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, 2024

☐ 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, 2024, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $1.14 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, 2025, there were 63,282,727 Class A Ordinary Shares, $0.0001 par value (the "Class A Ordinary Shares"), and 729,320 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 2025 Annual Meeting of Shareholders, to be held on or about June 5, 2025, 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.

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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 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, banking institution instability 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; and
- litigation 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.

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.

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. 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 VELA-1 trial (M1095-HS-301) and VELA-2 trial (M1095-HS-302). We expect primary endpoint data from the VELA-1 and VELA-2 clinical trials as of mid-2025.

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. 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 March 2024, we announced plans to initiate clinical studies of SLK in additional indications, including a Phase 3 trial in adolescent patients with HS (the VELA-TEEN trial (M1095-HS-304)), a Phase 2 trial in patients with PPP (the LEDA trial (M1095-PPP-201)), a Phase 2 trial in patients with axSpA (the S-OLARIS trial (M1095-axSpA-202)) and another Phase 2 trial applying novel imaging techniques in patients with PsA (the P-OLARIS trial (M1095-snSpA-202)). In January 2025, we

announced that first patients have been screened in the VELA-TEEN, the LEDA, and the S-OLARIS clinical trials. We expect patient enrollment for the P-OLARIS trial to commence in the first half of 2025.

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 to the three Phase 2b trials, Phase 1 single ascending and multiple ascending dosing trials were previously completed, bringing the total number of patients in completed SLK-related trials to more than 700.

We expect to submit a first Biologics License Application ("BLA") for SLK in 2026 and, subject to FDA approval, a first commercial launch in the U.S. in 2027.

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* — We began the Phase 2b MIRA trial for HS and the Phase 2b ARGO trial for PsA in May 2022 and December 2022, respectively. We announced positive top-line results for the MIRA trial and the ARGO trial in June 2023 and November 2023, respectively. The clinical trials employ established therapeutic endpoints, such as response criteria defined by HiSCR and ACR, that reflect real-world improvement in patient outcomes. In February 2024 and 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 programs of SLK in HS and PsA, respectively. In May 2024, we announced the screening of the first patients in the Phase 3 VELA program in HS and expect primary endpoint data as of mid 2025. We commenced the Phase 3 IZAR program in PsA in November 2024, and expect primary endpoint data in the first half of 2026. In January 2025, we announced that patients have been screened in the Phase 3 VELA-TEEN trial and the Phase 2 LEDA and S-OLARIS trials, and we expect to initiate patient enrollment in the Phase 2 P-OLARIS trial in the first half of 2025.

- *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 U.S. in HS and adolescent HS. We expect to submit the BLA in 2026 after completion of the VELA program, and, subject to FDA approval, we expect a commercial launch in the U.S. in 2027. We plan to further invest in our commercial capabilities. In 2024, we started hiring dedicated personnel to our marketing, access and pricing functions and intend to continue building out this team to prepare for commercial launches of SLK in our target indications. We also expect to establish a presence in the United States by early 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. Technology transfers for drug substance and drug product to commercial scale contract manufacturing organizations ("CMOs") have already been executed in 2022, but we may pursue additional technology transfers and process improvements. This was 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 providing adequate access to our product candidates, if approved, for investigators, physicians, and patients. We also plan to start the stock-piling of drug substance as pre-launch inventory in 2025.

- *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, 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).

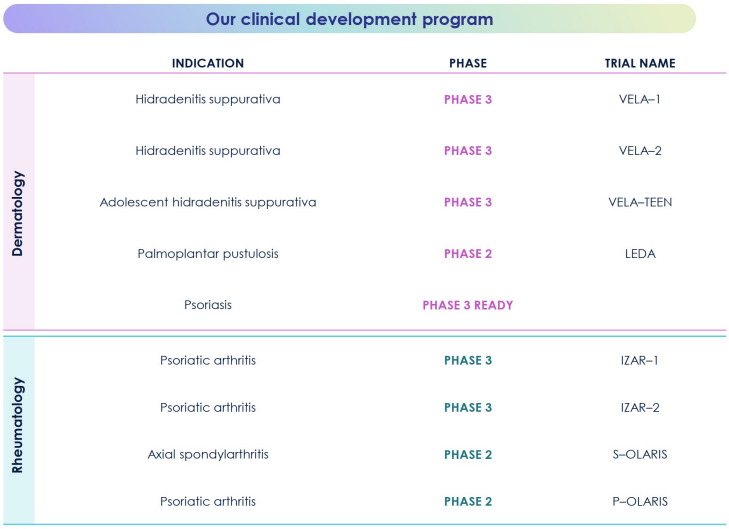


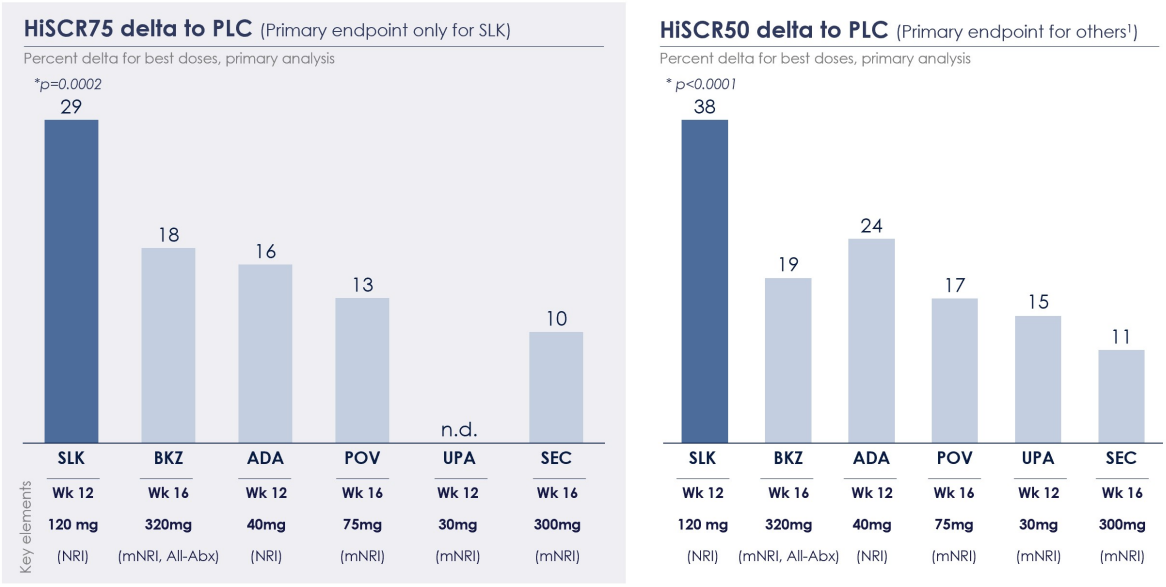
Figure 1 — Overview of development pipeline for SLK

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 ("AN") count with no increase in abscess or draining tunnel count relative to baseline. The trial also evaluated a number of secondary endpoints, including the proportion of patients achieving HiSCR50, the change from baseline in International Hidradenitis Suppurativa Severity Score System ("IHS4"), the proportion of patients achieving a Dermatology Life Quality Index ("DLQI") total score of ≤5, and the proportion of patients achieving at least 30% reduction from baseline in Numerical Rating Scale 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 29 percentage points ("ppt") delta to placebo on HiSCR75 ($p=0.0002$) and a 38 ppt delta to placebo on HiSCR50 ($p<0.0001$). The results suggest that, as early as week 12, SLK, relative to placebo, reaches the highest clinical activity among all other therapies tested in similarly stringent pivotal-like trials (Figure 2).



Note: This is a comparison across trials, with inherent limitations. No head-to-head trials. 1 POV used mean AN count reduction as primary endpoint. 2 Estimation of HiSCR75 delta to PLC at wk 16 using the avg. response of the 2 crossed-over groups from PLC to SLK doses at wk 12 (PLC plateaus already from week 8) and the wk 16 response for the 120mg arm; PLC, Placebo; SLK, Sonelokimab (MIRA study); BKZ, Bimekizumab (pooled BE HEARD I/II); ADA, Adalimumab (pooled PIONEER I/II); POV, Povorcitinhib (NCT04476043); UPA, Upadacitinib (NCT04430855); SEC, Secukinumab (pooled SUNRISE/SUNSHINE)

Figure 2 — Comparison of HiSCR75 and HiSCR50 deltas to placebo between the MIRA trial and other pivotal-like trials

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.

Rates of complete resolution of inflammatory nodules and abscesses (AN 100) together with complete resolution of draining tunnels (DT 100) also increased between week 12 and 24 (31% and 49% of patients achieving this high level of response at week 24 with 120mg respectively, an increase of up to 15 ppt). Complete inflammatory remission (IHS4-100) was achieved in 1 in 4 patients (24%) treated with 120mg at week 24. Clinical responses translated to profound improvements in patient-reported outcomes at 24 weeks including quality of life, pain, and patient global impression of severity. 43% of patients reached self-reported absent or minimal disease activity on the PGI-S scale.

Results obtained with placebo patients re-randomized to SLK 120mg or 240mg in Part B, after the primary analysis, replicated the dose responses observed in Part A. Difficult-to-treat subgroup analysis (*e.g.*, in Hurley stage III patients or those previously exposed to biologics) confirms the advantage of the 120mg dose. Similarly, PK analysis support the use of the monthly maintenance 120mg dose. For patients who were inadequate responders to adalimumab at week 12 switching to SLK resulted in HiSCR75 response rates similar to responses in those randomized to SLK at baseline. SLK provided better durability of response compared to that observed with adalimumab in other studies.

The safety profile of SLK was consistent with that observed in previous studies. Overall, SLK continues to show a favorable safety profile, in line with the known profile of IL-17 inhibitors. Based on the efficacy and safety results, Q4W maintenance dosing of SLK 120mg has been confirmed as the optimal dose, in terms of speed and depth of response, and overall benefit-risk profile, for progression into Phase 3 development.

Phase 3 Clinical Trials in HS: The VELA Program

The VELA program is expected to enroll 800 patients across VELA-1 and VELA-2. Both global, randomized, double-blind, placebo-controlled trials are identical in design to evaluate the efficacy and safety of SLK, administered subcutaneously, in adult patients with active moderate-to-severe HS. Similar to the design of the Phase 2 MIRA trial, the primary endpoint is the

percentage of participants achieving HiSCR75. The trials will 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.

From week 16, all patients will receive the 120mg dose of SLK through to 52 weeks, followed by an open-label extension for up to two years (Figure 3). The VELA program will use a protocol design consistent with the Phase 2 MIRA trial, which identified the optimal dose of SLK for HS. The topline primary endpoint readout (week 16) from the VELA program is expected as of mid-2025.

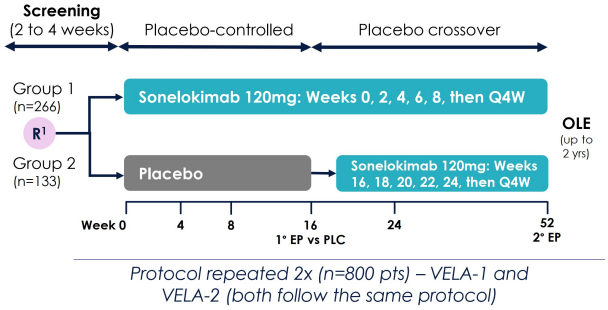


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Figure 3 — Design of the Phase 3 VELA program in HS.

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 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. Topline data for the primary and secondary endpoints, including the higher clinical response level of HiSCR75, are anticipated in 2026.

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 achieved a PASI90 response at week 12 to the 60mg dose (ITT-NRI, p<0.001 versus placebo). For this dose, 58% of patients achieved complete skin clearance (PASI100) at week 12. 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 (Figure 4). 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.

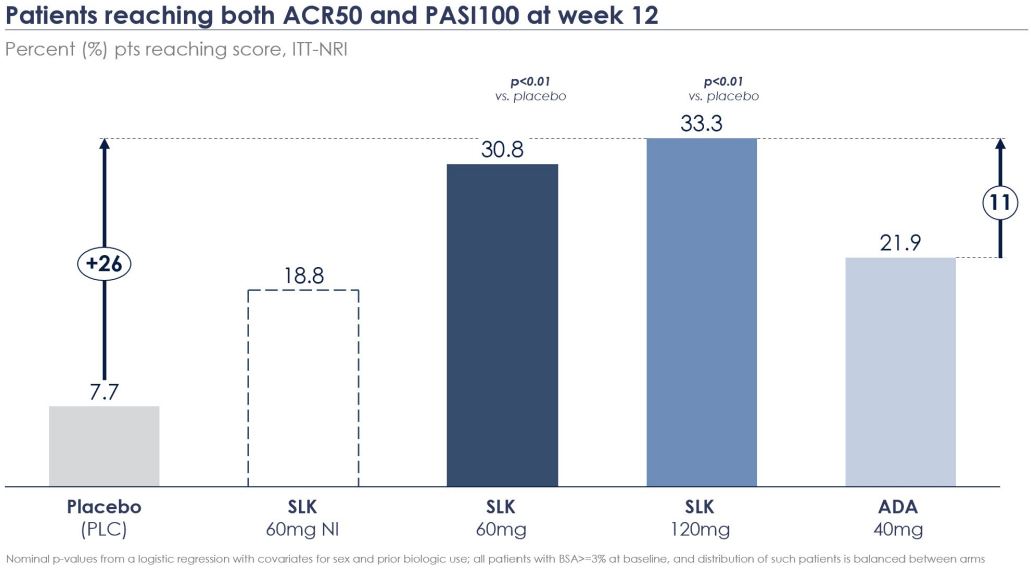


Figure 4 — Patients reaching both ACR50 and PASI100 in the ARGO trial at week 12.

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.

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.

