 2025, participants received an interest rate of return of 4.0% on retirement assets under the Swiss Federal Law on Occupational Retirement, Survivors' and Disability Pension Plans (BVG) and 4.0% on extra-mandatory retirement assets. Pensionable salary under the MoonLake AG Swiss Plan is the annual base salary. The Present Value of Accumulated Benefit reported in the table above is the actual account value in the named executive officer's pension fund, converted to USD from CHF using the exchange rate of 1.266 USD to 1 CHF as of December 31, 2025.

Annual benefits under the MoonLake AG Swiss Plan are calculated at a named executive officer's retirement date and are equal to a percentage of the named executive officer's account balance specified in the MoonLake AG Swiss Plan based on his age and retirement year. Under Swiss pension law, participants who were covered by the pension plan of another employer are required to transfer the termination benefit of that pension plan into the MoonLake AG Swiss Plan. Participants are permitted to withdraw part of the termination benefit, or pledge the termination benefit, for home ownership. Valuation assumptions with respect to the MoonLake AG Swiss Plan are included in our audited consolidated financial statements as of and for the period ended December 31, 2025 in our Annual Report on Form 10-K.

Potential Payments Upon Termination or Change of Control

The table below reflects the amount of compensation that would become payable to each of the named executive officers under existing plans and arrangements if that named executive officer's employment had terminated on December 31, 2025 (pursuant to the executive's arrangements then in effect) and/or a change of control had occurred on such date, given the named executive officer's compensation levels as of such date and, if applicable, based on the Company's closing share price on that date of $13.18. These benefits are in addition to benefits available prior to the occurrence of any termination of employment, including benefits generally available to salaried employees, such as distributions under the Company's 401(k) plan. The actual amounts that would be paid upon a named executive officer's termination of employment can be determined only at the time of such named executive officer's separation from the Company. Due to the number of factors that affect the nature and amount of any benefits provided upon the events discussed below, any actual amounts paid or distributed may be higher or lower than reported below.

In the event of a termination of employment by either Dr. Santos da Silva or Reich, he will be entitled to receive a prorated payment of his annual bonus based on the level of achievement through the date of termination. In the event of a termination of employment of either such executive by MoonLake AG, the board of directors of MoonLake AG will determine whether a bonus will be paid and the amount to be paid. Mr. Bodenstedt is not eligible for a bonus if at the time of the payment of the bonus, his employment is pending termination.

Each of the Executive Employment Agreements includes an intellectual property assignment agreement, as well as a perpetual covenant prohibiting the officer from utilizing and disclosing confidential information, a non-competition covenant, an employee non-solicitation covenant and a customer non-solicitation covenant. For Drs. Santos da Silva and Reich, each of these covenants is in effect during the employment term and for a period of six months following a termination of employment. For Mr. Bodenstedt, the non-competition covenant is in effect

during the employment term and for a period of twelve months following a termination of employment, and the employee non-solicitation covenant and the customer non-solicitation covenant are in effect during the employment term and for a period of eighteen months following a termination of employment. Such non-compete and non-solicitation covenants are referred to herein as the ‘‘post-termination restrictive covenants’’.

If either Drs. Santos da Silva or Reich terminates his employment, then he is entitled to receive monthly compensation during the duration of such post-termination restrictive covenants in an amount of his last monthly fixed salary (gross). If he terminates his employment without just cause, then MoonLake AG may waive its right to enforce such post-termination restrictive covenants and thereby cease making such post-termination payments to the officer.

If MoonLake AG terminates the officer’s employment, then he is entitled to receive monthly compensation during the duration of such post-termination restrictive covenants in an amount of his monthly fixed salary (gross) plus an amount equal to one-twelfth of his annual target bonus. The officer would be entitled to receive such payments even if MoonLake AG waives its right to enforce the post-termination restrictive covenants.

In the event an officer, including Mr. Bodenstedt, breaches his obligations under the post-termination restrictive covenants, he would owe a contractual penalty to MoonLake AG of CHF 100,000 for each individual breach. MoonLake AG would also be entitled to additional damages and to seek specific performance as a remedy. In addition, the officer would forfeit any remaining amounts that would have otherwise been payable during the duration of the post-termination restrictive covenants, and the officer would be required to repay any payments he previously received during the post-termination restrictive covenant period.

If the post-termination restrictive covenants are unenforceable, lapse or are not effective under applicable law, then Drs. Santos da Silva and Reich will instead receive a severance payment equal to 50% of his then current annual gross salary (plus 50% of his annual target bonus in the event MoonLake AG is the party that terminates employment) payable ratably over the six-month post-termination period.

In the event of a change in control, all unvested equity awards would vest immediately.

Potential Payments Upon Termination or Change of Control Table

Name	Voluntary Termination ($)	Involuntary Termination (Without Cause or for Good Reason) Not in Connection with a Change in Control ($)	Involuntary Termination in Connection with a Change in Control ($)	Change in Control ($)
Dr. Jorge Santos da Silva				
Base Salary	398,924	398,924	398,924	—
Healthcare	—	—	—	—
Bonus	—	219,408	219,408	—
Option Awards	—	—	—	—
Stock Awards	—	—	1,359,701	1,359,701
Total	**398,924**	**618,332**	**1,978,033**	**1,359,701**
Matthias Bodenstedt				
Base Salary	—	—	—	—
Healthcare	—	—	—	—
Bonus	—	—	—	—
Option Awards	—	—	—	—
Stock Awards	—	—	1,408,467	1,408,467
Total	**—**	**—**	**1,408,467**	**1,408,467**
Dr. Kristian Reich				
Base Salary	398,924	398,924	398,924	—
Healthcare	—	—	—	—
Bonus	—	219,408	219,408	—
Option Awards	—	—	—	—
Stock Awards	—	—	97,545	97,545
Total	**398,924**	**618,332**	**715,877**	**97,545**

CEO Pay Ratio

Pursuant to Item 402(u) of Regulation S-K, we are required to calculate and disclose the median of the annual total compensation of all of our employees (excluding our CEO, Dr. Santos da Silva), the annual total compensation of Dr. Santos da Silva, and the ratio of these two amounts.

As permitted under the SEC rules, we used the same median employee as last year because we believe we did not experience any changes in our employee population or employee compensation arrangements that would significantly impact the pay ratio disclosure. Our median employee was identified using the entire population of our employees as of December 31, 2024 based on a consistently applied compensation measure, or CACM, that reasonably reflects the annual compensation of our employees. The CACM selected by us for our disclosure was the base salary per December 31, 2024 plus the target bonus opportunity.

Based on the CACM methodology described above, we identified the median employee and then calculated the fiscal 2025 compensation for this selected employee in the same manner we determine the annual total compensation of our NEOs for purposes of the Summary Compensation Table. The median of the annual total compensation of all our employees was $237,155. Dr. Santos da Silva's fiscal 2025 annual total compensation as disclosed in the 2025 Summary Compensation Table was $4,943,209. As a result, our CEO to median employee pay ratio for fiscal 2025 is 20.8:1.

This pay ratio is a reasonable estimate calculated by a method consistent with the SEC requirements, described above, based on our payroll and employment records. As a result of a variety of factors, including employee populations, potential differences in the components used for the CACM, compensation philosophies and certain assumptions, pay ratios reported by other companies may not be comparable to our pay ratio. The pay ratio is not utilized by our management or our Compensation Committee for compensation-related decisions.

Pay Versus Performance

As required by Section 953(a) of the Dodd-Frank Wall Street Reform and Consumer Protection Act, and Item 402(v) of Regulation S-K, we are providing the following information about the relationship between executive compensation actually paid and certain financial performance of the Company.

Year	Summary Compensation Table Total for PEO[1]	Compensation Actually Paid to PEO[2]	Average Summary Compensation Table Total for Non-PEO NEOs[3]	Average Compensation Actually Paid to Non-PEO NEOs[4]	Value of Initial Fixed $100 Investment Based On: Total Shareholder Return ("TSR")[5]	Value of Initial Fixed $100 Investment Based On: Peer Group TSR[6]	Net Loss[7]	Company-Selected Measure[8]
2025 . . .	$4,943,209	$ 340,955	$4,744,035	$ (423,555)	$133	$ 109	$(227,317,723)	
2024 . . .	$1,406,038	$ (225,066)	$1,167,747	$ (800,701)	$548	$80.6	$(118,935,517)	
2023 . . .	$1,198,215	$17,019,715	$1,061,251	$18,652,222	$611	$79.8	$ (36,007,260)	
2022 . . .	$4,477,381	$ 2,129,527	$5,099,113	$ 3,999,495	$106	$74.1	$ (49,973,249)	

(1) The dollar amounts reported are the amounts of total compensation reported in our Summary Compensation Table.

(2) The dollar amounts reported represent the amount of "compensation actually paid", as computed in accordance with SEC rules. The dollar amounts do not reflect the actual amount of compensation earned by or paid during the applicable year. In accordance with SEC rules, these amounts reflect "Total Compensation" as set forth in the Summary Compensation Table for each year, adjusted as shown below for the most recent fiscal year. Equity values are calculated in accordance with ASC Topic 718, and the valuation assumptions used to calculate fair values did not materially differ from those disclosed at the time of grant.

Compensation Actually Paid to PEO	2025
Summary Compensation Table Total	$ 4,943,209
Less, value of "Stock Awards" and "Option Awards" reported in Summary Compensation Table	(4,000,021)
Plus, year-end fair value of outstanding and unvested equity awards granted in the year	1,262,156
Plus, fair value as of vesting date of equity awards granted and vested in the year	—
Plus (less), year over year change in fair value of outstanding and unvested equity awards granted in prior years	(303,199)
Plus (less), change in fair value from prior fiscal year end to vesting date of equity awards granted in prior years that vested in the year	(1,471,227)

Compensation Actually Paid to PEO	2025
Less, prior year-end fair value for any equity awards forfeited in the year	—
Less, change in accumulated benefits under defined benefit and actuarial pension plans reported in Summary Compensation Table	(155,880)
Plus, aggregate defined benefit and actuarial pension plan service cost and prior service cost	65,917
Plus, dividends or other earnings paid on awards in the covered fiscal year prior to vesting if not otherwise included in the Summary Compensation Table Total for the covered fiscal year	—
Compensation Actually Paid to PEO	$ 340,955

(3) The dollar amounts reported represent the average of the amounts reported for the Company's named executive officers (NEOs) as a group (excluding our CEO) in the ''Total'' column of the Summary Compensation Table in each applicable year. The names of each of the NEOs (excluding our CEO) included for purposes of calculating the average amounts in each applicable year are Dr. Reich and Mr. Bodenstedt.