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 to 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. Overall, SLK continues to show a favorable safety profile.

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 is expected to enroll biologic-naïve patients and include an evaluation of radiographic progression, while IZAR-2 is expected to enroll patients with an inadequate response to tumor necrosis factor-α inhibitors (TNF-IR) — reflecting patients commonly seen in clinical practice — and will be the first PsA trial to include 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 and nail outcomes, multidomain outcomes, and patient-reported outcome measures such as pain and quality of life assessments.

The IZAR program will assess 60mg and 120mg doses of SLK (Figure 5). The readout of the primary endpoint for both IZAR-1 and IZAR-2 is anticipated in the first half of 2026.

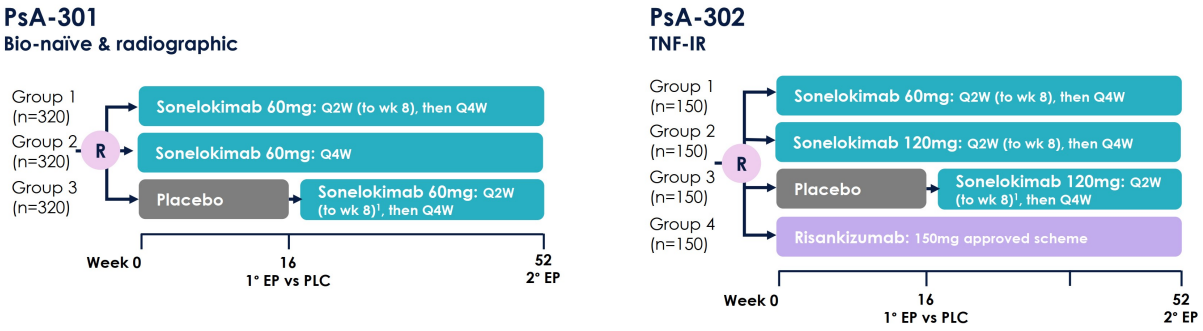


Figure 5 — Design of the Phase 3 IZAR program in PsA.

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 per lesion 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. We expect to start enrollment of patients in the first half of 2025 and the topline primary endpoint readout in the first 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 Palmoplantar Psoriasis Area and Severity Index (ppPASI) with important secondary endpoints including ppPASI75 (at least 75% improvement in the ppPASI). The LEDA trial features an innovative translational research program using peripheral blood and tissue biomarkers as trial controls.

The trial design has been informed by previous successful studies of SLK, including the landmark Phase 2 MIRA trial in HS, which identified the optimal dosing and demonstrated the potential of SLK to target deep tissue inflammation effectively. The topline primary endpoint readout is expected during 2025.

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 (CfB) 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 (e.g., ASAS), scores related to physical function, spinal mobility, and enthesitis as well as patient reported outcomes. The trial also includes an exploratory peripheral blood and tissue biomarker program. The topline primary endpoint readout is expected in early 2026.

Phase 2b Clinical Trial in Psoriasis

In May 2021, data for the Phase 2b trial of SLK in PsO was published. This trial was conducted by Avillion under a 2017 co-development agreement with MHKDG. The randomized, double-blind, placebo-controlled, multi-center trial was designed to assess efficacy, safety and tolerability of SLK in patients with moderate-to-severe chronic plaque-type PsO, over a total period of 52 weeks (inclusive of a 40-week follow-up assessment). In all cases, patients were administered SLK via subcutaneous injection.

The primary objective of the trial was to evaluate the efficacy of four dose regimens of SLK compared to placebo on achievement of an Investigator's Global Assessment ("IGA") score of 0 or 1 after 12 weeks of treatment in patients with moderate to severe chronic plaque-type PsO. The secondary objectives were to evaluate the efficacy of four dose regimens of SLK compared to placebo during a 12-week treatment period on secondary endpoints: PASI 75, PASI 90, PASI 100, change in mean PASI and shift in IGA, to assess the dose-regimen efficacy relationship for SLK after 12, 24, 36, and 48 weeks of treatment, to evaluate the longer-term efficacy of SLK at week 24 and at weeks 36 and 48, and to assess the safety and tolerability of SLK. Other exploratory objectives were also considered.

Primary and secondary end-points, associated with the described objectives were achieved. Doses up to 120 mg showed rapid and significant differences in PASI 100 compared with placebo (Figure 2). In the highest dosage group, nearly six out of ten patients (57%) achieved total skin clearance (PASI 100 response) after 24 weeks. Rapid response was demonstrated with one of three patients already achieving nearly clear skin (PASI 90 response) by week four. Analysis of an individualized dosing scheme including off-drug periods in controlled patients revealed durable responses over one year. SLK was generally well tolerated, with a safety profile similar to the active control, secukinumab, and an overall Candida infection rate of 2.9% from week 0 to week 12 and 6.4% in the period from week 12 to week 52 across all doses.

Ongoing and Planned Clinical Development

Subject to positive results of the LEDA and the S-OLARIS trials, we plan to initiate Phase 3 clinical trials in PPP and axSpA in 2026. 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 ("RHB") based in Bovenau, Germany. Effective July 1, 2021, we entered into a contract manufacturing agreement with RHB 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 Phase 2 clinical trials, the MIRA trial and the ARGO trial. 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. We plan to conduct necessary pharmacokinetic and human factor studies in 2025 to launch SLK with the autoinjector as an approved device for administration of SLK.

Intellectual Property

As of December 31, 2024, 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 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, 2024, our patent portfolio also includes two 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 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 307.1 million ($319.3 million using a December 31, 2024 exchange rate) are potentially payable, of which EUR 7.5 million ($8.0 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"), and the Public Health Service Act (the "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 ("IND") application, 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. 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.

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.

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 shorten.

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 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 disease or condition for which the product was designated. 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 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. In July 2018, the FDA announced an action plan to encourage the development and efficient review of biosimilars, including the establishment of a new office within the agency that will focus on therapeutic biologics and biosimilars. 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 U.S., 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 U.S.

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 activities from AKS prosecution, but they are drawn narrowly and practices that involve remuneration, such as consulting agreements, that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an 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. Instead, 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.

Civil and criminal false claims laws, including the FCA, and civil monetary penalty laws, which can be enforced through civil whistleblower or qui tam actions, prohibit, 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, govern the collection, use, disclosure, and protection of health-related and other personal information 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 ("HITECH"), and their respective implementing regulations imposes 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 the HITECH Act 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, as amended by the California Privacy Rights Act of 2020 ("CCPA"), 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 - unless it is subject to HIPAA - and is included under a new category of personal information, "sensitive personal information," which is offered greater protection. The numerous other comprehensive privacy laws that have passed or are being considered in other states, as well as at the federal and local levels, also exempt some data processed in the context of clinical trials; but 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 U.S. 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 U.S. 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 European Union 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 European Union do not follow price structures of the U.S. 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 legislative 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 response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

Notwithstanding the IRA, continued legislative and enforcement interest exists in the United States with respect to specialty drug pricing practices. Specifically, we expect regulators 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 U.S. 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 collection and use of personal health data and other personal data in the EU is governed by the provisions of the European General Data Protection Regulation (EU) 2016/679 (“GDPR”), which came into force 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, including collecting, analyzing and transferring, personal data of individuals, in particular 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 the 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.

In addition, the GDPR imposes specific restrictions on the transfer of personal data to countries outside of the European Economic Area ("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 SCCs, data exporters 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 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 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 EU to the United Kingdom ("UK"), personal data may freely flow from the EEA to the UK since the UK is deemed to have an adequate data protection level. 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 revenues 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 Clinical Trials Regulation No. 536/2014 ("the Clinical Trials Regulation or 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.

Additionally, following the UK's withdrawal from the EU and the EEA, companies also have to comply with the UK's data protection laws (including the UK GDPR (as defined in section 3(10) (as supplemented by section 205(4)) of the Data Protection Act 2018 (the "DPA 2018")), the DPA 2018, and related data protection laws in the UK). Separate from the fines that can be imposed by the GDPR, the UK regime has the ability to fine up to the greater of £17.5 million or 4% of global turnover. Companies are subject to specific transfer rules under the UK regime which broadly mirror the 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 ("Addendum") and a document setting out transitional provisions. The IDTA and Addendum came into force on March 21, 2022 and replaced the old SCCs for the purposes of the UK regime. Regarding transfers from the UK to the EEA, personal data may flow freely 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, the UK government has adopted an adequacy decision for the United States, 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 transfer is to a U.S. company participating in the EU-US Data Privacy Framework and the UK Extension.

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 former regime, which will expire after a transition period of three years as outlined below in more detail, before a clinical trial can be initiated, it must be approved in each EU member state where there is a site at which the clinical trial is to be conducted. The approval must be obtained from two separate entities: the National Competent Authority (the "NCA") and one or more Ethics Committees. The NCA of the EU Member States in which the clinical trial will be conducted must authorize the conduct of the trial, and the independent Ethics Committee must grant a positive opinion in relation to the conduct of the clinical trial in the relevant EU member state before the commencement of the trial. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be submitted to or approved by the relevant NCA and Ethics Committees. 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 NCA and to the Ethics Committees of the EU Member State where they occur.

A more unified procedure will apply under the new CTR. A sponsor will be able to submit a single application for approval of a clinical trial through a centralized EU clinical trials portal ("the Clinical Trials Information System or 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. The CTR foresees a three-year transition period. EU Member States will work in the CTIS immediately after the system has gone live. 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. By January 31, 2025, all ongoing trials approved under the former Clinical Trials Directive will need to comply with the CTR and have to be transitioned to CTIS. On July 19, 2023, the EC published guidance concerning the steps to be taken in this transition. This guidance provides, among other things, that (i) documentation which was previously assessed will not be reassessed, (ii) templates that were developed and endorsed by the EU Clinical Trials Expert Group to provide compliance with the CTR do not need to be updated and (iii) there is no need to retrospectively create a site suitability form, which are only necessary for new trial sites.

Under both the former regime and the new CTR, national laws, regulations, and the applicable GCP and Good Laboratory Practice 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.

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 (the "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 a MA. To obtain an MA of a drug under European Union 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 obtained by a centralized application through EMA or a national application. National applications are governed by the Human Medicines Regulations (SI 2012/1916). Applications are made electronically through the Medicines and Healthcare products Regulatory Agency ("MHRA") Submissions Portal. The process from application to authorizations generally takes up to 210 days, excluding time taken to provide any additional information or data required by the MHRA.

On August 30, 2023, the MHRA published detailed guidance on its recently announced new International Reliance 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 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, established at the EMA, 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 EU 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. Conversion refers to the procedure by which, as of January 1, 2021, MAs granted on the basis of a centralized procedure in the EU are only valid in Northern Ireland but not in Great Britain, whereas, prior EU authorizations have all been automatically converted into UK MAs effective in Great Britain only.

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 European Union's regulatory authorities to include an 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. The current draft envisages e.g., a shortening of the periods of data exclusivity, however, there is currently neither a final version of this draft nor a date for its entry into force. While the European Parliament adopted its approving position on the reform on April 10, 2024, no further required legislative steps have been taken since.

Orphan Designation and Exclusivity

The criteria for designating an orphan medicinal product in the European Union 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 European Union (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 European Union 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, but a UK-wide orphan MA can only be considered in the absence of an active 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.

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 ("PDCO"). 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 Pediatric Investigation Plans ("PIPs") which, where possible, mirror the submission format and requirements of the EU system. EU PIPs remain applicable for Northern Ireland and EU PIPs agreed by the EMA prior to January 1, 2021 have been adopted as UK PIPs.

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 European Union 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 European Union with the intention to import the active pharmaceutical ingredients into the European Union. 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 European Union 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 European Union or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with GMP.

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 European Union 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 HMRs. 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 European Union. 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 have 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. The MMDA supplements the UK Medical Devices Regulations 2002 (the "Regulations"), which are based on the EU Medical Devices Directive as amended to reflect the United Kingdom's post-Brexit regulatory regime. Notably, the Regulations do not include any of the revisions that have been made by the EU Medical Devices Regulation (EU) 2017/745, which has gained full application in all EU Member States since May 26, 2021 but is not applicable in the UK as "retained law". Additionally, the MHRA launched a comprehensive consultation in 2021 with proposals to amend the regulatory framework for medical devices in the United Kingdom. The stated objectives of the proposals include expansion of the scope of the Regulations (for example, by expanding the in vitro diagnostic medical device definition to include software and other products, including products without an intended medical purpose but with similar functioning and risk profiles) and potentially through use of internationally recognized definitions (for example, by excluding products that contain viable biological substances and excluding food), remove trade barriers, further the availability of medical devices and improve the favorability of the UK market. The consultation period closed on November 25, 2021 and on June 26, 2022, the MHRA published a response to its consultation, which sets out the proposed new UK regulatory framework for medical devices and in vitro diagnostic medical devices. The proposals are intended to improve patient safety and public health through appropriate regulatory oversight, improve the traceability of medical devices, improve the regulation of the rules governing software and AI as medical devices and introduce alternative routes to market to ensure the UK aligns with any superior international best practices. Core aspects of the new framework are expected to apply from July 1, 2025 with appropriate transitional measures and the introduction of secondary legislation.
For other countries outside of the European Union, 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 100 employees as of December 31, 2024. 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 2025 and beyond to expand our expertise and bandwidth across functions. We expect to establish a presence in the United States by early 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 were originally incorporated on August 13, 2020 in the Cayman Islands as a special purpose acquisition company under the name Helix Acquisition Corp., and our subsidiary, MoonLake AG, was incorporated in Switzerland in 2021. In connection with the consummation of the Business Combination (as defined in *Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations*), we changed our name from Helix Acquisition Corp. to MoonLake Immunotherapeutics. 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.

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 payers, 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.

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 preclinical 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 payers;
- 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 on March 10, 2021. Our net losses were $121.2 million for the year ended December 31, 2024. 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 to the end of 2026. 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.

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 October 2023, we announced full 24-week data from the global Phase 2 MIRA clinical trial. In February 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 VELA program. In May 2024, we announced the screening of the first patients in the VELA-1 and VELA-2 trials. 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 January 2025, we announced the screening of the first patients in the VELA-TEEN trial in adolescent HS, in the LEDA trial in PPP and in the S-OLARIS trial in axSpA.

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, nor that they 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.

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 ("MoonLake AG Common Shares"). 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.

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 October 2023, we announced full 24-week data from the global Phase 2 MIRA clinical trial in HS. In May 2024, we announced the screening of the first patients in the Phase 3 VELA-1 and VELA-2 trials in HS. We expect primary endpoint data from the VELA trials as of mid-2025. In March 2024, we announced full 24-week data from the Phase 2 ARGO trial in PsA. We commenced the Phase 3 IZAR program in PsA in November 2024 and expect primary endpoint data in the first half of 2026. In January 2025, we announced that first patients have been screened in the Phase 3 VELA-TEEN trial in adolescent HS, in the Phase 2 LEDA trial in PPP, and in the Phase 2 S-OLARIS trial in axSpA. We expect primary endpoint data from the LEDA trial in 2025, the VELA-TEEN trial in 2026 and the S-OLARIS trial in 2026.

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 particular, in October 2023, we announced full 24-week data from the global Phase 2 MIRA clinical trial in HS and, in March 2024, we announced full 24-week data from the global Phase 2 ARGO trial in PsA. In May 2024, we announced the screening of the first patients in the Phase 3 VELA program in HS and we expect primary endpoint data as of mid-2025. We commenced the Phase 3 IZAR program in PsA in November 2024 and expect primary endpoint data in the first half of 2026. Although data from the Phase 2 MIRA and ARGO clinical trials for SLK in patients established SLK as a highly promising and differentiated therapeutic solution in HS and PsA, respectively, the Phase 3 VELA trials and the Phase 3 IZAR trials of the efficacy of SLK in patients with HS and PsA, respectively, may not yield similar results. If a Phase 3 study is conducted for SLK in patients with PSO, the outcome may be different than those observed in the Phase 2 trial. In addition, we may not observe positive results in our clinical trials for other indications, including adolescent HS, axSpA and PPP. 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), 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 preclinical 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 and other barriers to trade, 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. 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 predicative of success elsewhere.

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. 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.

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.

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 payers 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 payers 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 U.S. 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 standard contractual clauses (“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.

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, Portugal and Belgium. Therefore, Swiss, British, Portuguese and Belgian 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 sophisticated, change frequently, and may originate from less regulated and remote areas of the world. 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 violates 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.

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. 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;
- 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.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. 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, 2024, 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 "MAA") 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 MAA; 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 MAA 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, it 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 36-4 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 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 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 Director 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.

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, and approximately 2,000 square feet of office space under a 2-year initial term agreement set to expire in October 2029, with two extendable periods of 3 years each. 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

We are not currently subject to any material 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.

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, 2025, there were five 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.

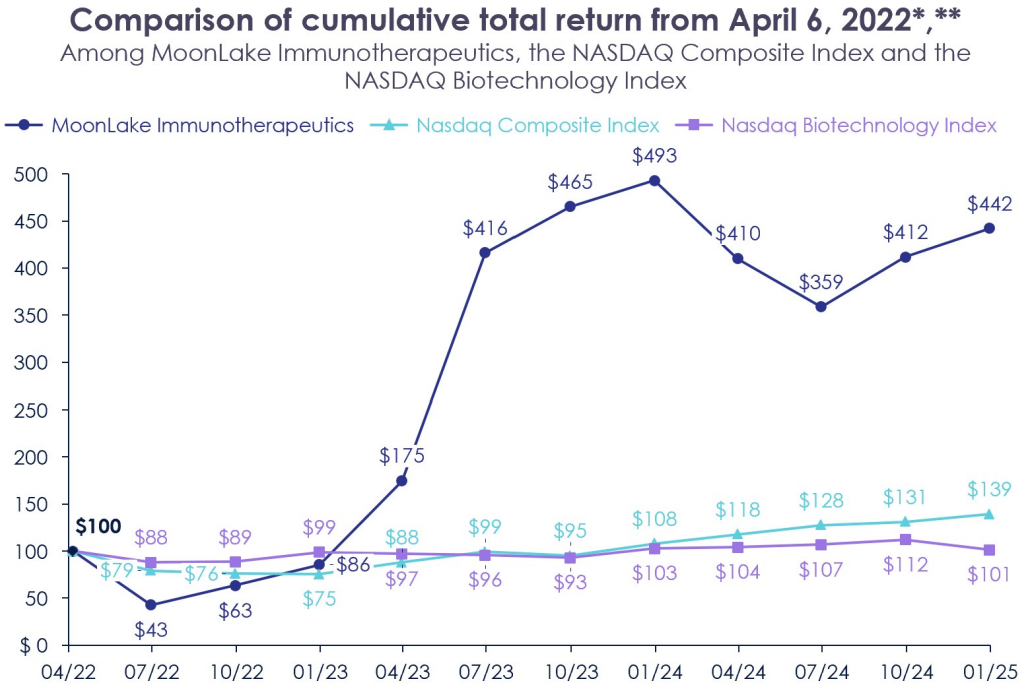
Recent Sales of Unregistered Securities

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 (as defined in *Item 7 - 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.



**April 6, 2022, represents the first day that our shares traded on Nasdaq following our consummation of the Business Combination (as defined in Item 7 – Business Combination)*
*** 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, 2023 compared to December 31, 2022 can be found under Part II - Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2023, which was filed with the Securities and Exchange Commission (SEC) on February 29, 2024, as amended by Amendment No. 1 on Form 10-K/A for the year ended December 31, 2023, which was filed with the SEC on May 7, 2024.

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 ("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 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.

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. 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 VELA-1 trial (M1095-HS-301) and VELA-2 trial (M1095-HS-302). We expect primary endpoint data from the VELA-1 and VELA-2 clinical trials as of mid-2025.

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. 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 March 2024, we announced plans to initiate clinical studies of SLK in additional indications, including a Phase 3 trial in adolescent patients with HS (the VELA-TEEN trial (M1095-HS-304)), a Phase 2 trial in patients with PPP (the LEDA trial (M1095-PPP-201)), a Phase 2 trial in patients with axSpA (the S-OLARIS trial (M1095-axSpA-202)) and another Phase 2 trial applying novel imaging techniques in patients with PsA (the P-OLARIS trial (M1095-snSpA-202)). In January 2025, we announced that first patients have been screened in the VELA-TEEN, the LEDA, and the S-OLARIS clinical trials. We expect patient enrollment for the P-OLARIS trial to commence in the first half of 2025.

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 to the three Phase 2b trials, Phase 1 single ascending and multiple ascending dosing trials were previously completed, bringing the total number of patients in completed SLK-related trials to more than 700.

We expect to submit a first Biologics License Application ("BLA") for SLK in 2026 and, subject to FDA approval, a first commercial launch in the U.S. in 2027.

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 significant expenses and operating losses for at least the next three years as we continue the development of SLK and prepare for commercial launches. It is expected that operating losses will fluctuate significantly from year to year depending on the timing of our planned clinical development programs and efforts to achieve regulatory approval.

As of December 31, 2024, we had $180.4 million of cash and cash equivalents. Based on our current operating plans, we believe that our existing cash, cash equivalents and short-term marketable securities, together amounting to $448.0 million, will be sufficient to fund our operating expenses and capital expenditure requirements until the end of 2026.

Equity Offerings

On April 5, 2022, we completed the Business Combination (as defined below) which raised $134.7 million net of transaction related expenses. In May 2023, June 2023, December 2023, January 2024 and February 2024, we completed equity offerings which raised additional gross proceeds of $15.2 million, $460.0 million, $31.7 million, $39.6 million, and $13.7 million, respectively.

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, 2024, there was $265.0 million remaining for future sales under the August 2023 ATM Sales Agreement.

For the years ended December 31, 2024 and 2023, we sold 914,828 and 1,070,818 Class A Ordinary Shares, respectively, through the Sales Agreements for net proceeds of $52.5 million and $45.8 million, respectively, after deducting sales agent's commissions and transaction costs. For the three months ended December 31, 2024, 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 "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 Offering closed on June 30, 2023, and net proceeds from the Offering, 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 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.

Options Exercised under the Equity Incentive Plan

In the year ended December 31, 2024, certain participants exercised their stock options under the Equity Incentive Plan (as defined below) for an aggregate of 48,796 Class A Ordinary Shares and total cash consideration of $242,004.

Business Combination

On April 5, 2022, we consummated the previously announced business combination pursuant to that certain Business Combination Agreement, dated October 4, 2021 (the "Business Combination Agreement"), by and among 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 (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. The ML Parties received the right to transfer their MoonLake AG Common Shares to the Company in exchange for 33.638698 MoonLake Immunotherapeutics Class A Ordinary Shares (the "Exchange Ratio"). 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. Under this method of accounting, Helix was treated as the "acquired" company for financial reporting purposes. Accordingly, the Business Combination was treated as the equivalent of MoonLake AG issuing shares for the net assets of Helix, accompanied by a recapitalization, whereby no goodwill or other intangible assets was recorded. Operations prior to the Business Combination are those of MoonLake AG.

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 and clinical studies;
- 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 significant 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 significant 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 significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant 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 significant 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 and the ongoing Phase 2 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 U.S. in HS and adolescent HS. We expect to incur significant 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 U.S. We expect to submit the BLA in 2026 after completion of the VELA program, and, subject to FDA approval, we expect a commercial launch in the U.S. in 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. Technology transfers for drug substance and drug product to commercial scale CMOs have already been executed in 2022, 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 also plan to start the stock-piling of drug substance as pre-launch inventory in 2025.
- *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 ("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 ("ESPP").

We also expect to incur additional legal, accounting, investor relations and other expenses associated with operating as a public company and 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 Biologics License Application for SLK. Clinical development involves a lengthy and expensive process with uncertain outcomes and is subject to risks described in Item 1A, including that our preclinical 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 do not have any committed external source of funds. We expect to finance future cash needs through public or private equity or debt offerings 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, including recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures, 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 translation are included in the consolidated statements of operations and comprehensive loss in "other income, net". We recognized a foreign currency transaction loss of $42,186 for the year

ended December 31, 2024, a foreign currency transaction gain of $151,493 for the year ended December 31, 2023, and a foreign currency transaction gain of $325,317 for the year ended December 31, 2022.

Results of Operations

Comparison of the years ended December 31, 2024 and 2023

	Year Ended December 31, 2024	Year Ended December 31, 2023	Change	Change %
Operating expenses				
Research and development	$ (112,771,302)	$ (31,801,880)	$ (80,969,422)	254.6 %
General and administrative	(30,319,780)	(22,321,216)	(7,998,564)	35.8 %
Total operating expenses	**(143,091,082)**	**(54,123,096)**	**(88,967,986)**	**164.4 %**
Operating loss	**(143,091,082)**	**(54,123,096)**	**(88,967,986)**	**164.4 %**
Other income, net	22,128,881	10,138,367	11,990,514	118.3 %
Loss before income tax	**(120,962,201)**	**(43,984,729)**	**(76,977,472)**	**175.0 %**
Income tax expense	(282,199)	(94,388)	(187,811)	199.0 %
Net loss	**(121,244,400)**	**(44,079,117)**	**(77,165,283)**	**175.1 %**
Net unrealized gain on marketable securities and short-term investments	2,686,220	2,330,101	356,119	15.3 %
Actuarial loss on employee benefit plans	(87,278)	(336,579)	249,301	(74.1) %
Other comprehensive income	**2,598,942**	**1,993,522**	**605,420**	**30.4 %**
Comprehensive loss	**$ (118,645,458)**	**$ (42,085,595)**	**$ (76,559,863)**	**181.9 %**

Research and Development

Research and development expenses were $112.8 million for the year ended December 31, 2024, compared to $31.8 million for the year ended December 31, 2023. The increase of $81.0 million primarily related to an increase of $47.7 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 additional increase of $23.7 million related to supply and logistic services for such clinical development trials, including the purchase of a comparator drug for the IZAR-2 trial in PsA, and an increase of $5.4 million in personnel-related costs to support our research and development efforts. In the years ended December 31, 2024 and 2023, research and development expenses were predominantly made up of external costs.

General and Administrative

General and administrative expenses were $30.3 million for the year ended December 31, 2024, compared to $22.3 million for the year ended December 31, 2023. The increase of $8.0 million primarily related to an increase of $3.3 million in personnel-related costs to support organizational growth, an increase of $2.4 million in expenses for advisory and professional services to support organizational growth, an increase of $1.6 million in office expenses driven by the new leases for additional office space, and an increase of $1.2 million in market research expenses.

Other Income, Net

Other income, net was $22.1 million for year ended December 31, 2024, compared to $10.1 million for the year ended December 31, 2023. The increase of $12.0 million primarily related to an increase of $12.3 million in realized interest on cash held in bank and cash investments in short-term marketable debt securities.

Income Tax Expense

Income tax expense was $0.3 million for the year ended December 31, 2024, compared to $0.1 million for the year ended December 31, 2023. The expense is related to corporate income tax of our subsidiaries in the U.K. and Portugal.

Other Comprehensive Income

Other comprehensive income was $2.6 million for the year ended December 31, 2024, compared to $2.0 million for the year ended December 31, 2023. The increase of $0.6 million primarily related to an increase in net unrealized gain in short-term marketable debt securities.

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;
- 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
- continue operating as a public company.