(4) The dollar amounts reported represent the average amount of ''compensation actually paid'' to the NEOs as a group (excluding our CEO), as computed in accordance with SEC rules. The dollar amounts do not reflect the actual average amount of compensation earned by or paid to the NEOs as a group (excluding our CEO) during the applicable year. In accordance with the SEC rules, these amounts reflect ''Total'' as set forth in the Summary Compensation Table for each year, adjusted as shown below for the most recent fiscal year. Equity values are calculated in accordance with ASC Topic 718, and the valuation assumptions used to calculate fair values did not materially differ from those disclosed at the time of the grant.

Average Compensation Actually Paid to Non-PEO NEOs	2025
Average Summary Compensation Table Total	$ 4,744,035
Less, average value of ''Stock Awards'' and ''Option Awards'' reported in Summary Compensation Table	(4,000,021)
Plus, average year-end fair value of outstanding and unvested equity awards granted in the year	1,057,581
Plus, average fair value as of vesting date of equity awards granted and vested in the year	—
Plus (less), average year over year change in fair value of outstanding and unvested equity awards granted in prior years	(378,999)
Plus (less), average change in fair value from prior fiscal year end to vesting date of equity awards granted in prior years that vested in the year	(1,839,034)
Less, prior year-end fair value for any equity awards forfeited in the year	—
Less, change in accumulated benefits under defined benefit and actuarial pension plans reported in Summary Compensation Table	(33,012)
Plus, aggregate defined benefit and actuarial pension plan service cost and prior service cost	25,895
Plus, dividends or other earnings paid on awards in the covered fiscal year prior to vesting if not otherwise included in the Summary Compensation Table Total for the covered fiscal year	—
Average Compensation Actually Paid to Non-PEO NEOs	$ (423,555)

(5) Cumulative TSR is calculated by dividing the sum of the cumulative amount of dividends for the measurement period, assuming dividend reinvestment, and the difference between the Company's share price at the end and the beginning of the measurement period by the Company's share price at the beginning of the measurement period. The beginning of the measurement period for each year in the table is December 31, 2021. No dividends were paid during the periods presented.

(6) The peer group used for this purpose is the Nasdaq Biotechnology Index.

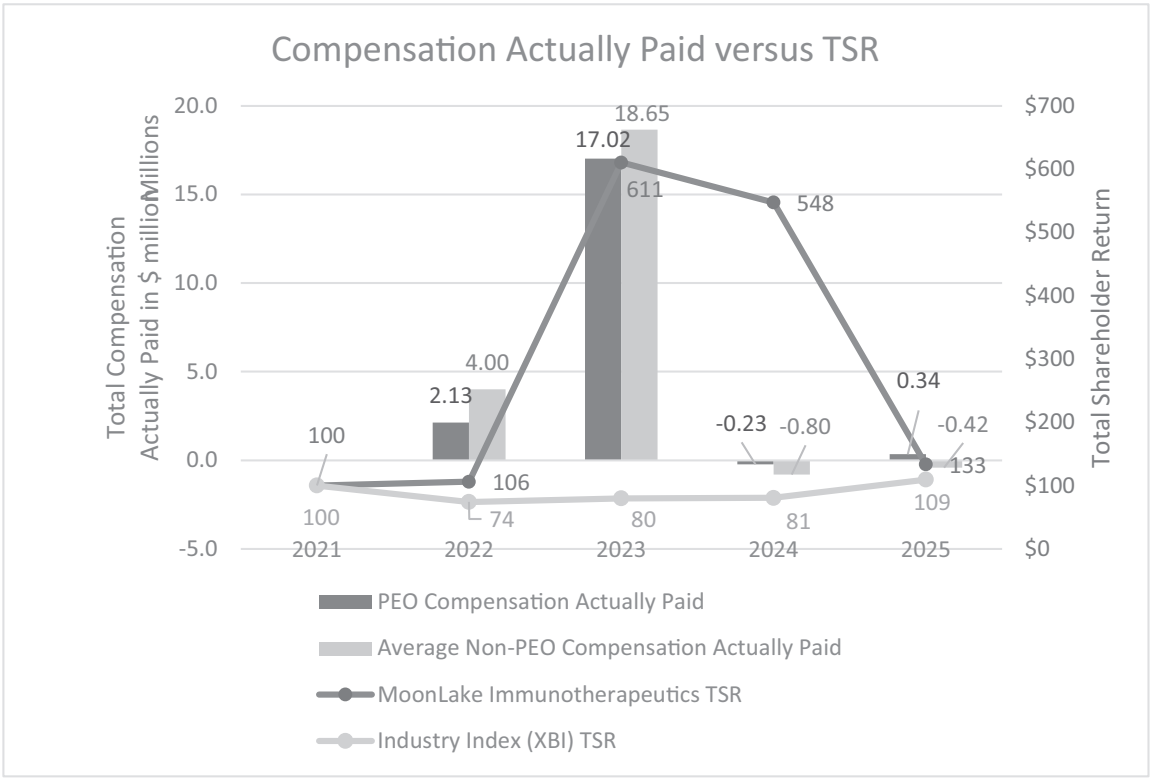
(7) The dollar amounts reported represent the amount of net loss attributable to controlling interest shareholders, reflected in the Company's audited financial statements for the applicable year.

(8) The Company does not use any financial performance measures to link executive compensation actually paid to Company performance. Consequently, no ''Company Selected Measure'' is included in the table above.

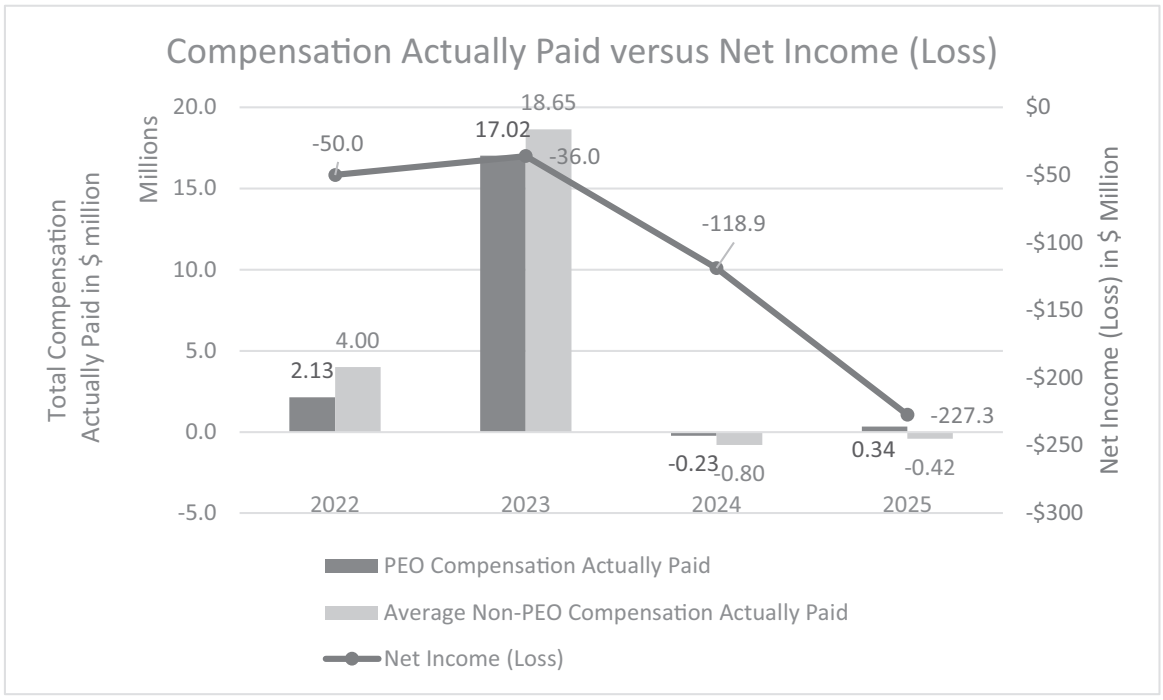
Analysis of the Information Presented in the Pay versus Performance Table

Our executive compensation program reflects a variable pay-for-performance philosophy. While we utilize several performance measures to align executive compensation with Company performance, all of those Company measures are not presented in the Pay versus Performance table. Moreover, we generally seek to incentivize long-term performance, and therefore do not specifically align the Company's performance measures with compensation that is actually paid (as computed in accordance with SEC rules) for a particular year. In accordance with SEC rules, we are providing the following descriptions of the relationships between information presented in the Pay versus Performance table.

Compensation Actually Paid, Cumulative TSR, and Peer Group TSR



Compensation Actually Paid and Net Income (Loss)



Financial Performance Measures

As described in greater detail in the Compensation Discussion and Analysis section, the Company's executive compensation program reflects a variable pay-for-performance philosophy. The metrics that the Company uses for our short-term incentive awards are selected based on an objective of incentivizing our NEOs to increase the value of our enterprise for our shareholders. The Company does not currently use any financial performance measures to link executive compensation actually paid to our performance. However, the most important performance measures used by the Company to link executive compensation actually paid to the Company's NEOs, for the most recently completed fiscal year, to the Company's performance are as follows:

- Building the Company and its profile with key stakeholders including execution against hiring plans;
- Delivering the SLK development programs across indications including study initiation and enrollment as per plans;
- Securing financial stability by raising capital, securing non-dilutive sources of financing and managing cash burn; and
- Building the foundations for pre-market activities for a successful launch of SLK in 2027.

CERTAIN INFORMATION ABOUT OUR ORDINARY SHARES

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information known to us regarding the beneficial ownership of our voting ordinary shares as of April 1, 2026 (except as otherwise indicated in the footnotes to the table), by:

- each shareholder or group of shareholders known by us as of such date to be the beneficial owner of more than five percent (5%) of the outstanding shares of each class of our voting ordinary shares;
- each of our directors and nominees;
- each of our named executive officers; and
- all of our current directors and executive officers as a group.