For the year ended December 31, 2024, we incurred a loss of $121.2 million, which includes non-cash items such as share-based compensation expense of $7.3 million, and cash outflow from operations of $116.6 million. As of December 31, 2024, we had a total of $448.0 million in cash, cash equivalents and short-term marketable securities. Based on our current operating plans, we believe our available cash, cash equivalents and short-term marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements until the end of 2026.

We expect to incur significant expenses and operating losses for at least the next three 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 will require substantial additional funding to bring our product candidate to market and support our continuing operations. 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.

Cash Flows

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

	Year Ended December 31, 2024	Year Ended December 31, 2023
Net cash used in operating activities	$ (116,587,263)	$ (42,778,167)
Net cash used in investing activities	(205,595,299)	(25,184,324)
Net cash provided by financing activities	51,311,708	479,701,508
Effect of movements in exchange rates on cash held	127,966	(75,307)
Net (decrease) increase in cash and cash equivalents	**$ (270,742,888)**	**$ 411,663,710**

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 $116.6 million and $42.8 million for the year ended December 31, 2024 and 2023, respectively. The increase of net cash used in operating activities of $73.8 million was primarily driven by the increase in operating loss of $77.2 million and the increase in cash paid for changes in prepaid expenses of $6.5 million. The increases were partially offset by an increase in cash from changes in trade and other payables of $5.6 million and a decrease in cash paid for changes in accrued expenses and other current liabilities of $5.5 million.

Cash Flows from Investing Activities

During the year ended December 31, 2024, net cash used by 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. During the year ended December 31, 2023, net cash used in investing activities was $25.2 million, consisting predominantly of $175.7 million related to the purchase of short-term marketable debt securities, partially offset by $150.8 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, 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. During the year ended December 31, 2023, net cash provided by financing activities was $479.7 million consisting primarily of $482.5 million in the net proceeds from the shares sold under the Sales Agreements and the Offering.

Contractual Obligations and Commitments

The following summarizes our significant contractual obligations and other obligations as of December 31, 2024, which we generally expect to satisfy with cash on hand and the maturity of short-term marketable debt securities:

	Total	Less than 1 year	1 to 5 Years
Purchase obligations[1]	$ 220,873,390	$ 150,955,740	$ 69,917,650
Lease commitments[2]	2,978,429	1,468,313	1,510,116
Total contractual obligations	**$ 223,851,819**	**$ 152,424,053**	**$ 71,427,766**

(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.

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. Our management’s judgement was required to determine whether the IPR&D had any alternative future use. Our management determined that at the time of acquisition, and without significant additional research, there was no alternative future use other than the development of SLK for the treatment of immunological diseases. Therefore, in accordance with our policy, the aggregate consideration for the IPR&D was recorded as research and development expenses during the year ended December 31, 2021.

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 Business Combination, given that there had been no public market for MoonLake AG's common shares, the estimated fair value of MoonLake AG's 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 Class A Ordinary Shares as reported by Nasdaq on the date of grant and multiplied by the Exchange Ratio.

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 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 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 and clinical trial materials.

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 3 — *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 and our results of operations and cash flows.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

As of December 31, 2024, we have cash and cash equivalents and short-term marketable securities of $448.0 million, which consist primarily of bank deposits, commercial papers and certificates of deposits. 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 deposits and commercial papers, 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% increase or decrease in interest rates would not have had a material effect on our financial results or financial condition as of December 31, 2024.

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, 2024, 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 of 1934, as amended, or the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2024, 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, 2024, 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, 2024.

The effectiveness of our internal control over financial reporting as of December 31, 2024 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 of 1934, as amended, or the Exchange Act) during the three months ended December 31, 2024, 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 Plans

On October 29, 2024, Dr. Kristian Reich, the Chief Scientific Officer of the Company, adopted a trading plan intended to satisfy the affirmative defense of Rule 10b5-1(c). Dr. Reich's plan provides for the sale, subject to certain conditions, of up to 126,981 Class A Ordinary Shares through March 6, 2025.

During the three months ended December 31, 2024, 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 2025 Annual General Meeting of Shareholders (the "2025 Proxy Statement"), which we expect to be filed with the SEC within 120 days of the end of our fiscal year ended December 31, 2024, 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 2025 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 2025 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 2025 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 2025 Proxy Statement, including under the heading "Ratification of Independent Auditor Selection".

Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as part of this report:

(a) Financial Statements:

(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	Loan Agreement, dated October 15, 2021, by and among MoonLake Immunotherapeutics AG and the Lenders named therein (incorporated by reference to Exhibit 10.28 of the Company's Form S-1/A, filed with the SEC on March 8, 2022).
10.11	Amendment to the Loan Amendment, dated January 18, 2022, by and among MoonLake Immunotherapeutics AG and the Lenders named therein (incorporated by reference to Exhibit 10.29 of the Company's Form S-1/A, filed with the SEC on March 8, 2022).
10.12	Second Amendment to the Loan Agreement, dated February 15, 2022, by and among MoonLake Immunotherapeutics AG and the Lenders named therein (incorporated by reference to Exhibit 10.30 of the Company's Form S-1/A, filed with the SEC on March 8, 2022).
10.13	Convertible Loan Agreement, dated as of February 20, 2022, by and among Cormorant Private Healthcare Fund IV. L.P., MoonLake Immunotherapeutics AG, Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., Biotechnology Value Trading Fund OS, L.P. and Helix Acquisition Corp. (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K, filed with the SEC on February 25, 2022).
10.14†#	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).
10.15	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).
10.16+	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).
10.17+	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).
10.18+	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).
10.19+	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).
10.20+	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).
10.21+	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).

10.22†+	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).
10.23+	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).
10.24+	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).
10.25+	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).
10.26+	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).
10.27+	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).
10.28+	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).
10.29+	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 26, 2025	Name:	Dr. Jorge Santos da Silva
		Title:	Chief Executive Officer
			(Principal Executive Officer)
			/s/ Matthias Bodenstedt
Date:	February 26, 2025	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 26, 2025
/s/ Matthias Bodenstedt Matthias Bodenstedt	Chief Financial Officer (Principal Financial and Accounting Officer)	February 26, 2025
/s/ Simon Sturge Simon Sturge	Chairperson; Director	February 26, 2025

SIGNATURES

/s/ Spike Loy Spike Loy	Director	February 26, 2025
/s/ Catherine Moukheibir Catherine Moukheibir	Director	February 26, 2025
/s/ Dr. Andrew Phillips Dr. Andrew Phillips	Director	February 26, 2025
/s/ Dr. Ramnik Xavier Dr. Ramnik Xavier	Director	February 26, 2025

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MOONLAKE IMMUNOTHERAPEUTICS

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, 2024 and 2023, 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, 2024, 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, 2024, 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 present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, 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, 2024, 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 Management's Annual Report on Internal Control Over Financial Reporting in Item 9A of this Annual Report on Form 10-K. 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 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 that 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

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrued Research and Development Costs

As discussed in Notes 3 and 9 to the consolidated financial statements, 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 and makes significant judgments and estimates in determining the accrued balances at the end of any reporting period.

We identified the accrual of research and development costs as a critical audit matter. The Company’s estimates are based on a number of factors, including the Company’s knowledge of the status of each of the research and development project milestones, and contract terms together with related executed change orders. Higher degree of auditor judgment was required in evaluating the results of our audit procedures regarding the Company’s estimates, because of the subjectivity and estimation uncertainty in the significant assumptions used in the calculation.

How the Critical Audit Matter was Addressed in Our Audit

Our audit procedures related to management’s estimates used in the accrued research and development costs included the following, among others:

- We obtained an understanding of the Company’s process for estimating the amount of accrued research and development costs incurred by the contract research organizations and contract manufacturing organizations (the “R&D service providers”).
- We evaluated and tested the design and operating effectiveness of the Company's internal controls over completeness of accrued research and development costs.
- We inquired with the Company’s personnel outside of the finance function responsible for overseeing the research and development activities about the progress of the activities completed as of year-end for selected R&D service providers.

- We obtained external confirmations for select R&D service providers as to the completion status for billed and unbilled services and compared responses to management's accrual estimates.
- We tested the completeness and accuracy of the underlying data used in the calculation of estimated research and development costs.
- We compared the Company's estimate of the research and development costs incurred as of year-end to a selection of cash disbursements and third-party invoices received after year-end but prior to the issuance of the Company's consolidated financial statements.

/s/ Baker Tilly US, LLP

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

San Jose, California
February 26, 2025

MOONLAKE IMMUNOTHERAPEUTICS

CONSOLIDATED BALANCE SHEETS

(Amounts in USD, except share data)

	December 31, 2024	December 31, 2023
Current assets		
Cash and cash equivalents	$ 180,426,449	$ 451,169,337
Short-term marketable debt securities	267,600,900	59,838,900
Other receivables	2,843,198	1,056,862
Prepaid expenses - current	23,418,298	2,102,203
Total current assets	**474,288,845**	**514,167,302**
Non-current assets		
Operating lease right-of-use assets	2,922,211	3,628,480
Property and equipment, net	722,226	320,865
Prepaid expenses - non-current	—	8,423,468
Total non-current assets	**3,644,437**	**12,372,813**
Total assets	**$ 477,933,282**	**$ 526,540,115**
Current liabilities		
Trade and other payables	$ 8,992,479	$ 1,837,684
Short-term portion of operating lease liabilities	1,371,962	1,197,876
Accrued expenses and other current liabilities	12,099,420	6,930,120
Total current liabilities	**22,463,861**	**9,965,680**
Non-current liabilities		
Long-term portion of operating lease liabilities	1,457,598	2,499,990
Pension liability	620,684	583,426
Total non-current liabilities	**2,078,282**	**3,083,416**
Total liabilities	**24,542,143**	**13,049,096**
Commitments and contingencies (Note 16)		
Equity		
Class A Ordinary Shares: $0.0001 par value; 500,000,000 shares authorized; 63,077,431 shares issued and outstanding as of December 31, 2024, 60,466,453 shares issued and outstanding as of December 31, 2023	6,308	6,047
Class C Ordinary Shares: $0.0001 par value; 100,000,000 shares authorized; 841,269 shares issued and outstanding as of December 31, 2024, 2,505,476 shares issued and outstanding as of December 31, 2023	84	251
Additional paid-in capital	677,414,830	609,969,236
Accumulated deficit	(235,592,989)	(116,657,472)
Accumulated other comprehensive income	4,996,769	2,357,621
Total shareholders' equity	**446,825,002**	**495,675,683**
Noncontrolling interests	6,566,137	17,815,336
Total equity	**453,391,139**	**513,491,019**
Total liabilities and equity	**$ 477,933,282**	**$ 526,540,115**

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

MOONLAKE IMMUNOTHERAPEUTICS

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Amounts in USD, except share and per share data)

	Year Ended December 31, 2024	Year Ended December 31, 2023	Year Ended December 31, 2022
Operating expenses			
Research and development	$ (112,771,302)	$ (31,801,880)	$ (42,048,954)
General and administrative	(30,319,780)	(22,321,216)	(23,012,463)
Total operating expenses	**(143,091,082)**	**(54,123,096)**	**(65,061,417)**
Operating loss	**(143,091,082)**	**(54,123,096)**	**(65,061,417)**
Other income, net	22,128,881	10,138,367	591,732
Loss before income tax	**(120,962,201)**	**(43,984,729)**	**(64,469,685)**
Income tax expense	(282,199)	(94,388)	(36,366)
Net loss	**$ (121,244,400)**	**$ (44,079,117)**	**$ (64,506,051)**
Of which: net loss attributable to controlling interests shareholders	*(118,935,517)*	*(36,007,260)*	*(49,973,249)*
Of which: net loss attributable to noncontrolling interests shareholders	*(2,308,883)*	*(8,071,857)*	*(14,532,802)*
Net unrealized gain on marketable securities and short-term investments	2,686,220	2,330,101	390,753
Actuarial income (loss) on employee benefit plans	(87,278)	(336,579)	269,893
Other comprehensive income	2,598,942	1,993,522	660,646
Comprehensive loss	**$ (118,645,458)**	**$ (42,085,595)**	**$ (63,845,405)**
Comprehensive loss attributable to controlling interests shareholders	*(116,383,147)*	*(34,511,723)*	*(49,437,461)*
Comprehensive loss attributable to noncontrolling interests	*(2,262,311)*	*(7,573,872)*	*(14,407,944)*
Weighted-average number of Class A Ordinary Shares, basic and diluted	62,870,237	49,122,534	29,361,353
Basic and diluted net loss per share attributable to controlling interests shareholders	**$ (1.89)**	**$ (0.73)**	**$ (1.70)**

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

MOONLAKE IMMUNOTHERAPEUTICS

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

(Amounts in USD, except share data)

	MoonLake AG Series A Preferred Shares		MoonLake AG Common Shares		MoonLake AG Common Shares Held In Treasury		Class A Ordinary Shares		Class C Ordinary Shares		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity (Deficit)	Noncontrolling Interests	Total Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount						
Balance at January 1, 2022, pre effect of Business Combination	**680,196**	**$ 72,466**	**361,528**	**$ 38,537**	**(57,756)**	**$ (6,202)**	**—**	**$ —**	**—**	**$ —**	**$ 42,061,984**	**$ (53,643,615)**	**$ (168,177)**	**$ (11,645,007)**	**$ —**	**$ (11,645,007)**
Retroactive application of the recapitalization due to the Business Combination (Note 2)	22,200,712	—	11,799,803	—	(1,885,081)	—	—	—	—	—	—	—	—	—	—	—
Balance at January 1, 2022, effect of Business Combination	**22,880,908**	**$ 72,466**	**12,161,331**	**$ 38,537**	**(1,942,837)**	**$ (6,202)**	**—**	**$ —**	**—**	**$ —**	**$ 42,061,984**	**$ (53,643,615)**	**$ (168,177)**	**$ (11,645,007)**	**$ —**	**$ (11,645,007)**
Noncontrolling interests recognized on historical net assets of MoonLake AG in connection with the Business Combination	—	(23,939)	—	(12,730)	—	797	—	—	—	—	(14,551,870)	22,966,652	(32,404)	**8,346,506**	**(8,346,506)**	—
Conversion of MoonLake AG shares into Class A Ordinary Shares and issuance of Class C Ordinary Shares following the Business Combination	(22,880,908)	(48,527)	(12,161,331)	(25,807)	765,483	1,614	18,501,284	1,850	15,775,472	1,578	70,870	—	—	**1,578**	—	**1,578**
Issuance of Class A Ordinary Shares upon Business Combination	—	—	—	—	—	—	18,424,355	1,843	—	—	90,782,093	—	—	**90,783,936**	**43,869,268**	**134,653,204**
Conversion of MoonLake Class C Ordinary Shares into Class A Ordinary Shares	—	—	—	—	—	—	2,051,961	205	(2,051,961)	(205)	3,520,306	—	15,739	**3,536,045**	**(3,536,045)**	—
Emission fees and capital tax payments on share issuance	—	—	—	—	—	—	—	—	—	—	(40,078)	—	—	**(40,078)**	**(16,162)**	**(56,240)**
Share-based compensation granted under the ESPP, ESOP, Equity Incentive Plan, and reverse vesting of Restricted Founder Shares	—	—	—	—	1,177,354	3,791	—	—	—	—	7,348,986	—	—	**7,352,777**	**2,305,791**	**9,658,568**
Net loss for the year ended December 31, 2022	—	—	—	—	—	—	—	—	—	—	—	(49,973,249)	—	**(49,973,249)**	**(14,532,802)**	**(64,506,051)**
Other comprehensive income	—	—	—	—	—	—	—	—	—	—	—	—	535,788	**535,788**	**124,858**	**660,646**
Balance at December 31, 2022	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**38,977,600**	**$ 3,898**	**13,723,511**	**$ 1,373**	**$ 129,192,291**	**$ (80,650,212)**	**$ 350,946**	**$ 48,898,296**	**$ 19,868,402**	**$ 68,766,698**

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

MOONLAKE IMMUNOTHERAPEUTICS

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

(Amounts in USD, 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**	**$ 3,898**	**13,723,511**	**$ 1,373**	**$ 129,192,291**	**$ (80,650,212)**	**$ 350,946**	**$ 48,898,296**	**$ 19,868,402**	**$ 68,766,698**
Issuance of Class A Ordinary Shares, net of transaction costs (Note 12)	10,270,818	1,027	—	—	482,453,399	—	—	**482,454,426**	—	**482,454,426**
Capital injection from MoonLake to MoonLake AG (Note 12)	—	—	—	—	(60,061,761)	—	1,135	**(60,060,626)**	**57,310,111**	**(2,750,515)**
Conversion of MoonLake Class C Ordinary Shares into Class A Ordinary Shares	11,218,035	1,122	(11,218,035)	(1,122)	52,479,045	—	510,003	**52,989,048**	**(52,989,048)**	—
Share-based compensation under the ESPP, ESOP, Equity Incentive Plan, and reverse vesting of Restricted Founder Shares	—	—	—	—	5,907,406	—	—	**5,907,406**	**1,198,599**	**7,106,005**
Refund of stamp duty fees	—	—	—	—	(1,144)	—	—	**(1,144)**	**1,144**	—
Net loss for the year ended December 31, 2023	—	—	—	—	—	(36,007,260)	—	**(36,007,260)**	**(8,071,857)**	**(44,079,117)**
Other comprehensive income	—	—	—	—	—	—	1,495,537	**1,495,537**	**497,985**	**1,993,522**
Balance at December 31, 2023	**60,466,453**	**$ 6,047**	**2,505,476**	**$ 251**	**$ 609,969,236**	**$ (116,657,472)**	**$ 2,357,621**	**$ 495,675,683**	**$ 17,815,336**	**$ 513,491,019**

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

MOONLAKE IMMUNOTHERAPEUTICS

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

(Amounts in USD, 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**	**$ 6,047**	**2,505,476**	**$ 251**	**$ 609,969,236**	**$ (116,657,472)**	**$ 2,357,621**	**$ 495,675,683**	**$ 17,815,336**	**$ 513,491,019**
Issuance of Class A Ordinary Shares, net of transaction costs (Note 12)	914,828	91	—	—	52,540,099	—	—	**52,540,190**	—	**52,540,190**
Capital injection from MoonLake to MoonLake AG (Note 12) net of stamp duty fee refund	—	—	—	—	(4,577,281)	—	19	**(4,577,262)**	**3,059,100**	**(1,518,162)**
Conversion of MoonLake Class C Ordinary Shares into Class A Ordinary Shares	1,647,354	165	(1,647,354)	(165)	11,873,058	—	85,855	**11,958,913**	**(11,958,913)**	—
Share-based compensation under the ESPP and Equity Incentive Plan	—	—	—	—	7,254,563	—	—	**7,254,563**	**27,033**	**7,281,596**
Buyback of unvested MoonLake AG Common Shares by MoonLake AG into treasury following an employee contract termination (Note 12)	—	—	—	—	113,154	—	904	**114,058**	**(114,108)**	**(50)**
Cancellation of MoonLake Class C Ordinary Shares following an employee contract termination in MoonLake AG (Note 12)	—	—	(16,853)	(2)	2	—	—	—	—	—
Options exercised under the Equity Incentive Plan (Note 12)	48,796	5	—	—	241,999	—	—	**242,004**	—	**242,004**
Net loss for the year ended December 31, 2024	—	—	—	—	—	(118,935,517)	—	**(118,935,517)**	**(2,308,883)**	**(121,244,400)**
Other comprehensive income	—	—	—	—	—	—	2,552,370	**2,552,370**	**46,572**	**2,598,942**
Balance at December 31, 2024	**63,077,431**	**$ 6,308**	**841,269**	**$ 84**	**$ 677,414,830**	**$ (235,592,989)**	**$ 4,996,769**	**$ 446,825,002**	**$ 6,566,137**	**$ 453,391,139**

MOONLAKE IMMUNOTHERAPEUTICS

CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in USD, except share and per share data)

	Year Ended December 31, 2024	Year Ended December 31, 2023	Year Ended December 31, 2022
Cash flow from operating activities			
Net loss	$ (121,244,400)	$ (44,079,117)	$ (64,506,051)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,384,729	370,316	164,783
Share-based compensation expense	7,281,596	7,106,005	9,654,778
Net periodic pension benefit (gain) cost for the qualified pension plan	1,300	(85,254)	304,031
Other non-cash items	(227,012)	127,604	68,454
Changes in operating assets and liabilities:			
Other receivables	(1,786,336)	(839,733)	(68,355)
Operating lease right-of-use assets	(5,445)	(65,513)	—
Prepaid expenses	(12,892,627)	(6,346,203)	(2,730,373)
Trade and other payables	7,154,795	1,582,712	(1,314,318)
Operating lease liabilities	(1,423,163)	(222,259)	(152,425)
Accrued expenses and other current liabilities	5,169,300	(326,725)	2,685,576
Net cash flow used in operating activities	**(116,587,263)**	**(42,778,167)**	**(55,893,900)**
Cash flow from investing activities			
Purchase of short-term marketable debt securities	(350,278,776)	(175,732,711)	(42,226,021)
Proceeds from maturities of short-term marketable debt securities	145,202,997	150,833,021	9,901,437
Purchase of property and equipment	(519,520)	(284,634)	(16,009)
Net cash flow used in investing activities	**(205,595,299)**	**(25,184,324)**	**(32,340,593)**
Cash flow from financing activities			
Issuance of Class A Ordinary Shares, net of transaction costs	52,540,190	482,454,426	—
Stamp duty on capital injection from MoonLake to MoonLake AG	(1,470,436)	(2,752,918)	—
Proceeds from options exercised under the Equity Incentive Plan	242,004	—	—
Proceeds from Business Combination	—	—	134,646,009
Contribution for par value of Class V Shares	—	—	42,935
Repayment of loan liability	—	—	(15,000,000)
Grants of additional shares under ESPP	—	—	3,791
Buyback of unvested MoonLake AG Common Shares by MoonLake AG following an employee contract termination	(50)	—	—
Net cash flow provided by financing activities	**51,311,708**	**479,701,508**	**119,692,735**
Effect of movements in exchange rates on cash held	127,966	(75,307)	8,540
Net change in cash and cash equivalents	**(270,742,888)**	**411,663,710**	**31,466,782**
Cash and cash equivalents, beginning of period	451,169,337	39,505,627	8,038,845
Cash and cash equivalents, end of period	**$ 180,426,449**	**$ 451,169,337**	**$ 39,505,627**
Supplementary disclosure of cash flow information:			
Cash paid for income taxes, net of refunds received	$ 147,294	$ 41,713	$ 4,312
Non-cash operating lease right-of-use assets obtained in exchange for lease obligations	554,857	3,637,545	435,005

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

Note 1 — Overview of the Company

Corporate Information

MoonLake Immunotherapeutics 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.

Unless the context otherwise requires, "MoonLake" and the "Company" refer to the combined company following the Business Combination (as defined in Note 2 — *Business Combination Agreement with Helix and Recapitalization*), together with its subsidiaries.

Note 2 — Business Combination Agreement with Helix and Recapitalization

On April 5, 2022 (the "Closing Date"), MoonLake Immunotherapeutics, a Cayman Islands exempted company (formerly known as Helix Acquisition Corp.) (prior to the Closing Date, "Helix" and after the Closing Date, "MoonLake" or the "Company") consummated the previously announced business combination (the "Closing") pursuant to that certain Business Combination Agreement dated October 4, 2021 (the "Business Combination Agreement"), by and among Helix, 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"), 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 (the "Sponsor"), and the representative of the ML Parties (such transactions contemplated by the Business Combination Agreement collectively, the "Business Combination"). Net proceeds from the Business Combination totaled $134.7 million, which included funds held in Helix's trust account and the completion of a concurrent PIPE investment.

Pursuant to the Business Combination Agreement, approved by the boards of directors of each of MoonLake AG and Helix, (i) the Company changed its name from Helix Acquisition Corp. to MoonLake Immunotherapeutics, and (ii) MoonLake AG merged with and into MoonLake, with MoonLake AG as the surviving company in the Business Combination and, after giving effect to such Business Combination, MoonLake AG as a subsidiary of MoonLake.

The Business Combination Agreement provided for, among other things, the following transactions:

i. Two business days prior to the Closing Date, the ML Parties and MoonLake AG effectuated a restructuring of MoonLake AG's share capital to, among other things, (x) convert the Series A preferred shares of MoonLake AG, par value of CHF 0.10 per share, into an equal number of MoonLake AG Common Shares such that the ML Parties held a single class of capital share of MoonLake AG immediately prior to the Closing and (y) approve a capital increase for the issuance of 4,006,736 Class V Voting Shares of MoonLake AG, par value CHF 0.01 per share, to Helix, each Class V Voting Share due to its lower par value having ten times the voting power of a MoonLake AG Common Share (the "Restructuring").
ii. At the Closing, 2,875,000 Class B ordinary shares of Helix, par value $0.0001 per share (the "Class B Ordinary Shares"), constituting all of the then-outstanding Class B Ordinary Shares, were automatically converted into Class A Ordinary Shares on a one-for-one basis.
iii. At the Closing, Helix amended and restated its existing memorandum and articles of association to, among other things, establish a share structure consisting of the Class A Ordinary Shares, which carry economic and voting rights, and Class C Ordinary Shares, which carry voting rights but no economic rights.

iv. On the Closing Date, Helix paid all unpaid transaction expenses and contributed $134.7 million to MoonLake AG, including $15.0 million loan repayment pursuant to a convertible loan agreement dated March 20, 2022, by and between MoonLake AG and Cormorant Asset Management LP ("Cormorant"), and assigned by Cormorant to Helix on March 31, 2022.
v. On the Closing Date, following the Restructuring, Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., and Biotechnology Value Trading Fund OS, L.P. (collectively, the "BVF Shareholders") assigned all of their MoonLake AG Common Shares to Helix and Helix issued to the BVF Shareholders 18,501,284 Class A Ordinary Shares.
vi. On the Closing Date, following the Restructuring, Helix issued 15,775,472 Class C Ordinary Shares to the ML Parties (other than the BVF Shareholders). Please refer to Note 12 — *Shareholders' Equity* for additional details on the exchange mechanism adopted.

Additionally, on the Closing Date, Helix issued to the PIPE Investors (as defined below in the section entitled "PIPE Financing") an aggregate of 11,700,000 Class A Ordinary Shares.

As of the open of trading on April 6, 2022, the Class A Ordinary Shares, formerly those of Helix, began trading on The Nasdaq Capital Market ("Nasdaq") under the trading symbol "MLTX".

PIPE Financing

On October 4, 2021, concurrently with the execution of the Business Combination Agreement, and subsequently on March 31, 2022 and April 4, 2022, Helix entered into subscription agreements with certain investors (collectively, the "PIPE Investors", which includes affiliates of the Sponsor and certain existing equityholders of MoonLake AG) pursuant to which, and on the terms and subject to the conditions of which, the PIPE Investors have collectively subscribed for 11,700,000 Class A Ordinary Shares, 11,600,000 shares of which were issued at a price of $10.00 per share for gross proceeds of $116.0 million and 100,000 shares of which were issued to placement agents of the PIPE in satisfaction of an aggregate of $1.0 million of fees owed by Helix to such placement agents.