Beneficial ownership is determined according to the rules of the SEC, which generally provide that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power over that security, including any shares that the individual has the right to acquire within 60 days after the date of this table. Unless otherwise indicated, to our knowledge and subject to community property rules, we believe that all persons named in the table below have sole voting and sole investment power with respect to the voting securities beneficially owned by them.

Pursuant to our MAA, each Class A Ordinary Share entitles the holders thereof to one vote per share and such economic rights as are set forth in the MAA. The beneficial ownership in the table below is based on 72,605,691 Class A Ordinary Shares outstanding as of the date of this table.

Name and Address of Beneficial Owners	Number of Shares Beneficially Owned	% of Shares Beneficially Owned
Named Executive Officers and Directors[1]		
Dr. Jorge Santos da Silva	3,074,893	4.2%
Dr. Kristian Reich[2]	3,044,758	4.2%
Matthias Bodenstedt	1,276,305	1.8%
Dr. Andrew Phillips[3]	70,667	*
Spike Loy[3]	25,667	*
Catherine Moukheibir[3]	47,167	*
Dr. Ramnik Xavier[3]	70,667	*
All Current Executive Officers and Directors as a Group (Seven Individuals)[4]	7,610,124	10.4%
Greater than Five Percent Holders		
Certain funds managed by BVF Partners L.P.[5]	16,001,284	22.0%
Entities affiliated with Deep Track Capital, LP[6]	4,610,071	6.3%
Entities affiliated with Cormorant Asset Management, LP[7]	4,355,433	6.0%

* Represents beneficial ownership of less than one percent.

(1) Unless otherwise noted, the business address of each of the entities or individuals listed is Dorfstrasse 29, 6300 Zug, Switzerland.

(2) Includes (i) 2,974,551 Class A Ordinary Shares held by JeruCon Beratungsgesellschaft mbH, (ii) 35,389 Class A Ordinary Shares held by Dr. Reich and (iii) 34,818 Class A Ordinary Shares underlying options exercisable within 60 days of the date of this table. Dr. Reich may be deemed to beneficially own the shares held by JeruCon Beratungsgesellschaft mbH.

(3) Consists entirely of Class A Ordinary Shares underlying options exercisable within 60 days of the date of this table.

(4) Consists of (i) 7,361,138 Class A Ordinary Shares and (ii) 248,986 Class A Ordinary Shares underlying options exercisable within 60 days of the date of this table.

(5) Based on a Schedule 13D/A filed on April 2, 2026 and consists of (i) 8,302,735 Class A Ordinary Shares held by Biotechnology Value Fund, L.P. (“BVF”), (ii) 6,599,722 Class A Ordinary Shares held by Biotechnology Value Fund II, L.P. (“BVF2”), (iii) 1,039,238 Class A Ordinary Shares held by Biotechnology Value Trading Fund OS, L.P. (“Trading Fund OS”) and (iv) 59,589 Class A Ordinary Shares held by a certain managed account (the “Partners Managed Account”). BVF I GP LLC (“BVF GP”), as the general partner of BVF, may be deemed to beneficially own the shares beneficially owned by BVF. BVF II GP LLC (“BVF2 GP”), as the general partner of BVF2, may be deemed to beneficially own the shares beneficially owned by BVF2. BVF Partners OS Ltd. (“Partners OS”), as the general partner of Trading Fund OS, may be deemed to beneficially own the shares beneficially owned by Trading Fund OS. BVF GP Holdings LLC (“BVF GPH”), as the sole member of each of BVF GP and BVF2 GP, may be deemed to beneficially own the shares beneficially owned in the aggregate by BVF and BVF2. Partners, as the investment manager of each of BVF, BVF2, Trading Fund OS and the Partners Managed Account, and the sole member

of Partners OS, may be deemed to beneficially own the shares beneficially owned in the aggregate by BVF, BVF2, Trading Fund OS and held in the Partners Managed Account. BVF Inc., as the general partner of Partners, may be deemed to beneficially own the shares beneficially owned by Partners. Mark Lampert, as a director and officer of BVF Inc., may be deemed to beneficially own the shares beneficially owned by BVF Inc. Pursuant to a certain agreement entered into between Mr. Loy and Partners, Mr. Loy is obligated to transfer to Partners the economic benefit, if any, received upon the sale of the shares issuable upon the exercise of his options. BVF GP disclaims beneficial ownership of the shares beneficially owned by BVF. BVF2 GP disclaims beneficial ownership of the shares beneficially owned by BVF2. Partners OS disclaims beneficial ownership of the shares beneficially owned by Trading Fund OS. BVF GPH disclaims beneficial ownership of the shares beneficially owned by BVF and BVF2. Each of Partners, BVF Inc. and Mr. Lampert disclaims beneficial ownership of the shares beneficially owned by BVF, BVF2 and Trading Fund OS and held in the Partners Managed Account. Mr. Loy disclaims beneficial ownership of the shares that he does not directly own. The business address for each of the entities and Mr. Lampert is 44 Montgomery St., 40th Floor, San Francisco, California 94104.

(6) Based on a Schedule 13G filed on November 12, 2025 and consists of 4,610,071 Class A Ordinary Shares held by entities affiliated with Deep Track Capital, LP (“Deep Track”). Deep Track, Deep Track Biotechnology Master Fund, Ltd. (“Master Fund”) and David Kroin hold shared voting and dispositive power over the shares. The business address of Deep Track and Mr. Kroin is 200 Greenwich Ave., 3rd Floor, Greenwich, Connecticut 06830. The business address of Master Fund is c/o Walkers Corporate Limited, 190 Elgin Ave., George Town, KY1-9001, Cayman Islands.

(7) Based on a Schedule 13G filed on February 17, 2026 and consists of 4,355,433 Class A Ordinary Shares held by entities affiliated with Cormorant Asset Management, LP (“Cormorant”). Cormorant and Bihua Chen hold shared voting and dispositive power over the shares. The business address of Cormorant and Ms. Chen is 200 Clarendon St., 52nd Floor, Boston, Massachusetts 02116.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table contains information about our equity compensation plans as of December 31, 2025. As of December 31, 2025, we had outstanding awards under the Incentive Plan.

Plan Category	Number of Securities to Be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders	2,156,512[1]	$24.76[2]	1,836,618[3]
Equity compensation plans not approved by security holders	—	—	—
Total	2,156,512	$24.76	1,836,618

(1) Represents share options granted under the Incentive Plan.

(2) Reflects the weighted-average exercise price of share options granted under the Incentive Plan.

(3) Represents shares available under the Incentive Plan.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a summary of each transaction or series of similar transactions since January 1, 2025, or any currently proposed transaction, to which we were or are a party in which:

- the amount involved exceeds $120,000; and
- any of our directors or executive officers, any holder of more than 5% of any class of our voting ordinary shares or any member of his or her immediate family had or will have a direct or indirect material interest, other than compensation and other arrangements that are described under the section titled ‘‘Executive Compensation’’ or that were approved by our Compensation Committee.

Beneficial ownership of securities is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to such securities.

Related Party Transactions

Amended and Restated Registration Rights Agreement

On April 5, 2022, MoonLake AG entered into the Amended and Restated Registration Rights Agreement with Helix Holdings LLC, a Cayman Islands limited liability company, and the existing equityholders of MoonLake AG and equityholders of MoonLake AG that executed joinders to the Business Combination Agreement dated October 4, 2021, pursuant to which, among other things, the parties thereto were granted certain customary registration rights with respect to Class A Ordinary Shares beneficially held by them, directly or indirectly, and subject to transfer restrictions with respect to the Class A Ordinary Shares and Class C Ordinary Shares beneficially held by them, as applicable.

Related Party Transaction Policy

We have adopted a written related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person (as defined above) are, were or will be participants in which the amount involved exceeds the lesser of $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years. Transactions involving compensation for services provided to us as an employee or director, among other limited exceptions, are deemed to have standing pre-approval by the Audit Committee but may be specifically reviewed if appropriate in light of the facts and circumstances.

Under the policy, if a transaction has been identified as a related person transaction, our Audit Committee must review the material facts and either approve or disapprove of the entry into the transaction. If advance approval of the transaction is not feasible, then the transaction will be considered and, if the Audit Committee determines it to be appropriate, ratified at the next regularly scheduled meeting. In addition, under our Code of Business Conduct and Ethics, our employees and directors have an affirmative responsibility to avoid activities that create or give the appearance of a conflict of interest, and directors and executive officers must consult and seek prior approval of potential conflicts of interest from the Audit Committee. In considering related party transactions, our Audit Committee will take into account the relevant available facts and circumstances including, but not limited to:

- whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances; and
- the extent of the related person’s interest in the transaction.

The related party transactions described above were consummated prior to our adoption of the formal, written policy described above, and, accordingly, the foregoing policies and procedures were not followed with respect to these transactions. However, we believe that the terms obtained or consideration that we paid or received, as applicable, in connection with these transactions were comparable to terms available or the amounts that would be paid or received, as applicable, in arm’s-length transactions at such time.

OTHER MATTERS

Shareholder Proposals and Director Nominations for Next Year's Annual General Meeting

Pursuant to Rule 14a-8 of the Exchange Act, shareholders who wish to submit proposals for inclusion in the proxy statement for the 2027 Annual General Meeting of Shareholders must send such proposals to our Corporate Secretary at the address set forth on the first page of this Proxy Statement. Such proposals must be received by us as of the close of business (6:00 p.m. Central European Time) on December 22, 2026 and must comply with Rule 14a-8 of the Exchange Act. The submission of a shareholder proposal does not guarantee that it will be included in the proxy statement.

As set forth in our MAA, if a shareholder intends to make a nomination for director election or present a proposal for other business (other than pursuant to Rule 14a-8 of the Exchange Act) at the 2027 Annual General Meeting of Shareholders, the shareholder's notice must be received by our Corporate Secretary at the address set forth on the first page of this Proxy Statement no earlier than the 120th day and no later than the 90th day before the anniversary of the last annual general meeting; provided, however, that if the date of the annual general meeting is more than 30 days before or after such anniversary date, the shareholder's notice must be delivered not later than the later of (x) the close of business on the 90th day prior to such annual general meeting and (y) if the first public announcement of the date of such meeting is less than 100 days prior to the meeting, 10 days following the date of the first public announcement of the meeting date. Therefore, unless the 2027 Annual General Meeting of Shareholders is more than 30 days before or after the anniversary of the Annual Meeting, notice of proposed nominations or proposals (other than pursuant to Rule 14a-8 of the Exchange Act) must be received by our Corporate Secretary no earlier than February 4, 2027 and no later than the close of business (6:00 p.m. Central European Time) on March 6, 2027. Any such director nomination or shareholder proposal must be a proper matter for shareholder action and must comply with the terms and conditions set forth in our MAA. If a shareholder fails to meet these deadlines or fails to satisfy the requirements of Rule 14a-4 of the Exchange Act, we may exercise discretionary voting authority under proxies we solicit to vote on any such proposal as we determine appropriate. In addition to satisfying the deadlines in the advance notice provisions of our MAA, a shareholder who intends to solicit proxies in support of nominees submitted under these advance notice provisions for the 2027 Annual General Meeting of Shareholders must provide the notice required under Rule 14a-19 of the Exchange Act to our Corporate Secretary in writing not later than the close of business (6:00 p.m. Central European Time) on April 5, 2027. We reserve the right to reject, rule out of order or take other appropriate action with respect to any nomination or proposal that does not comply with these and other applicable requirements.

Delivery of Documents to Shareholders Sharing an Address

A number of brokerage firms have adopted a procedure approved by the SEC called ''householding''. Under this procedure, certain shareholders who have the same address and do not participate in electronic delivery of proxy materials will receive only one copy of the proxy materials, including this Proxy Statement, the Notice and our Annual Report on Form 10-K for the year ended December 31, 2025, until such time as one or more of these shareholders notifies us that they wish to receive individual copies. This procedure helps to reduce duplicate mailings and save printing costs and postage fees, as well as natural resources. If you received a ''householding'' mailing this year and would like to have additional copies of the proxy materials mailed to you, please send a written request to our Corporate Secretary at the address set forth on the first page of this Proxy Statement, or call 41-41-510-8022, and we will promptly deliver the proxy materials to you. Please contact your broker if you received multiple copies of the proxy materials and would prefer to receive a single copy in the future, or if you would like to opt out of ''householding'' for future mailings.

Availability of Additional Information

We will provide, free of charge, a copy of our Annual Report on Form 10-K for the year ended December 31, 2025, including exhibits, on the written or oral request of any shareholder of the Company. Please send a written request to our Corporate Secretary at the address set forth on the first page of this Proxy Statement, or call the number above.

APPENDIX A: MOONLAKE IMMUNOTHERAPEUTICS AMENDED AND RESTATED 2022 EQUITY INCENTIVE PLAN

1. Purpose

The purpose of this MoonLake Immunotherapeutics 2022 Amended and Restated Equity Incentive Plan (the "***Plan***") is to promote and closely align the interests of employees, officers, non-employee directors and other service providers of MoonLake Immunotherapeutics and its shareholders by providing share-based compensation and other performance-based compensation. The objectives of the Plan are to attract and retain the best available employees for positions of substantial responsibility and to motivate Participants to optimize the profitability and growth of the Company through incentives that are consistent with the Company's goals and that link the personal interests of Participants to those of the Company's shareholders. The Plan provides for the grant of Options, Stock Appreciation Rights, Restricted Stock Units, Restricted Stock and Other Share-Based Awards and for Incentive Bonuses, which may be paid in cash, Common Shares or a combination thereof, as determined by the Committee.

2. Definitions

As used in the Plan, the following terms shall have the meanings set forth below:

(a) "***Act***" means the U.S. Securities Exchange Act of 1934, as amended.

(b) "***Affiliate***" means any entity in which the Company has a substantial direct or indirect equity interest, as determined by the Committee from time to time.

(c) "***Award***" means an Option, Stock Appreciation Right, Restricted Stock Unit, Restricted Stock, Other Share-Based Award or Incentive Bonus granted to a Participant pursuant to the provisions of the Plan, any of which may be subject to performance conditions.

(d) "***Award Agreement***" means a written or electronic agreement or other instrument as may be approved from time to time by the Committee and designated as such implementing the grant of each Award. An Award Agreement may be in the form of an agreement to be executed by both the Participant and the Company (or an authorized representative of the Company) or certificates, notices or similar instruments as approved by the Committee and designated as such.

(e) "***Beneficial Owner***" shall have the meaning set forth in Rule 13d-3 under the Act.

(f) "***Board***" means the Board of Directors of the Company.

(g) "***Cause***" has the meaning set forth in the written employment, offer, services or severance agreement or letter between the Participant and the Company or an Affiliate, or, if there is no such agreement or no such term is defined in such agreement, means a Participant's Termination of Employment by the Company or an Affiliate by reason of (i) the Participant's material breach of any agreement between the Participant and the Company or an Affiliate or any policy of the Company of an Affiliate; (ii) the willful failure or refusal by the Participant to substantially perform his or her duties; (iii) the commission or conviction of the Participant of, or the entering of a plea of nolo contendere by the Participant with respect to, (A) a felony or (B) a misdemeanor involving moral turpitude; or (iv) the Participant's gross misconduct that causes harm to the reputation of the Company. A Participant's employment or service will be deemed to have been terminated for Cause if it is determined subsequent to such Participant's Termination of Employment that grounds for a Termination of Employment for Cause existed at the time of such Termination of Employment, as determined by the Committee.

(h) "***Change in Control***" means, except as otherwise provided in an Award Agreement, the occurrence of any one of the following:

(i) any Person is or becomes the Beneficial Owner, directly or indirectly, of securities of the Company (not including in the securities beneficially owned by such Person or any securities acquired directly from the Company or its Affiliates) representing 50% or more of the combined voting power of the Company's then outstanding securities, excluding any Person who becomes such a Beneficial Owner in connection with a transaction described in Section 2(h)(iii) below;

(ii) the following individuals cease for any reason to constitute a majority of the number of directors then serving: (A) individuals who, on the Effective Date (as defined below), constitute the Board and (B) any new director (other than a director whose initial assumption of office is in connection with an actual or

threatened election contest, including a consent solicitation, relating to the election of directors of the Company) whose appointment or election by the Board or nomination for election by the Company's shareholders was approved or recommended by a vote of at least a majority of the directors then still in office who were either directors on the Effective Date or whose appointment, election or nomination for election was previously so approved or recommended;

(iii) there is consummated a merger or consolidation of the Company or any direct or indirect subsidiary of the Company with any other corporation, other than a merger or consolidation which would result in the holders of the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or any parent thereof) at least 50% of the combined voting power of the securities of the Company or such surviving entity or any parent thereof outstanding immediately after such merger or consolidation; or

(iv) the implementation of a plan of complete liquidation or dissolution of the Company; or

(v) there is consummated a sale or disposition by the Company of all or substantially all of the Company's assets, other than a sale or disposition by the Company of all or substantially all of the Company's assets to an entity, at least 50% of the combined voting power of the voting securities of which is owned by shareholders of the Company in substantially the same proportions as their ownership of the Company immediately prior to such sale.

(i) "***Class A Shares***" means the Class A ordinary shares of the Company, $0.0001 par value per share.

(j) "***Code***" means the U.S. Internal Revenue Code of 1986, as amended from time to time, and the rulings and regulations issued thereunder.

(k) "***Committee***" means the Compensation Committee of the Board (or any successor committee) or such other committee as designated by the Board to administer the Plan under Section 6.

(l) "***Common Share***" means the Class A Shares, or such other class or kind of shares or other securities as may be applicable under Section 16.

(m) "***Company***" means MoonLake Immunotherapeutics, a Cayman Islands exempted company, and except as utilized in the definition of Change in Control, any successor corporation.

(n) "***Disability***" has the meaning set forth in a written employment, offer, services or severance agreement or letter between the Participant and the Company or an Affiliate, or, if there is no such agreement or no such term is defined in such agreement, means the inability of the Participant to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment. A determination of Disability shall be made by the Committee on the basis of such medical evidence as the Committee deems warranted under the circumstances, and in this respect, Participants shall submit to an examination by a physician upon request by the Committee.

(o) "***Dividend Equivalent***" mean an amount payable in cash or Common Shares, as determined by the Committee, equal to the dividends that would have been paid to the Participant if the Common Share with respect to which the Dividend Equivalent relates had been owned by the Participant.

(p) "***Effective Date***" means the date on which the Plan takes effect, as defined pursuant to Section 4.

(q) "***Eligible Person***" means any current or prospective employee, officer, non-employee director or other service provider of the Company or any of its Subsidiaries; provided however that Incentive Stock Options may only be granted to employees of the Company or any of its "subsidiary corporations" within the meaning of Section 424 of the Code.

(r) "***Fair Market Value***" means as of any date, the value of a Common Share determined as follows: (i) if the Common Share is listed on any established stock exchange, system or market, its Fair Market Value shall be the closing price for the Common Share as quoted on such exchange, system or market as reported in the Wall Street Journal or such other source as the Committee deems reliable (or, if no sale of Common Share is reported for such date, on the next preceding date on which any sale shall have been reported); and (ii) in the absence of an established market for the Common Share, the Fair Market Value thereof shall be determined in good faith by the Committee by the reasonable application of a reasonable valuation method, taking into account factors consistent with Treas. Reg. § 409A-1(b)(5)(iv)(B) as the Committee deems appropriate.

(s) "***Incentive Bonus***" means a bonus opportunity awarded under Section 12 pursuant to which a Participant may become entitled to receive an amount based on satisfaction of such performance criteria established for a specified performance period as specified in the Award Agreement.

(t) "***Incentive Stock Option***" means an Option that is intended to qualify as an "incentive stock option" within the meaning of Section 422 of the Code.

(u) "***Nonqualified Stock Option***" means an Option that is not intended to qualify as an "incentive stock option" within the meaning of Section 422 of the Code.

(v) "***Option***" means a right to purchase a number of Common Shares at such exercise price, at such times and on such other terms and conditions as are specified in or determined pursuant to an Award Agreement. Options granted pursuant to the Plan may be Incentive Stock Options or Nonqualified Stock Options.

(w) "***Other Share-Based Award***" means an Award granted to an Eligible Person under Section 11.

(x) "***Participant***" means any Eligible Person to whom Awards have been granted from time to time by the Committee and any authorized transferee of such individual.