Summary of Net Proceeds
The following table summarizes the elements of the net proceeds from the Business Combination:

		in thousands
Investments held in Trust Account	$	115,051
Less cash to cover redemptions of the Class A Ordinary Shares issued by Helix prior to the Closing Date		(80,842)
Plus PIPE investment		116,000
Less Helix transaction expense		(15,520)
of which accrued expenses		*(5,798)*
of which deferred IPO underwriting fee		*(4,025)*
of which other transaction expenses		*(5,697)*
Available Closing Date Cash	**$**	**134,689**

Summary of Ordinary Shares Issued
The following table summarizes the number of Ordinary Shares outstanding immediately following the consummation of the Business Combination:

Helix Acquisition Corp. Ordinary Shares prior to the Business Combination	14,805,000
Of which Class A Ordinary Shares (Helix management - IPO private placement shares)	*430,000*
Of which Class A Ordinary Shares redeemable	*11,500,000*
Of which Class B Ordinary Shares (Helix management - sponsor promote)	*2,875,000*

Less redemptions of the Class A Ordinary Shares issued by Helix prior to the Closing Date	(8,080,645)
Plus issuance of Helix Class A Ordinary Shares to PIPE Investors	11,700,000
Plus issuance of Helix Class A Ordinary Shares to BVF Shareholders	18,501,284
Total MoonLake Class A Ordinary Shares Outstanding at Closing	**36,925,639**
Plus issuance of Helix Class C Ordinary Shares to ML Parties (other than the BVF Shareholders)	15,775,472
Total MoonLake Class A and Class C Ordinary Shares Outstanding at Closing	**52,701,111**

Further information about the Business Combination can be found on Form S-1/A filed with the SEC on July 26, 2022, declared effective on August 2, 2022 and to the exhibits included therein, available at www.sec.gov.

Note 3 — 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, MoonLake Immunotherapeutics Ltd., a private limited company incorporated in the United Kingdom, and MNLK Immunotherapeutics, Unipessoal Lda ("MNLK PT"), a private limited company incorporated in Portugal, after elimination of all intercompany accounts and transactions. The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("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").

Pursuant to ASC 805, 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. Accordingly, the Business Combination was treated as the equivalent of MoonLake AG issuing shares for the net assets of Helix, accompanied by a recapitalization. The net assets of Helix were stated at historical costs, with no goodwill or other intangible assets recorded, and are consolidated with MoonLake AG's financial statements on the Closing Date.

In accordance with the Business Combination Agreement, the ML Parties received 33.638698 Ordinary Shares in the Company for every MoonLake AG Common Share or Series A Preferred Share (the "Exchange Ratio"). The BVF Shareholders received 18,501,284 Class A Ordinary Shares whereas the rest of the ML Parties (excluding the BVF Shareholders) received 15,775,472 Class C Ordinary Shares which can be converted into Class A Ordinary Shares at the discretion of the shareholder (refer to Note 12 — *Shareholders' Equity* for further details on the classes of ordinary shares). The number of shares, and the number of shares within the net loss per share held by the ML Parties in MoonLake AG prior to the Business Combination have been adjusted by the Exchange Ratio to reflect the equivalent number of ordinary shares in the Company (identified as "the equivalent of" throughout these consolidated financial statements).

Certain MoonLake AG shareholders (ML Parties other than the BVF Shareholders) did not exchange their shares in MoonLake AG for Class A Ordinary Shares in the Company and therefore continued to hold an economic interest in MoonLake AG and Class C Ordinary Shares in the Company. The Company recognized a noncontrolling interest equal to the ML Parties' (other than the BVF Shareholders) proportionate interest in the net assets of MoonLake AG.

All amounts are presented in U.S. Dollar ("$"), unless otherwise indicated. The term "Swiss franc" 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 whether a transaction should be accounted for as a business combination or an asset acquisition;
- determining whether the in-process research and development expenditure ("IPR&D") has an alternative future use;
- 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.

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. As of December 31, 2024, the Company considers $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, 2023, the Company considered $129.4 million of short-term marketable debt securities in the form of eurocommercial papers and certificates of deposit to be cash equivalents.

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

The Company follows the guidance included in ASC 820, *Fair Value Measurement*. 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.

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.

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, 2024, 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, 2024, 2023, and 2022.

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 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. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company’s estimates. The Company’s historical accrual estimates have not been materially different from the actual costs.

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 judgements 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*) has historically been 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 translation are included in the consolidated statements of operations and comprehensive loss in "other income, net". The Company recognized foreign currency transaction loss of $42,186 for the year ended December 31, 2024, a foreign currency transaction gain of $151,493 for the year ended December 31, 2023, and a foreign currency transaction gain of $325,317 for the year ended December 31, 2022.

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. A technology is considered to have an alternative future use if it is probable that the Company will use the asset in its current, incomplete state as it existed at the acquisition date, in another research and development project that has not yet commenced, and economic benefit is anticipated from that use. If a technology is determined to have an alternative future use, then the fair value of the program would be recorded as an asset on the balance sheet rather than expensed.

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.

Pension

The Company accounts for pension assets and liabilities in accordance with ASC 715, *Compensation – Retirement Benefits*, which requires the recognition of the funded status of pension plans in the Company's consolidated balance sheet. 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 as of December 31, 2024 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.

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, 2024, 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 Azedevo 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 sheet, 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.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, *Segment reporting — Improvements to Reportable Segment Disclosures*, which amends guidance on reportable segment disclosure requirements. It is effective for fiscal years beginning after December 15, 2023. The Company adopted ASU No. 2023-07 during the year ended December 31, 2024. See Note 17 — *Segment Information and Geographic Data* for further detail.

Recently Issued Accounting Pronouncements Not Yet Adopted

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. It is effective for fiscal years beginning after December 15, 2024. The Company is currently evaluating the impact.

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.

Prior Period Reclassifications

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”. The change did not have any impact on the net cash flow used in operating activities.

Note 4 — 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 significant expenses and operating losses for at least the next three years as the Company continues the development of SLK and prepares for commercial launches. It is expected that operating losses will fluctuate significantly from year to year depending on the timing of the Company's planned clinical development programs and efforts to achieve regulatory approval.

The Company incurred a loss of $121.2 million for the year ended December 31, 2024. As of December 31, 2024, the Company's current assets exceeded its current liabilities by $451.8 million.

As of December 31, 2024, the Company had $180.4 million of cash and cash equivalents. Based on the Company's current operating plan, management believes that the Company has sufficient capital to fund its operations and capital expenditures until the end of 2026.

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:

	December 31, 2024		December 31, 2023	
	Level 2	**Total**	**Level 2**	**Total**
Eurocommercial Papers	$ 207,701,100	**$ 207,701,100**	$ 109,608,915	**$ 109,608,915**
Certificates of Deposit	119,582,400	**119,582,400**	79,626,727	**79,626,727**
Total	**$ 327,283,500**	**$ 327,283,500**	**$ 189,235,642**	**$ 189,235,642**

Cash and accounts payable approximate their fair values as of December 31, 2024 and 2023, due to their short-term nature. Pension plan assets fair value is determined based on Level 2 inputs.

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, 2024 and 2023 are as follows:

	December 31, 2024			
	Amortized cost	**Gross unrealized gains**	**Gross unrealized losses**	**Fair value**
Eurocommercial Papers	$ 204,571,819	$ 3,129,280	$ —	$ 207,701,099
Certificates of Deposit	117,304,606	2,277,794	—	119,582,400
Total	**$ 321,876,425**	**$ 5,407,074**	**$ —**	**$ 327,283,499**

Of which classified within cash and cash equivalents	59,310,976	371,623	—	59,682,599
Of which classified within short-term marketable debt securities	262,565,449	5,035,451	—	267,600,900

	December 31, 2023			
	Amortized cost	**Gross unrealized gains**	**Gross unrealized losses**	**Fair value**
Eurocommercial Papers	$ 107,624,341	$ 1,984,574	$ —	$ 109,608,915
Certificates of Deposit	78,890,447	736,280	—	79,626,727
Total	**$ 186,514,788**	**$ 2,720,854**	**$ —**	**$ 189,235,642**
Of which classified within cash and cash equivalents	128,197,581	1,199,161	—	129,396,742
Of which classified within short-term marketable debt securities	58,317,207	1,521,693	—	59,838,900

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 as of December 31, 2024 and 2023:

Beginning balance, January 1, 2024	**$ 2,720,854**
Other comprehensive income before reclassifications	16,433,112
Amounts reclassified from accumulated other comprehensive income	(13,746,892)
Ending balance, December 31, 2024	**$ 5,407,074**

Beginning balance, January 1, 2023	**$ 390,753**
Other comprehensive income before reclassifications	8,751,307
Amounts reclassified from accumulated other comprehensive income	(6,421,206)
Ending balance, December 31, 2023	**$ 2,720,854**

As of December 31, 2024, the Company's marketable debt securities maturities are all due within one year.

Note 7 — Prepaid Expenses

Prepaid expenses - current		**December 31, 2024**		**December 31, 2023**
Non-clinical research and clinical development services	$	14,136,396	$	842,729
Supply and manufacturing services		7,715,621		1,205
Insurance		1,112,758		1,077,478
Other prepayments		453,523		180,791
Total	**$**	**23,418,298**	**$**	**2,102,203**

Prepaid expenses - non-current		**December 31, 2024**		**December 31, 2023**
Supply and manufacturing services	$	—	$	8,423,468
Total	**$**	**—**	**$**	**8,423,468**

Supply and manufacturing services, current and non-current, primarily relate to advance payments made to a contract manufacturing organization pursuant to a manufacturing run reservation agreement for the commercial-scale manufacturing of SLK in 2025.

Note 8 — Trade and Other Payables

		December 31, 2024		**December 31, 2023**
Research and development services	$	5,081,306	$	911,454
Supply and manufacturing fees payable		3,597,102		553,459
Legal advisory services		92,591		47,095
Other payables		221,480		325,676
Total	**$**	**8,992,479**	**$**	**1,837,684**

Note 9 — Accrued Expenses and Other Current Liabilities

		December 31, 2024		**December 31, 2023**
Supply and manufacturing services	$	4,474,060	$	1,603,739
Bonuses and related employees compensation expenses		4,237,029		2,780,219
Research and development services and license fees		2,022,011		1,226,281
Tax liabilities		642,114		367,976
Consultant and other fees		585,786		853,905
Legal fees		138,420		98,000
Total	**$**	**12,099,420**	**$**	**6,930,120**

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. The Company estimated the effective duration of the lease at inception and determined a period of 3 years,

with expected expiration in November 2024. 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 Azedevo 860, 4150-335, Porto, Portugal. This lease has a 3-year initial term, with two extendable periods of 3 years each. It is expected to be extended once until 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 Azevodo 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 it 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, 2024 and 2023 were as follows:

	December 31, 2024	December 31, 2023
Weighted average remaining lease term (in months)	29	39
Weighted average discount rate	4.7 %	4.9 %

The future minimum annual lease payments under these operating leases as of December 31, 2024 are as follows:

Year ending December 31,		Amount
2025	$	1,468,313
2026		1,160,459
2027		130,395
2028		130,395
2029		88,867
Thereafter		—
Total lease payments		2,978,429
Less imputed interest		(148,869)
Total lease liability		2,829,560
Less current portion of lease liability		(1,371,962)
Long-term portion operating lease liability	**$**	**1,457,598**

Operating cash outflows for amounts included in the measurement of lease liabilities was $1,474,865, $422,250 and $150,650 for the years ended December 31, 2024, 2023 and 2022, respectively.

The Company recorded the following lease and variable lease expenses:

	Year Ended December 31, 2024	Year Ended December 31, 2023	Year ended December 31, 2022
Operating lease expense	$ 1,424,265	$ 399,882	$ 155,552
Variable lease expense[1]	16,021	—	—
Total lease expense	**$ 1,440,286**	**$ 399,882**	**$ 155,552**

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, 2024, 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:

	Year Ended December 31, 2024	Year Ended December 31, 2023	Year ended December 31, 2022
Beginning PBO	$ 2,494,481	$ 1,321,969	$ 1,322,874
Service cost	280,627	122,698	451,075
Interest cost	33,097	30,639	5,056
Contributions by plan participants	259,937	200,424	138,243
Actuarial (gain) / losses	41,260	487,991	(374,317)
Benefits paid	10,917	229,902	(204,695)
Foreign currency exchange rates changes	(199,065)	208,608	(16,267)
Plan amendment	—	(107,750)	—
Ending PBO	**$ 2,921,254**	**$ 2,494,481**	**$ 1,321,969**

	Year Ended December 31, 2024	Year Ended December 31, 2023	Year ended December 31, 2022
Beginning fair value of plan assets	$ 1,911,056	$ 1,039,763	$ 1,083,014
Expected return on plan assets	60,530	36,523	15,522
Return on plan assets above / (below) expected return	(47,492)	48,938	(115,877)
Contributions by the employer	259,937	200,424	138,243
Contributions by plan participants	259,937	200,424	138,243
Benefits paid	10,917	229,902	(204,695)
Foreign currency exchange rates changes	(154,315)	155,082	(14,687)
Ending fair value of plan assets	**$ 2,300,570**	**$ 1,911,056**	**$ 1,039,763**

[1] *Variable lease expense resulting from increased lease payments linked to changes in the reference index.*

Amounts recorded on the consolidated balance sheets:

	December 31, 2024	December 31, 2023
Fair value of plan assets	$ 2,300,570	$ 1,911,056
Present value of projected benefit obligation	(2,921,254)	(2,494,481)
Funded status	**$ (620,684)**	**$ (583,425)**

Amounts recorded in accumulated other comprehensive income:

	Year Ended December 31, 2024	Year Ended December 31, 2023	Year ended December 31, 2022
Actuarial (gain) / loss beginning of year	$ 234,863	$ (101,716)	$ 168,177
Actuarial (gain) / loss of current year	87,384	444,329	(268,076)
Amortization	(10,284)	—	(1,817)
Prior service (cost) / credit recognized in current year	10,178	(107,750)	—
Total	**$ 322,141**	**$ 234,863**	**$ (101,716)**

The assumptions used to calculate the ASC 715 liabilities are summarized in the table below:

	December 31, 2024	December 31, 2023
Discount rate	1.00% p.a.	1.35% p.a.
Expected return on plan assets	2.70% p.a.	3.00% p.a.
Inflation	1.00% p.a.	1.80% p.a.
Long-term expected rate of salary increase	1.50% p.a.	2.30% p.a.