(y) "***Person***" shall have the meaning given in Section 3(a)(9) of the Act, as modified and used in Sections 14(d) and 15(d) thereof, except that such term shall not include (i) the Company or any of its Affiliates, (ii) a trustee or other fiduciary holding securities under an employee benefit plan of the Company or any of its Subsidiaries, (iii) an underwriter temporarily holding securities pursuant to an offering of such securities or (iv) a corporation owned, directly or indirectly, by the shareholders of the Company in substantially the same proportions as their ownership of shares of the Company.

(z) "***Restricted Stock***" means an Award or issuance of Common Shares the grant, issuance, vesting and/or transferability of which is subject during specified periods of time to such conditions (including continued employment or engagement or performance conditions) and terms as the Committee deems appropriate.

(aa) "***Restricted Stock Unit***" means an Award denominated in units of Common Shares under which the issuance of Common Shares (or cash payment in lieu thereof) is subject to such conditions (including continued employment or engagement or performance conditions) and terms as the Committee deems appropriate.

(bb) "***Separation from Service***" or "***Separates from Service***" means a Termination of Employment that constitutes a "separation from service" within the meaning of Section 409A of the Code.

(cc) "***Stock Appreciation Right***" or "***SAR***" means a right granted that entitles the Participant to receive, in cash or Common Shares or a combination thereof, as determined by the Committee, value equal to the excess of (i) the Fair Market Value of a specified number of Common Shares at the time of exercise over (ii) the exercise price of the right, as established by the Committee on the date of grant.

(dd) "***Subsidiary***" means any business association (including a corporation or a partnership, other than the Company) in an unbroken chain of such associations beginning with the Company if each of the associations other than the last association in the unbroken chain owns equity interests (including shares or partnership interests) possessing 50% or more of the total combined voting power of all classes of equity interests in one of the other associations in such chain.

(ee) "***Substitute Awards***" means Awards granted or Common Shares issued by the Company in assumption of, or in substitution or exchange for, awards previously granted, or the right or obligation to make future awards, by a company acquired by the Company or any Subsidiary or with which the Company or any Subsidiary combines.

(ff) "***Termination of Employment***" means ceasing to serve as an employee of the Company and its Subsidiaries or, with respect to a non-employee director or other service provider, ceasing to serve as such for the Company and its Subsidiaries, except that with respect to all or any Awards held by a Participant (i) the Committee may determine that a leave of absence or employment on a less than full-time basis is considered a "Termination of Employment," (ii) the Committee may determine that a transition from employment to service with a partnership, joint venture or corporation not meeting the requirements of a Subsidiary in which the Company or a Subsidiary is a party is not considered a "Termination of Employment," (iii) service as a member of the Board (or another capacity as a service provider) shall constitute continued employment with respect to Awards granted to a Participant while he or she served as an employee, (iv) service as an employee of the Company or a Subsidiary shall constitute continued employment with respect to Awards granted to a Participant while he or she served as a

member of the Board or other service provider, and (v) the Committee may determine that a transition from employment with the Company or a Subsidiary to service to the Company or a Subsidiary other than as an employee shall constitute a ''Termination of Employment''. The Committee shall determine whether any corporate transaction, such as a sale or spin-off of a division or Subsidiary that employs or engages a Participant, shall be deemed to result in a Termination of Employment with the Company and its Subsidiaries for purposes of any affected Participant's Awards, and the Committee's decision shall be final and binding.

3. Eligibility

Any Eligible Person is eligible for selection by the Committee to receive an Award.

4 Effective Date and Termination of Plan

This Plan, as most recently amended and restated, was approved by the Board on April 17, 2026 and will become effective on the date it is approved by the shareholders of the Company (the ''***Effective Date***''). The Plan shall remain available for the grant of Awards until the 10th anniversary of the Effective Date; provided, however, that Incentive Stock Options may not be granted under the Plan after the 10th anniversary of the date of the Board's approval of the Plan. Notwithstanding the foregoing, the Plan may be terminated at such earlier time as the Board may determine. Termination of the Plan will not affect the rights and obligations of the Participants and the Company arising under Awards theretofore granted.

5. Shares Subject to the Plan and to Awards

(a) *Aggregate Limits*. The aggregate number of Common Shares issuable under the Plan shall be equal to 9,353,948. The aggregate number of Common Shares available for grant under this Plan and the number of Common Shares subject to Awards outstanding at the time of any event described in Section 16 shall be subject to adjustment as provided in Section 16. The Common Shares issued pursuant to Awards granted under this Plan may be shares that are authorized and unissued or shares that were reacquired by the Company, including shares purchased in the open market.

(b) *Issuance of Shares*. For purposes of Section 5(a), the aggregate number of Common Shares issued under this Plan at any time shall equal only the number of Common Shares actually issued upon exercise or settlement of an Award. Common Shares subject to Awards that have been canceled, expired, forfeited or otherwise not issued under an Award and Common Shares subject to Awards settled in cash shall not count as Common Shares issued under this Plan. The aggregate number of shares available for issuance under this Plan at any time shall not be reduced by (i) shares subject to Awards that have been terminated, expired unexercised, forfeited or settled in cash or (ii) shares subject to Awards that otherwise do not result in the issuance of shares in connection with payment or settlement thereof. Notwithstanding the foregoing, shares subject to an Award granted under this Plan may not again be made available for issuance under this Plan if such shares are: (x) shares that were subject to a stock-settled Stock Appreciation Right and were not issued upon the net settlement or net exercise of such Stock Appreciation Right, (y) shares that have been delivered (either actually or by attestation) to, or retained or withheld by, the Company in payment or satisfaction of the exercise price, purchase price or tax withholding obligation of an Award, or (z) shares that have been repurchased on the open market with the proceeds of an Option exercise.

(c) *Substitute Awards*. Substitute Awards shall not reduce the Common Shares authorized for issuance under the Plan or authorized for grant to a Participant in any calendar year. Additionally, in the event that a company acquired by the Company or any Subsidiary, or with which the Company or any Subsidiary combines, has shares available under a pre-existing plan approved by shareholders and not adopted in contemplation of such acquisition or combination, the shares available for grant pursuant to the terms of such pre-existing plan (as adjusted, to the extent appropriate, using the exchange ratio or other adjustment or valuation ratio or formula used in such acquisition or combination to determine the consideration payable to the holders of Common Share of the entities party to such acquisition or combination) may be used for Awards under the Plan and shall not reduce the Common Shares authorized for issuance under the Plan; provided that, Awards using such available shares (i) shall not be made after the date awards or grants could have been made under the terms of the pre-existing plan, absent the acquisition or combination, (ii) shall only be made to individuals who were employees of such acquired or combined company before such acquisition or combination, and (iii) shall comply with the requirements of any stock exchange or market or quotation system on which the Common Share is traded, listed or quoted.

(d) *Tax Code Limits*. The aggregate number of Common Shares that may be issued pursuant to the exercise of Incentive Stock Options granted under this Plan shall be equal to 9,353,948, which number shall be calculated

and adjusted pursuant to Section 16 only to the extent that such calculation or adjustment will not affect the status of any Option intended to qualify as an Incentive Stock Option under Section 422 of the Code.

(e) *Limits on Non-Employee Director Compensation.* The aggregate dollar value of equity-based (based on the grant date Fair Market Value of equity-based Awards) and cash compensation granted under this Plan or otherwise during any calendar year to any non-employee director shall not exceed $750,000; provided, however, that in the calendar year in which a non-employee director first joins the Board or during any calendar year in which a non-employee director is designated as Chairperson of the Board or Lead Director, the maximum aggregate dollar value of equity-based and cash compensation granted to the non-employee director may be up to $1,000,000.

(f) *Award Vesting Limitations.* Notwithstanding any other provision of the Plan to the contrary, Awards granted under the Plan may not become exercisable, vest or be settled, in whole or in part, prior to the one (1) year anniversary of the date of grant except (i) with respect to an Award that is granted in connection with a merger or other acquisition as a substitute or replacement award for awards held by grantees of the acquired business and (ii) with respect to an Award granted to a non-employee director that vests on the earlier of the one-year anniversary of the date of grant and the next annual meeting of shareholders which is at least 50 weeks after the immediately preceding year's annual meeting; provided, that up to 5% of the aggregate number of Shares authorized for issuance under this Plan (as described in Section 5(a)) may be issued pursuant to Awards subject to any, or no, vesting conditions, as the Committee determines appropriate; and, provided, further, that the foregoing restriction does not apply to the Committee's discretion to provide for accelerated exercisability or vesting of any Award, including in cases of retirement, death, Disability, or a Change in Control, in the terms of the Award or otherwise.

6. Administration of the Plan

(a) *Administrator of the Plan*. The Plan shall be administered by the Committee. Any power of the Committee may also be exercised by the Board, except to the extent that the grant or exercise of such authority would cause any Award or transaction to become subject to (or lose an exemption under) the short-swing profit recovery provisions of Section 16 of the Act. To the extent that any permitted action taken by the Board conflicts with action taken by the Committee, the Board action shall control. To the maximum extent permissible under applicable law, the Committee (or any successor) may by resolution delegate any or all of its authority to one or more subcommittees composed of one or more directors and/or officers of the Company, and any such subcommittee shall be treated as the Committee for all purposes under this Plan. Notwithstanding the foregoing, if the Board or the Committee (or any successor) delegates to a subcommittee comprised of one or more officers of the Company (who are not also directors) the authority to grant Awards, the resolution so authorizing such subcommittee shall specify the total number of Common Shares such subcommittee may award pursuant to such delegated authority, and no such subcommittee shall designate any officer serving thereon or any officer (within the meaning of Section 16 of the Act) or non-employee director of the Company as a recipient of any Awards granted under such delegated authority. The Committee may further designate and delegate to one or more additional officers or employees of the Company or any Subsidiary, and/or one or more agents, authority to assist the Committee in any or all aspects of the day-to-day administration of the Plan and/or of Awards granted under the Plan.

(b) *Powers of Committee*. Subject to the express provisions of this Plan, the Committee shall be authorized and empowered to do all things that it determines to be necessary or appropriate in connection with the administration of this Plan, including:

(i) to prescribe, amend and rescind rules and regulations relating to this Plan and to define terms not otherwise defined herein;

(ii) to determine which Persons are Eligible Persons, to which of such Eligible Persons, if any, Awards shall be granted hereunder and the timing of any such Awards;

(iii) to prescribe and amend the terms of the Award Agreements, to grant Awards and determine the terms and conditions thereof;

(iv) to establish and verify the extent of satisfaction of any performance goals or other conditions applicable to the grant, issuance, retention, vesting, exercisability or settlement of any Award;

(v) to prescribe and amend the terms of or form of any document or notice required to be delivered to the Company by Participants under this Plan;

(vi) to determine the extent to which adjustments are required pursuant to Section 16;

(vii) to interpret and construe this Plan, any rules and regulations under this Plan and the terms and conditions of any Award granted hereunder, and to make exceptions to any such provisions if the Committee, in good faith, determines that it is appropriate to do so;

(viii) to approve corrections in the documentation or administration of any Award;

(ix) to make all other determinations deemed necessary or advisable for the administration of this Plan; and

(x) to adopt such procedures and sub-plans as are necessary or appropriate (A) to permit or facilitate participation in this Plan by persons eligible to receive Awards under this Plan who are not citizens of or subject to taxation by, or who are employed outside, the United States or (B) to allow Awards to qualify for special tax treatment in a jurisdiction other than the United States. Committee approval will not be necessary for immaterial modifications to this Plan or any Award Agreement that are required for compliance with the laws of the relevant jurisdiction.

Notwithstanding anything in this Plan to the contrary, the Committee shall exercise its discretion in a manner that causes Awards to be compliant with or exempt from the requirements of Section 409A of the Code. Without limiting the foregoing, unless expressly agreed to in writing by the Participant holding an Award that is ''deferred compensation'' under Section 409A of the Code, the Committee shall not take any action with respect to any Award which constitutes (x) a modification of a stock right within the meaning of Treas. Reg. § 1.409A-1(b)(5)(v)(B) so as to constitute the grant of a new stock right, (y) an extension of a stock right, including the addition of a feature for the deferral of compensation within the meaning of Treas. Reg. § 1.409A-1 (b)(5)(v)(C), or (z) an impermissible acceleration of a payment date or a subsequent deferral of a stock right subject to Section 409A of the Code within the meaning of Treas. Reg. § 1.409A-1(b)(5)(v)(E).

The Committee may, in its sole and absolute discretion, without amendment to the Plan but subject to the limitations otherwise set forth in Section 20, waive or amend the operation of Plan provisions respecting exercise after Termination of Employment. The Committee or any member thereof may, in its sole and absolute discretion, except as otherwise provided in Section 20, waive, settle or adjust any of the terms of any Award so as to avoid unanticipated consequences or address unanticipated events (including any temporary closure of an applicable stock exchange, disruption of communications or natural catastrophe).

(c) *Determinations by the Committee*. All decisions, determinations and interpretations by the Committee regarding the Plan, any rules and regulations under the Plan and the terms and conditions of, or operation of, any Award granted hereunder, shall be final and binding on all Participants, beneficiaries, heirs, assigns or other persons holding or claiming rights under the Plan or any Award. The Committee shall consider such factors as it deems relevant, in its sole and absolute discretion, to making such decisions, determinations and interpretations, including the recommendations or advice of any officer or other employee of the Company and such attorneys, consultants and accountants as it may select. Members of the Board and members of the Committee acting under the Plan shall be fully protected in relying in good faith upon the advice of counsel and shall incur no liability except for as a result of gross negligence or willful misconduct in the performance of their duties.

(d) *Subsidiary Awards*. In the case of a grant of an Award to any Participant employed by a Subsidiary, such grant may, if the Committee so directs, be implemented by the Company issuing any subject Common Shares to the Subsidiary, for such lawful consideration as the Committee may determine, upon the condition or understanding that the Subsidiary will transfer the Common Shares to the Participant in accordance with the terms of the Award specified by the Committee pursuant to the provisions of the Plan. Notwithstanding any other provision hereof, such Award may be issued by and in the name of the Subsidiary and shall be deemed granted on such date as the Committee shall determine.

7. Plan Awards

(a) *Terms Set Forth in Award Agreement*. Awards may be granted to Eligible Persons as determined by the Committee at any time and from time to time prior to the termination of the Plan. The terms and conditions of each Award shall be set forth in an Award Agreement in a form approved by the Committee for such Award, which Award Agreement may contain such terms and conditions as specified from time to time by the Committee, provided such terms and conditions do not conflict with the Plan. The Award Agreement for any Award (other than Restricted Stock Awards) shall include the time or times at or within which and the consideration, if any, for which

any Common Shares or cash, as applicable, may be acquired from the Company. The terms of Awards may vary among Participants, and the Plan does not impose upon the Committee any requirement to make Awards subject to uniform terms. Accordingly, the terms of individual Award Agreements may vary.

(b) *Termination of Employment*. Subject to the express provisions of the Plan, the Committee shall specify before, at, or after the time of grant of an Award the provisions governing the effect(s) upon an Award of a Participant's Termination of Employment.

(c) *Rights of a Shareholder*. A Participant shall have no rights as a shareholder with respect to Common Shares covered by an Award (including voting rights) until the date the Participant becomes the holder of record of such Common Shares. No adjustment shall be made for dividends or other rights for which the record date is prior to such date, except as provided in Sections 10(b), 11(b) or 16 of this Plan or as otherwise provided by the Committee.

8. Options

(a) *Grant, Term and Price*. The grant, issuance, retention, vesting and/or settlement of any Option shall occur at such time and be subject to such terms and conditions as determined by the Committee or under criteria established by the Committee, which may include conditions based on continued employment or engagement, passage of time, attainment of age and/or service requirements, and/or satisfaction of performance conditions. The term of an Option shall in no event be greater than 10 years; provided, however, the term of an Option (other than an Incentive Stock Option) shall be automatically extended if, at the time of its scheduled expiration, the Participant holding such Option is prohibited by law or the Company's insider trading policy from exercising the Option, which extension shall expire on the 30th day following the date such prohibition no longer applies. The Committee will establish the price at which Common Shares may be purchased upon exercise of an Option, which in no event will be less than the Fair Market Value of such shares on the date of grant; provided, however, that the exercise price per Common Share with respect to an Option that is granted as a Substitute Award may be less than the Fair Market Value of the Common Shares on the date such Option is granted if such exercise price is based on a formula set forth in the terms of the options held by such optionees or in the terms of the agreement providing for such merger or other acquisition that satisfies the requirements of (i) Section 409A of the Code, if such options held by such optionees are not intended to qualify as ''incentive stock options'' within the meaning of Section 422 of the Code, and (ii) Section 424(a) of the Code, if such options held by such optionees are intended to qualify as ''incentive stock options'' within the meaning of Section 422 of the Code. The exercise price of any Option may be paid in cash or such other method as determined by the Committee, including an irrevocable commitment by a broker to pay over such amount from a sale of the Common Shares issuable under an Option, the delivery of previously owned Common Shares or withholding of Common Shares deliverable upon exercise.

(b) *No Repricing without Shareholder Approval*. Other than in connection with a change in the Company's capitalization (as described in Section 16), the Committee shall not, without shareholder approval, reduce the exercise price of a previously awarded Option, and at any time when the exercise price of a previously awarded Option is above the Fair Market Value of a Common Share, the Committee shall not, without shareholder approval, cancel and re-grant or exchange such Option for cash or a new Award with a lower (or no) exercise price.

(c) *No Reload Grants*. Options shall not be granted under the Plan in consideration for, and shall not be conditioned upon the delivery of, Common Shares to the Company in payment of the exercise price and/or tax withholding obligation under any other employee stock option.

(d) *Incentive Stock Options*. Notwithstanding anything to the contrary in this Section 8, in the case of the grant of an Incentive Stock Option, if the Participant owns shares possessing more than 10% of the combined voting power of all classes of shares of the Company, the exercise price of such Option must be at least 110% of the Fair Market Value of the Common Shares on the date of grant and the Option must expire within a period of not more than five years from the date of grant. Notwithstanding anything in this Section 8 to the contrary, Options designated as Incentive Stock Options shall not be eligible for treatment under the Code as Incentive Stock Options (and will be deemed to be Nonqualified Stock Options) to the extent that either (i) the aggregate Fair Market Value of the Common Shares (determined as of the time of grant) with respect to which such Options are exercisable for the first time by the Participant during any calendar year (under all plans of the Company and any Subsidiary) exceeds $100,000, taking Options into account in the order in which they were granted, or (ii) such Options otherwise remain exercisable but are not exercised within three months (or such other period of time provided in Section 422 of the Code) of separation of service (as determined in accordance with Section 3401(c) of the Code and the regulations promulgated thereunder).

(e) *No Shareholder Rights*. Participants shall have no voting rights and will have no rights to receive dividends or Dividend Equivalents in respect of an Option or any Common Shares subject to an Option until the Participant has become the holder of record of such shares.

9. Stock Appreciation Rights

(a) *General Terms*. The grant, issuance, retention, vesting and/or settlement of any Stock Appreciation Right shall occur at such time and be subject to such terms and conditions as determined by the Committee or under criteria established by the Committee, which may include conditions based on continued employment or engagement, passage of time, attainment of age and/or service requirements, and/or satisfaction of performance conditions. Stock Appreciation Rights may be granted to Participants from time to time either in tandem with or as a component of Options granted under the Plan ("***tandem SARs***") or not in conjunction with other Awards ("***freestanding SARs***"). Upon exercise of a tandem SAR as to some or all of the shares covered by the grant, the related Option shall be canceled automatically to the extent of the number of shares covered by such exercise. Conversely, if the related Option is exercised as to some or all of the shares covered by the grant, the related tandem SAR, if any, shall be canceled automatically to the extent of the number of shares covered by the Option exercise. Any Stock Appreciation Right granted in tandem with an Option may be granted at the same time such Option is granted or at any time thereafter before exercise or expiration of such Option, provided that the Fair Market Value of Common Share on the date of the SAR's grant is not greater than the exercise price of the related Option. All freestanding SARs shall be granted subject to the same terms and conditions applicable to Options as set forth in Section 8 and all tandem SARs shall have the same exercise price as the Option to which they relate. Subject to the provisions of Section 8 and the immediately preceding sentence, the Committee may impose such other conditions or restrictions on any Stock Appreciation Right as it shall deem appropriate. Stock Appreciation Rights may be settled in Common Share, cash, Restricted Stock or a combination thereof, as determined by the Committee and set forth in the applicable Award Agreement.