Service cost of $280,627, $122,698, and $451,075 was recognized in the net periodic benefit cost for the years ended December 31, 2024, 2023, and 2022, respectively.

The allocation of plan assets is presented below:

	December 31, 2024	December 31, 2023
Equities	34.00 %	34.00 %
Bonds	32.00 %	32.00 %
Mortgages	4.00 %	4.00 %
Liquidity	1.00 %	1.00 %
Real estate	26.00%	26.00%
Alternative investments	3.00%	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 2025, the Company presently anticipates contributing an estimated amount of $259,937 to fund the Plan.

Note 12 — Shareholders' Equity

	MoonLake AG Series A Preferred Shares[1]		MoonLake AG Common Shares[1]		MoonLake AG Common Shares Held In Treasury[2]	Class A Ordinary Shares[3]		Class C Ordinary Shares[3]		Total Number of Shares	
	Authorized	Issued	Authorized	Issued	Issued	Authorized	Issued	Authorized	Issued	Authorized	Issued and Outstanding
Balance at January 1, 2022	**22,880,908**	**22,880,908**	**13,119,092**	**12,161,331**	**(1,942,837)**	**—**	**—**	**—**	**—**	**36,000,000**	**33,099,402**
Share-based payment under the ESPP	—	—	—	—	1,177,354	—	—	—	—	—	1,177,354
Issuance of Class A Ordinary Shares upon Business Combination	—	—	—	—	—	500,000,000	18,424,355	100,000,000	—	600,000,000	18,424,355
Conversion of MoonLake AG shares into Class A Ordinary Shares and Class C Ordinary Shares following the Business Combination	(22,880,908)	(22,880,908)	(13,119,092)	(12,161,331)	765,483	—	18,501,284	—	15,775,472	(36,000,000)	—
Conversion of Class C Ordinary Shares into Class A Ordinary Shares	—	—	—	—	—	—	2,051,961	—	(2,051,961)	—	—
Balance at December 31, 2022	—	—	—	—	—	**500,000,000**	**38,977,600**	**100,000,000**	**13,723,511**	**600,000,000**	**52,701,111**
Issuance of Class A Ordinary Shares	—	—	—	—	—	—	10,270,818	—	—	—	10,270,818
Conversion of Class C Ordinary Shares into Class A Ordinary Shares	—	—	—	—	—	—	11,218,035	—	(11,218,035)	—	—
Balance at December 31, 2023	—	—	—	—	—	**500,000,000**	**60,466,453**	**100,000,000**	**2,505,476**	**600,000,000**	**62,971,929**
Conversion of Class C Ordinary Shares into Class A Ordinary Shares	—	—	—	—	—	—	1,647,354	—	(1,647,354)	—	—
Issuance of Class A Ordinary Shares under the ATM facility	—	—	—	—	—	—	914,828	—	—	—	914,828
Cancellation of Class C shares following an employee contract termination in MoonLake AG	—	—	—	—	—	—	—	—	(16,853)	—	(16,853)
Options exercised under the Equity Incentive Plan	—	—	—	—	—	—	48,796	—	—	—	48,796
Balance at December 31, 2024	—	—	—	—	—	**500,000,000**	**63,077,431**	**100,000,000**	**841,269**	**600,000,000**	**63,918,700**

(1) *Fully paid-in registered shares in MoonLake AG with a par value of CHF 0.10, share amounts after applying the exchange ratio*
(2) *Registered shares in MoonLake AG with a par value of CHF 0.10 held in treasury, share amounts after applying the exchange ratio*
(3) *Fully paid-in registered shares with a par value of $0.0001*

Class A Ordinary Shares

On April 6, 2022, the Company's Class A Ordinary Shares began trading on The Nasdaq Capital Market ("Nasdaq") under the symbol “MLTX”. As of December 31, 2024, there were 63,077,431 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, 2024, there were 841,269 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 each ML Party 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) imposes certain transfer and other restrictions on the ML Parties, (ii) provides for the waiver of certain statutory rights and (iii) establishes certain mechanics whereby MoonLake and each of the ML Parties are able to effect the conversion of MoonLake AG Common Shares and Class C Ordinary Shares into a number of Class A Ordinary Shares equal to the Exchange Ratio of 33.638698. During the year ended December 31, 2022, pursuant to the A&R Shareholders’ Agreement, 61,000 MoonLake AG Common Shares and 2,051,961 Class C Ordinary Shares were converted into 2,051,961 Class A Ordinary Shares. 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. 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, 2024, there was $265.0 million remaining for future sales under the August 2023 ATM Sales Agreement.

For the years ended December 31, 2024 and 2023, the Company sold 914,828 and 1,070,818 Class A Ordinary Shares, respectively, through the Sales Agreements for net proceeds of $52.5 million and $45.8 million, respectively, after deducting sales agent's commissions and transaction costs. For the three months ended December 31, 2024, there were no sales under the August 2023 Sales Agreement.

Public Offering of Class A Ordinary Shares
On June 27, 2023, the Company entered into an underwriting agreement with SVB Securities LLC 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 "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 Offering closed on June 30, 2023, and net proceeds from the Offering, 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 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.

Options Exercised under the Equity Incentive Plan

In the year ended December 31, 2024, certain participants exercised their stock options under the Equity Incentive Plan (as defined below) for an aggregate of 48,796 Class A Ordinary Shares and total cash consideration of $242,004.

There were no options exercised in the years ended December 31, 2023 and 2022.

Note 13 — Net Loss per Share

As a result of the Business Combination, the Company has retroactively restated the weighted average number of outstanding shares prior to April 5, 2022 to give effect to the Exchange Ratio.

The following table sets forth the net loss per share calculations for the years ended December 31, 2024, 2023, and 2022:

	Year Ended December 31, 2024	Year Ended December 31, 2023	Year Ended December 31, 2022
Numerator			
Net loss attributable to controlling interests shareholders	$ (118,935,517)	$ (36,007,260)	$ (49,973,249)
Denominator			
Total weighted average number of outstanding shares	62,870,237	49,122,534	29,361,353
Net loss per share – basic and diluted	**$ (1.89)**	**$ (0.73)**	**$ (1.70)**

There were 972,476, 312,400, and 180,000 common stock equivalents outstanding in the form of stock options under the Equity Incentive Plan as of December 31, 2024, 2023, and 2022, 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.

If the ML Parties elected to convert all of their MoonLake AG Common Shares and associated Class C Ordinary Shares into Class A Ordinary Shares as of January 1, 2024, the weighted average number of shares outstanding would have been 63,835,002 for the year ended December 31, 2024, resulting in a net loss per share – basic and diluted of $1.90. Upon conversion, all 841,269 Class C Ordinary Shares would be forfeited and there would no longer be any non-controlling interests.

Note 14 — Share-Based Compensation

As of December 31, 2024, 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 Immunotherapeutics.

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 main plans which remain active as of December 31, 2024 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, 2024, 2023, and 2022, the Company has recognized an increase in equity in the consolidated balance sheets and share-based compensation expense in the consolidated statements of operations and comprehensive loss of $7.3 million, $7.1 million, and $9.7 million, respectively. The share-based compensation expense was driven by the aforementioned two main active share-based compensation plans and programs:

Compensation Plan	**Year Ended December 31, 2024**	**Year Ended December 31, 2023**	**Year Ended December 31, 2022**
MoonLake AG Restricted Founder Shares	$ —	$ 1,574,300	$ 4,840,608
ESPP	2,932,711	3,352,885	3,910,076
ESOP	—	973,868	539,713
MoonLake Immunotherapeutics 2022 Equity Incentive Plan	4,348,885	1,204,952	364,381
Total share-based compensation expense	**$ 7,281,596**	**$ 7,106,005**	**$ 9,654,778**
Of which: included in research and development expense	*1,971,003*	*1,524,715*	*954,379*
Of which: included in general and administrative expense	*5,310,593*	*5,581,290*	*8,700,399*

We expect that all future employee awards will be made under the Equity Incentive Plan. As of December 31, 2024, 3,234,283 Class A Ordinary Shares from the authorized pool of 4,353,948 Class A Ordinary Shares remain available for future grants, and 972,476 and 98,393 Class A Ordinary Shares are reserved for issuance upon exercise of stock options granted under the Equity Incentive Plan and ESOP, respectively. The latter relate to awards not yet subjected to the conversion described above.

MoonLake AG - Restricted Founder Shares

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 (ESPP) 2021-2025 - 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.

Weighted average assumptions for the awards issued during the year ended December 31, 2022	
Estimated fair value per share of Common Shares on the grant date ($) [(1)]	336.39
Purchase price (CHF)	0.10

[(1)] MoonLake AG estimated the fair value of the Common Shares by dividing the Company Enterprise Value ($360,000,000) as defined by the Business Combination Agreement by the Company's fully diluted shares (1,070,196).

ESPP	**Number of Shares**	**Weighted-Average Grant Date Fair Value**
Awards unvested as of January 1, 2024	**630,490**	**$ 10.00**
Awards forfeited for the twelve months ended December 31, 2024	(16,853)	10.00
Awards vested for the twelve months ended December 31, 2024	(293,868)	10.00
Awards unvested as of December 31, 2024	**319,769**	**$ 10.00**

As of December 31, 2024, MoonLake AG had $3.1 million of total unrecognized compensation expense related to the ESPP that will be recognized over the weighted average period of 1.05 years.

Employee Stock Option Plan (ESOP) 2021-2025 - MoonLake AG

The ESOP grants will vest 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 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.

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, 2024	**585,078**	**$ 10.04**	**$ 29,456**	**8.41**
Awards converted from ESOP to Equity Incentive Plan for the year ended December 31, 2024	(486,685)	11.77		
Awards outstanding as of December 31, 2024	**98,393**	**$ 1.50**	**$ 5,180**	**6.73**
Awards exercisable as of December 31, 2024	**98,393**	**$ 1.50**	**$ 5,180**	**6.73**

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.

Weighted average assumptions for the awards issued during the year ended December 31, 2022[4]	
Estimated fair value of the option on the grant date using Black-Scholes model ($)	4.21
Exercise price ($)	3.64
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]	3%
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.

EIP	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, 2024	**312,400**	**$ 22.83**	**$ 11,733**	**8.87**
Awards granted for the year ended December 31, 2024	293,799	46.36		
Awards converted from ESOP to Equity Incentive Plan for the year ended December 31, 2024	486,685	11.77		
Awards exercised for the year ended December 31, 2024	(48,796)	4.96	2,263	
Awards forfeited for the year ended December 31, 2024	(71,612)	27.68		
Awards outstanding as of December 31, 2024	**972,476**	**$ 24.94**	**$ 28,588**	**8.18**
Awards exercisable as of December 31, 2024	**385,654**	**$ 13.39**	**$ 18,172**	**7.52**

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 $2.3 million for the year ended December 31, 2024. No options were exercised for the years ended December 31, 2023 and 2022.

Weighted average assumptions for the awards issued during the year ended December 31, 2024[4]	
Estimated fair value of the option on the grant date using Black-Scholes model ($)	31.82
Exercise price ($)	46.36
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]	4.3%
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.

Weighted average assumptions for the awards issued during the year ended December 31, 2023	
Estimated fair value of the option on the grant date using Black-Scholes model ($)	25.58
Exercise price ($)	37.22
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.

Weighted average assumptions for the awards issued during the year ended December 31, 2022	
Estimated fair value of the option on the grant date using Black-Scholes model ($)	8.25
Exercise price ($)	12.25
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]	3%
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.

As of December 31, 2024, the Company had $11.1 million of total unrecognized compensation expense related to the Equity Incentive Plan that will be recognized over the weighted average period of 1.82 years.

Note 15 — Income Taxes

The Company's effective tax rate ("ETR") was -0.2%, -0.3%, and 0.1% for the years ended December 31, 2024, 2023, and 2022, 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 non-deductible expense which includes the Swiss entity's recognition of taxable

income associated with the sale of treasury shares from MoonLake AG to MoonLake Immunotherapeutics. 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, 2024, 2023, and 2022, 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:

	Year Ended December 31, 2024	Year Ended December 31, 2023	Year Ended December 31, 2022
Switzerland	$ (120,417,158)	$ (43,469,946)	$ (62,115,251)
Foreign	(545,043)	(514,783)	(2,354,434)
Total	**$ (120,962,201)**	**$ (43,984,729)**	**$ (64,469,685)**

The provision for income taxes differs from the amount computed by applying the statutory income tax rate to loss before income taxes as follows:

	Year Ended December 31, 2024	Year Ended December 31, 2023	Year Ended December 31, 2022
Statutory income tax rate	11.8%	11.8%	11.9%
Effect of income taxed at different rates	(0.3)%	(0.4)%	— %
Change in prior year estimates	— %	(0.5)%	0.1 %
Utilization of unrecognized losses	— %	0.6 %	— %
Change in valuation allowance	(11.3)%	0.5 %	(10.0)%
Non-deductible expense	(0.5)%	(12.3)%	(1.4)%
Other	— %	— %	(0.5)%
Effective income tax rate	**(0.2)%**	**(0.3)%**	**0.1%**

Significant components of the Company’s deferred tax assets (liabilities) were:

	December 31, 2024	December 31, 2023
Intangible assets	$ 4,491,147	$ 4,493,559
Defined benefit plan	73,551	69,173
Lease liabilities	63,809	56,527
Net operating loss carry forward	20,372,989	6,715,534
Total deferred tax assets	**25,001,496**	**11,334,793**
Operating lease right-of-use assets	(69,639)	(55,862)
Total deferred tax liabilities	**(69,639)**	**(55,862)**
Total deferred tax assets (net)	**24,931,857**	**11,278,931**
Valuation allowance	(24,931,857)	(11,278,931)
Total deferred tax (net)	**$ —**	**$ —**

As of December 31, 2024, the Company’s net deferred tax assets before valuation allowance were $24.9 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. A valuation allowance of $24.9 million has been recorded against the deferred tax assets.