(b) *No Repricing without Shareholder Approval*. Other than in connection with a change in the Company's capitalization (as described in Section 16), the Committee shall not, without shareholder approval, reduce the exercise price of a previously awarded Stock Appreciation Right, and at any time when the exercise price of a previously awarded Stock Appreciation Right is above the Fair Market Value of a Common Share, the Committee shall not, without shareholder approval, cancel and re-grant or exchange such Stock Appreciation Right for cash or a new Award with a lower (or no) exercise price.

(c) *No Shareholder Rights*. Participants shall have no voting rights and will have no rights to receive dividends or Dividend Equivalents in respect of an Award of Stock Appreciation Rights or any Common Shares subject to an Award of Stock Appreciation Rights until the Participant has become the holder of record of such shares.

10. Restricted Stock and Restricted Stock Units

(a) *Vesting and Performance Criteria*. The grant, issuance, vesting and/or settlement of any Award of Restricted Stock or Restricted Stock Units shall occur at such time and be subject to such terms and conditions as determined by the Committee or under criteria established by the Committee, which may include conditions based on continued employment or engagement, passage of time, attainment of age and/or service requirements, and/or satisfaction of performance conditions. In addition, the Committee shall have the right to grant Restricted Stock or Restricted Stock Unit Awards as the form of payment for grants or rights earned or due under other shareholder-approved compensation plans or arrangements of the Company.

(b) *Dividends and Distributions*. Participants in whose name Restricted Stock is granted shall be entitled to receive all dividends and other distributions paid with respect to those Common Shares, unless determined otherwise by the Committee. The Committee will determine whether any such dividends or distributions will be automatically reinvested in additional shares of Restricted Stock and/or subject to the same restrictions on transferability as the Restricted Stock with respect to which they were distributed or whether such dividends or distributions will be paid in cash. Shares underlying Restricted Stock Units shall be entitled to dividends or distributions only to the extent provided by the Committee. Notwithstanding anything herein to the contrary, in no event will dividends or Dividend Equivalents be paid during the performance period with respect to unearned

Awards of Restricted Stock or Restricted Stock Units that are subject to performance-based vesting criteria. Dividends or Dividend Equivalents accrued on such shares shall become payable no earlier than the date the performance-based vesting criteria have been achieved and the underlying shares of Restricted Stock or Restricted Stock Units have been earned.

11. Other Share-Based Awards

(a) *General Terms.* The Committee is authorized, subject to limitations under applicable law, to grant to Eligible Persons such other Awards that may be denominated or payable in, valued in whole or in part by reference to, or otherwise based on, or related to, Common Shares, as deemed by the Committee to be consistent with the purposes of the Plan. The Committee shall determine the terms and conditions of such Other Share-Based Awards. Common Shares delivered pursuant to an Other Share-Based Award in the nature of a purchase right granted under this Section 11 shall be purchased for such consideration, paid for at such times, by such methods, and in such forms, including cash, Common Shares, other Awards, or other property, as the Committee shall determine.

(b) *Dividends and Distributions*. Shares underlying Other Share-Based Awards shall be entitled to dividends or distributions only to the extent provided by the Committee. Notwithstanding anything herein to the contrary, in no event will dividends or Dividend Equivalents be paid during the performance period with respect to unearned Other Share-Based Awards that are subject to performance-based vesting criteria. Dividends or Dividend Equivalents accrued on such shares shall become payable no earlier than the date the performance-based vesting criteria have been achieved and the shares underlying the Other Share-Based Award have been earned.

12. Incentive Bonuses

(a) *Performance Criteria*. The Committee shall establish the performance criteria and level of achievement versus such criteria that shall determine the amount payable under an Incentive Bonus, which may include a target, threshold and/or maximum amount payable and any formula for determining such achievement, and which criteria may be based on performance conditions.

(b) *Timing and Form of Payment*. The Committee shall determine the timing of payment of any Incentive Bonus. Payment of the amount due under an Incentive Bonus may be made in cash or in Common Share, as determined by the Committee.

(c) *Discretionary Adjustments*. Notwithstanding satisfaction of any performance goals and, the amount paid under an Incentive Bonus on account of either financial performance or personal performance evaluations may be adjusted by the Committee on the basis of such further considerations as the Committee shall determine.

13. Performance Awards

The Committee may establish performance criteria and level of achievement versus such criteria that shall determine the number of Common Shares, Restricted Stock Units, or cash to be granted, retained, vested, issued or issuable under or in settlement of or the amount payable pursuant to an Award (any such Award, a ''***Performance Award***''). A Performance Award may be identified as ''Performance Share,'' ''Performance Equity,'' ''Performance Unit'' or other such term as chosen by the Committee.

14. Deferral of Payment

The Committee may, in an Award Agreement or otherwise, provide for the deferred delivery of Common Shares or cash upon settlement, vesting or other events with respect to Restricted Stock Units, Other Share-Based Awards or in payment or satisfaction of an Incentive Bonus. Notwithstanding anything herein to the contrary, in no event will any election to defer the delivery of Common Shares or any other payment with respect to any Award be allowed if the Committee determines, in its sole discretion, that the deferral would result in the imposition of the additional tax under Section 409A(a)(1)(B) of the Code. No Award shall provide for deferral of compensation that does not comply with Section 409A of the Code. The Company, any Subsidiary or Affiliate which is in existence or hereafter comes into existence, the Board and the Committee shall have no liability to a Participant, or any other party, if an Award that is intended to be exempt from, or compliant with, Section 409A of the Code is not so exempt or compliant or for any action taken by the Board or the Committee.

15. Conditions and Restrictions Upon Securities Subject to Awards

The Committee may provide that the Common Shares issued upon exercise of an Option or Stock Appreciation Right or otherwise subject to or issued under an Award shall be subject to such further agreements, restrictions,

conditions or limitations as the Committee in its discretion may specify prior to the exercise of such Option or Stock Appreciation Right or the grant, vesting or settlement of such Award, including conditions on vesting or transferability, forfeiture or repurchase provisions and method of payment for the Common Shares issued upon exercise, vesting or settlement of such Award (including the actual or constructive surrender of Common Shares already owned by the Participant) or payment of taxes arising in connection with an Award. Without limiting the foregoing, such restrictions may address the timing and manner of any resales by the Participant or other subsequent transfers by the Participant of any Common Shares issued under an Award, including (a) restrictions under an insider trading policy or pursuant to applicable law, (b) restrictions designed to delay and/or coordinate the timing and manner of sales by the Participant and holders of other Company equity compensation arrangements, (c) restrictions as to the use of a specified brokerage firm for such resales or other transfers and (d) provisions requiring Common Shares be sold on the open market or to the Company in order to satisfy tax withholding or other obligations.

16. Adjustment of and Changes in the Shares

(a) The number and kind of Common Shares available for issuance under this Plan (including under any Awards then outstanding), and the number and kind of Common Shares subject to the limits set forth in Section 5, shall be equitably adjusted by the Committee to reflect any reorganization, reclassification, combination of shares, share split, reverse share split, spin-off, dividend or distribution of securities, property or cash (other than regular, quarterly cash dividends), or any other event or transaction that affects the number or kind of Common Shares outstanding. Such adjustment may be designed to comply with Section 424 of the Code or may be designed to treat the Common Shares available under the Plan and subject to Awards as if they were all outstanding on the record date for such event or transaction or to increase the number of such Common Shares to reflect a deemed reinvestment in Common Shares of the amount distributed to the Company's securityholders. The terms of any outstanding Award shall also be equitably adjusted by the Committee as to price, number or kind of Common Shares subject to such Award, vesting, and other terms to reflect the foregoing events, which adjustments need not be uniform as between different Awards or different types of Awards. No fractional Common Shares shall be issued or issuable pursuant to such an adjustment.

(b) Subject to Section 16(c), in the event there shall be any other change in the number or kind of outstanding Common Shares, or any shares or other securities into which such Common Shares shall have been changed, or for which it shall have been exchanged, by reason of a Change in Control, other merger, consolidation or otherwise, then the Committee shall determine the appropriate and equitable adjustment to be effected, which adjustments need not be uniform between different Awards or different types of Awards. In addition, in the event of such change described in this paragraph, the Committee may accelerate the time or times at which any Award may be exercised, consistent with and as otherwise permitted under Section 409A of the Code, and may provide for cancellation of such accelerated Awards that are not exercised within a time prescribed by the Committee in its sole discretion.

(c) In the event of a Change in Control, immediately prior to the Change in Control, all Awards shall be treated as follows effective immediately prior to the Change in Control: (A) in the case of an Option or Stock Appreciation Right, the Participant shall have the ability to exercise such Option or Stock Appreciation Right, including any portion of the Option or Stock Appreciation Right not previously exercisable, (B) in the case of any Award the vesting of which is in whole or in part subject to performance criteria or an Incentive Bonus, all conditions to the grant, issuance, retention, vesting or transferability of, or any other restrictions applicable to, such Award shall immediately lapse and the Participant shall have the right to receive a payment based on the greater of target level achievement or actual performance through the date of the Change in Control, and (C) in the case of outstanding Restricted Stock, Restricted Stock Units or Other Share-Based Awards (other than those referenced in subsection (B)), all conditions to the grant, issuance, retention, vesting or transferability of, or any other restrictions applicable to, such Award shall immediately lapse. In no event shall any action be taken pursuant to this Section 16(c) that would change the payment or settlement date of an Award in a manner that would result in the imposition of any additional taxes or penalties pursuant to Section 409A of the Code.

(d) Notwithstanding anything in this Section 16 to the contrary, in the event of a Change in Control, the Committee may provide for, following the application of the treatment set forth in Section 16(c), the cancellation and cash settlement of all outstanding Awards upon such Change in Control.

(e) Notwithstanding anything in this Section 16 to the contrary, an adjustment to an Option or Stock Appreciation Right under this Section 16 shall be made in a manner that will not result in the grant of a new Option or Stock Appreciation Right under Section 409A of the Code.

17. Transferability

Each Award may not be sold, transferred for value, pledged, assigned, or otherwise alienated or hypothecated by a Participant other than by will or the laws of descent and distribution, and each Option or Stock Appreciation Right shall be exercisable only by the Participant during his or her lifetime. Notwithstanding the foregoing, (a) outstanding Options may be exercised following the Participant's death by the Participant's beneficiaries or as permitted by the Committee and (b) a Participant may transfer or assign an Award as a gift to an entity wholly owned by such Participant (an "***Assignee Entity***"), provided that such Assignee Entity shall be entitled to exercise assigned Options and Stock Appreciation Rights only during the lifetime of the assigning Participant (or following the assigning Participant's death, by the Participant's beneficiaries or as otherwise permitted by the Committee) and provided further that such Assignee Entity shall not further sell, pledge, transfer, assign or otherwise alienate or hypothecate such Award.

18. Compliance with Laws and Regulations

(a) This Plan, the grant, issuance, vesting, exercise and settlement of Awards hereunder, and the obligation of the Company to sell, issue or deliver Common Shares under such Awards, shall be subject to all applicable foreign, federal, state and local laws, rules and regulations, stock exchange rules and regulations, and to such approvals by any governmental or regulatory agency as may be required. The Company shall not be required to register in a Participant's name or deliver Common Shares prior to the completion of any registration or qualification of such shares under any foreign, federal, state or local law or any ruling or regulation of any government body which the Committee shall determine to be necessary or advisable. To the extent the Company is unable to or the Committee deems it infeasible to obtain authority from any regulatory body having jurisdiction, which authority is deemed by the Company's counsel to be necessary to the lawful issuance and sale of any Common Shares hereunder, the Company and its Subsidiaries shall be relieved of any liability with respect to the failure to issue or sell such Common Shares as to which such requisite authority shall not have been obtained. No Option shall be exercisable and no Common Share shall be issued and/or transferable under any other Award unless a registration statement with respect to the Common Share underlying such Option is effective and current or the Company has determined, in its sole and absolute discretion, that such registration is unnecessary.

(b) In the event an Award is granted to or held by a Participant who is employed or providing services outside the United States, the Committee may, in its sole discretion, modify the provisions of the Plan or of such Award as they pertain to such individual to comply with applicable foreign law or to recognize differences in local law, currency or tax policy. The Committee may also impose conditions on the grant, issuance, exercise, vesting, settlement or retention of Awards in order to comply with such foreign law and/or to minimize the Company's obligations with respect to tax equalization for Participants employed outside their home country.

19. Withholding

To the extent required by applicable federal, state, local or foreign law, the Committee may, and/or a Participant shall, make arrangements satisfactory to the Company for the satisfaction of any withholding tax obligations that arise with respect to any Award or the issuance or sale of any Common Shares. The Company shall not be required to recognize any Participant rights under an Award, to issue Common Shares or to recognize the disposition of such Common Shares until such obligations are satisfied. To the extent permitted or required by the Committee, these obligations may or shall be satisfied by the Company withholding cash from any compensation otherwise payable to or for the benefit of a Participant, the Company withholding a portion of the Common Shares that otherwise would be issued to a Participant under such Award or any other Award held by the Participant, or by the Participant tendering to the Company cash or, if allowed by the Committee, Common Shares.

20. Amendment of the Plan or Awards

The Board may amend, alter or discontinue this Plan, and the Committee may amend or alter any Award Agreement or other document evidencing an Award made under this Plan; however, except as provided pursuant to the provisions of Section 16, no such amendment shall, without the approval of the shareholders of the Company:

(a) increase the maximum number of Common Shares for which Awards may be granted under this Plan;

(b) reduce the price at which Options may be granted below the price provided for in Section 8(a);

(c) reprice outstanding Options or SARs as described in Sections 8(b) and 9(b);

(d) extend the term of this Plan;

(e) change the class of Persons eligible to be Participants;

(f) increase the individual maximum limits in Section 5(e); or

(g) otherwise amend the Plan in any manner requiring shareholder approval by law or the rules of any stock exchange or market or quotation system on which the Common Share is traded, listed or quoted.

No amendment or alteration to the Plan or an Award or Award Agreement shall be made which would materially impair the rights of the holder of an Award without such holder's consent; provided that no such consent shall be required if the Committee determines in its sole discretion and prior to the date of any Change in Control that such amendment or alteration either (i) is required or advisable in order for the Company, the Plan or the Award to satisfy any law or regulation or to meet the requirements of, or avoid adverse financial accounting consequences under, any accounting standard, or (ii) is not reasonably likely to significantly diminish the benefits provided under such Award, or that any such diminishment has been adequately compensated.

21. No Liability of Company

The Company, any Subsidiary or Affiliate which is in existence or hereafter comes into existence, the Board and the Committee shall not be liable to a Participant or any other person as to: (a) the non-issuance or sale of Common Shares as to which the Company has been unable to obtain from any regulatory body having jurisdiction the authority deemed by the Company's counsel to be necessary to the lawful issuance and sale of any Common Shares hereunder; and (b) any tax consequence expected, but not realized, by any Participant or other person due to the receipt, vesting, exercise or settlement of any Award granted hereunder.

22. Non-Exclusivity of Plan

Neither the adoption of this Plan by the Board nor the submission of this Plan to the shareholders of the Company for approval shall be construed as creating any limitations on the power of the Board or the Committee to adopt such other incentive arrangements as either may deem desirable, including the granting of Restricted Stock or Options otherwise than under this Plan, and such arrangements may be either generally applicable or applicable only in specific cases.

23. Governing Law

This Plan and any agreements or other documents hereunder shall be interpreted and construed in accordance with the laws of the Cayman Islands (without regard to its choice of law provisions). Any reference in this Plan or in the agreement or other document evidencing any Awards to a provision of law or to a rule or regulation shall be deemed to include any successor law, rule or regulation of similar effect or applicability.

24. No Right to Employment, Reelection or Continued Service

Nothing in this Plan or an Award Agreement shall interfere with or limit in any way the right of the Company, its Subsidiaries and/or its Affiliates to terminate any Participant's employment, service on the Board or service at any time or for any reason not prohibited by law, nor shall this Plan or an Award itself confer upon any Participant any right to continue his or her employment or service for any specified period of time. Neither an Award nor any benefits arising under this Plan shall constitute an employment contract with the Company, any Subsidiary and/or its Affiliates. Subject to Sections 4 and 20, this Plan and the benefits hereunder may be terminated at any time in the sole and exclusive discretion of the Board without giving rise to any liability on the part of the Company, its Subsidiaries and/or its Affiliates.

25. Specified Employee Delay

To the extent any payment under this Plan is considered deferred compensation subject to the restrictions contained in Section 409A of the Code, such payment may not be made to a specified employee (as determined in accordance with a uniform policy adopted by the Company with respect to all arrangements subject to Section 409A of the Code) upon Separation from Service before the date that is six months after the specified employee's Separation form Service (or, if earlier, the specified employee's death). Any payment that would otherwise be made during this period of delay shall be accumulated and paid on the sixth month plus one day following the specified employee's Separation from Service (or, if earlier, as soon as administratively practicable after the specified employee's death).

26. No Liability of Committee Members

No member of the Committee shall be personally liable by reason of any contract or other instrument executed by such member or on his or her behalf in his or her capacity as a member of the Committee nor for any mistake of judgment made in good faith, and the Company shall indemnify and hold harmless each member of the Committee and each other employee, officer or director of the Company to whom any duty or power relating to the administration or interpretation of the Plan may be allocated or delegated, against any cost or expense (including counsel fees) or liability (including any sum paid in settlement of a claim) arising out of any act or omission to act in connection with the Plan, unless arising out of such Person's own fraud or willful bad faith; provided, however, that approval of the Board shall be required for the payment of any amount in settlement of a claim against any such Person. The foregoing right of indemnification shall not be exclusive of any other rights of indemnification to which such Persons may be entitled under the Company's Certificate of Incorporation and Bylaws (as each may be amended from time to time), as a matter of law, or otherwise, or any power that the Company may have to indemnify them or hold them harmless.

27. Severability

If any provision of the Plan or any Award is or becomes or is deemed to be invalid, illegal, or unenforceable in any jurisdiction or as to any Person or Award, or would disqualify the Plan or any Award under any law deemed applicable by the Committee, such provision shall be construed or deemed amended to conform to the applicable laws, or if it cannot be construed or deemed amended without, in the determination of the Committee, materially altering the intent of the Plan or the Award, such provision shall be stricken as to such jurisdiction, Person or Award, and the remainder of the Plan and any such Award shall remain in full force and effect.

28. Unfunded Plan

The Plan is intended to be an unfunded plan. Participants are and shall at all times be general creditors of the Company with respect to their Awards. If the Committee or the Company chooses to set aside funds in a trust or otherwise for the payment of Awards under the Plan, such funds shall at all times be subject to the claims of the creditors of the Company in the event of its bankruptcy or insolvency.

29. Clawback/Recoupment

Awards granted under this Plan will be subject to recoupment in accordance with any clawback policy that the Company adopts or is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Committee may impose such other clawback, recovery or recoupment provisions in an Award Agreement as the Committee determines necessary or appropriate, including a reacquisition right in respect of previously acquired Common Shares or other cash or property upon the occurrence of misconduct. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for ''good reason'' or be deemed a ''constructive termination'' (or any similar term) as such terms are used in any agreement between any Participant and the Company.

30. Interpretation

Headings are given to the Sections and subsections of the Plan solely as a convenience to facilitate reference and shall not be deemed in any way material or relevant to the construction or interpretation of the Plan or any provision thereof. Words in the masculine gender shall include the feminine gender, and where appropriate, the plural shall include the singular and the singular shall include the plural. The use herein of the word ''including'' following any general statement, term or matter shall not be construed to limit such statement, term or matter to the specific items or matters set forth immediately following such word or to similar items or matters, whether or not non-limiting language (such as ''without limitation'', ''but not limited to'', or words of similar import) is used with reference thereto, but rather shall be deemed to refer to all other items or matters that could reasonably fall within the broadest possible scope of such general statement, term or matter. References herein to any agreement, instrument or other document means such agreement, instrument or other document as amended, supplemented and modified from time to time to the extent permitted by the provisions thereof and not prohibited by the Plan.

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