As of December 31, 2024, MoonLake AG had net operating losses of approximately $171.9 million of which $12.6 million will expire in 2028, $44.0 million will expire in 2029 and $115.3 million will expire in 2031.

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.

Note 16 — Commitments and Contingencies

Commitments

The Company has entered into agreements as of December 31, 2024 primarily in regards to the clinical and non-clinical development services with contract research organizations ("CROs"), as well as supply and logistics services with contract manufacturing organizations ("CMOs"), for the advancement of SLK. As of December 31, 2024, the total committed expense under these agreements amounted to $220.9 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 ($311.5 million using a December 31, 2024 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, 2024, 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, 2024, 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 3 — *Basis of Presentation and Significant Accounting Policies* section. The measure of segment assets is reported on the consolidated balance sheet as total assets. The measure of segment profit or loss is reported on the consolidated statement of operations 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 as "Research and development" and "General and administrative" for the years ended December 31, 2024, 2023, and 2022.

Non-cash share-based compensation is reported in Note 14 — *Share-Based Compensation* for the years ended December 31, 2024, 2023, and 2022. Non-cash depreciation and amortization for the years ended December 31, 2024, 2023, and 2022 was $1.4 million, $0.4 million, and $0.2 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, 2024 and 2023 are as follows:

Country		**December 31, 2024**		**December 31, 2023**
Switzerland	$	610,743	$	507,392
United Kingdom		1,776,843		2,704,555
Portugal		1,256,851		737,398
Total	**$**	**3,644,437**	**$**	**3,949,345**

Note 18 — Subsequent Events

Share Conversion

In January 2025, pursuant to the A&R Shareholders' Agreement, 3,328 MoonLake AG Common Shares and 111,949 Class C Ordinary Shares were converted into 111,949 Class A Ordinary Shares and 2,775 MoonLake AG Common Shares were converted to 93,347 Class A Ordinary Shares. Please refer to Note 12 — *Shareholders' Equity — Class C Ordinary Shares* for more information regarding the conversion mechanics.

Exhibit 4.1

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following is a brief description of the material provisions of the share capital of MoonLake Immunotherapeutics ("we," "us," "our" and the "Company"). As of December 31, 2024, our Class A ordinary share is the only class of our securities registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The following description of our share capital does not purport to be complete and is subject to and qualified in its entirety by our Memorandum and Articles of Association (the "MAA"), which is filed as an exhibit to the Annual Report on Form 10-K, of which this exhibit is a part, and the applicable provisions of the Companies Act of the Cayman Islands, as amended (the "Companies Act"). We encourage you to read the MAA and the applicable provisions of the Companies Act for more information.

Authorized and Outstanding Shares

The MAA authorizes the issuance of up to 655,000,000 ordinary shares, consisting of:

a. 500,000,000 Class A Ordinary Shares, par value US$0.0001 per share ("Class A Ordinary Shares");
b. 50,000,000 Class B Ordinary Shares, par value US$0.0001 per share ("Class B Ordinary Shares");
c. 100,000,000 Class C Ordinary Shares, par value US$0.0001 per share ("Class C Ordinary Shares"); and
d. 5,000,000 preference shares, par value US$0.0001 per share ("preference shares").

Class Rights

In the event of a winding up or dissolution of the Company, whether voluntary or involuntary or for the purposes of a reorganization or otherwise or upon any repayment or distribution of capital, the entitlement of the holders of Class C Ordinary Shares is determined in accordance with the MAA. Class C Ordinary Shares confer no other right to participate in the profits or assets of the Company (including, for the avoidance of doubt, any right to receive a dividend or other distribution).

Class A Ordinary Shares carry the right to receive notice of and to attend, to speak at and to vote at any general meeting of the Company, rights in a winding up or repayment or distribution of capital and the right to participate in the profits or assets of the Company, in each case, in accordance with the MAA.

Except as otherwise provided by the rights attached to any ordinary shares in the MAA, rights attaching to the Class A Ordinary Shares and the Class C Ordinary Shares rank pari passu in all respects, and the Class A Ordinary Shares and Class C Ordinary Shares vote together as a single class on all matters.

The MAA authorizes 5,000,000 preference shares and provides that preference shares may be issued from time to time in one or more series. Our board of directors (the "Board") is authorized to fix the voting rights, if any, designations, powers, preferences, the relative, participating, optional or other special rights and any qualifications, limitations and restrictions thereof, applicable to the shares of each series.

The Board is able to, without shareholder approval, issue preference shares with voting and other rights that could adversely affect the voting power and other rights of the holders of the ordinary shares and could have anti-takeover effects. The ability of the Board to issue preference shares without shareholder approval could have the effect of delaying, deferring or preventing a change of control of us or the removal of existing management. We have no preference shares issued and outstanding at the date hereof. Although we do not currently intend to issue any preference shares, we cannot assure you that we will not do so in the future.

There are no Class B Ordinary Shares issued or outstanding.

Register of Members

As required under Cayman Islands law, we keep a register of members that states:

- the names and addresses of the members, a statement of the shares held by each member and the amount paid or agreed to be considered as paid on the shares of each member and the voting rights of the shares of each member;
- whether voting rights are attached to the share in issue;
- the date on which the name of any person was entered on the register as a member; and

- the date on which any person ceased to be a member.

Under Cayman Islands law, the register of members of our Company is prima facie evidence of the matters set out therein (i.e., the register of members raises a presumption of fact on the matters referred to above unless rebutted) and a member registered in the register of members is deemed as a matter of Cayman Islands law to have legal title to the shares as set against its name in the register of members. However, there are certain limited circumstances where an application may be made to a Cayman Islands court for a determination on whether the register of members reflects the correct legal position. Further, the Cayman Islands court has the power to order that the register of members maintained by a company should be rectified where it considers that the register of members does not reflect the correct legal position. If an application for an order for rectification of the register of members were made in respect of our ordinary shares, then the validity of such shares may be subject to re-examination by a Cayman Islands court.

Certain Differences in Corporate Law

Cayman Islands companies are governed by the Companies Act. The Companies Act is modeled on English Law but does not follow recent English Law statutory enactments, and differs from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of the material differences between the provisions of the Companies Act applicable to us and the laws applicable to companies incorporated in the United States and their shareholders.

Mergers and Similar Arrangements. In certain circumstances, the Companies Act permits mergers or consolidations between two Cayman Islands companies, or between a Cayman Islands exempted company and a company incorporated in another jurisdiction (provided that is permitted or not prohibited by the constitutional documents of the company incorporated in another jurisdiction and facilitated by the laws of that other jurisdiction).

Where the merger or consolidation is between two Cayman Islands companies, the directors of each company must approve a written plan of merger or consolidation containing certain prescribed information. That plan of merger or consolidation must then be authorized by (a) a special resolution (usually a majority of shareholders holding at least two-thirds of the voting shares voted at a general meeting) of the shareholders of each company; and (b) such other authorization, if any, as may be specified in such constituent company's articles of association. No shareholder resolution is required for a merger between a parent company (i.e., a company that holds issued shares that together represent 90% of the votes at a general meeting of the subsidiary company) and its subsidiary company, if a copy of the plan of merger is given to every member of each subsidiary company to be merged, unless that member agrees otherwise. The consent of each holder of a fixed or floating security interest of a constituent company must be obtained, unless the Cayman Islands court waives such requirement or makes such order as the Cayman Islands court otherwise considers reasonable. The directors of each company are required to provide a declaration of the assets and liabilities of the company made up to the latest practicable date before the making of the declaration, and are further required to make a declaration to the effect that: (i) the company is able to pay its debts as they fall due and that the merger or consolidation is bona fide and not intended to defraud unsecured creditors of the company; (ii) no petition or other similar proceeding has been filed and remains outstanding and that no order has been made or resolution adopted to wind up the company in any jurisdiction; (iii) no receiver, trustee, administrator or other similar person has been appointed in any jurisdiction and is acting in respect of the company, its affairs or its property or any part thereof; (iv) no scheme, order, compromise or other similar arrangement has been entered into or made in any jurisdiction whereby the rights of creditors of the company are and continue to be suspended or restricted; (v) in the case of a constituent company that is not a surviving company, the constituent company has retired from any fiduciary office held or will do so immediately prior to the merger or consolidation; and (vi) where relevant, the company has complied with any applicable requirements under Cayman Islands regulatory laws. If the Cayman Islands Registrar of Companies is satisfied that the requirements of the Companies Act (which includes certain other formalities) have been complied with, the Registrar of Companies will register the plan of merger or consolidation.

Where the merger or consolidation involves a foreign company and the surviving company is the Cayman Islands exempted company, the procedure is similar, save that where the surviving or consolidated company is the Cayman Islands exempted company, the Cayman Islands Registrar of Companies is required to be satisfied in respect of any constituent overseas company that: (i) the merger or consolidation is permitted or not prohibited by the constitutional documents of the foreign company and by the laws of the jurisdiction in which the foreign company is incorporated, and that those laws and any requirements of those constitutional documents have been or will be complied with; (ii) no petition or other similar proceeding has been filed and remains outstanding or order made or resolution adopted to wind up or liquidate the foreign company in the jurisdiction in which the foreign company is

existing; (iii) no receiver, trustee, administrator or other similar person has been appointed in any jurisdiction and is acting in respect of the foreign company, its affairs or its property or any part thereof; (iv) no scheme, order, compromise or other similar arrangement has been entered into or made in any jurisdiction whereby the rights of creditors of the foreign company are and continue to be suspended or restricted; (v) the foreign company is able to pay its debts as they fall due and that the merger or consolidation is bona fide and not intended to defraud unsecured creditors of the foreign company; (vi) in respect of the transfer of any security interest granted by the foreign company to the surviving or consolidated company (a) consent or approval to the transfer has been obtained, released or waived; (b) the transfer is permitted by and has been approved in accordance with the constitutional documents of the foreign company; and (c) the laws of the jurisdiction of the foreign company with respect to the transfer have been or will be complied with; (vii) the foreign company will, upon the merger or consolidation becoming effective, cease to be incorporated, registered or exist under the laws of the relevant foreign jurisdiction; and (viii) there is no other reason why it would be against the public interest to permit the merger or consolidation. The requirements set out in sections (i) to (vii) above shall be met by a director of the Cayman Islands exempted company making a declaration to the effect that, having made due enquiry, they are of the opinion that such requirements have been met, such declaration to include a statement of the assets and liabilities of the foreign company made up to the latest practicable date before making the declaration.

Where the above procedures are adopted, the Companies Act provides for a right of dissenting shareholders to be paid a payment of the fair value of their shares upon their dissenting to the merger or consolidation if they follow a prescribed procedure. In essence, that procedure is as follows: (a) the shareholder must give their written objection to the merger or consolidation to the constituent company before the vote on the merger or consolidation, including a statement that the shareholder proposes to demand payment for their shares if the merger or consolidation is authorized by the vote; (b) within 20 days following the date on which the merger or consolidation is approved by the shareholders, the constituent company must give written notice to each shareholder who made a written objection; (c) a shareholder must within 20 days following receipt of such notice from the constituent company, give the constituent company a written notice of their intention to dissent including, among other details, a demand for payment of the fair value of their shares; (d) within seven days following the date of the expiration of the period set out in paragraph (c) above or within seven days following the date on which the plan of merger or consolidation is filed, whichever is later, the constituent company, the surviving company or the consolidated company must make a written offer to each dissenting shareholder to purchase their shares at a price that the company determines is the fair value and if the company and the shareholder agree to the price within 30 days following the date on which the offer was made, the company must pay the shareholder such amount; and (e) if the company and the shareholder fail to agree to a price within such 30 day period, within 20 days following the date on which such 30 day period expires, the company shall (and any dissenting shareholder may) file a petition with the Cayman Islands Grand Court to determine the fair value and such petition must be accompanied by a list of the names and addresses of the dissenting shareholders with whom agreements as to the fair value of their shares have not been reached by the company. At the hearing of that petition, the Cayman Islands court has the power to determine the fair value of the shares together with a fair rate of interest, if any, to be paid by the company upon the amount determined to be the fair value. Any dissenting shareholder whose name appears on the list filed by the company may participate fully in all proceedings until the determination of fair value is reached. These rights of a dissenting shareholder are not available in certain circumstances, for example, to dissenters holding shares of any class in respect of which an open market exists on a recognized stock exchange or recognized interdealer quotation system at the relevant date or where the consideration for such shares to be contributed are shares of any company listed on a national securities exchange or shares of the surviving or consolidated company.

Moreover, Cayman Islands law has separate statutory provisions that facilitate the reconstruction or amalgamation of companies in certain circumstances, which will generally be more suited for complex mergers or other transactions involving widely held companies, commonly referred to in the Cayman Islands as a “scheme of arrangement” which may be tantamount to a merger. In the event that a merger was sought pursuant to a scheme of arrangement (the procedures for which are more rigorous and take longer to complete than the procedures typically required to consummate a merger in the United States), the arrangement in question must be approved by (i) in respect a scheme of arrangement proposed between a company and its shareholders (or any class of shareholder), 75% in value of the shareholders (or each class of shareholder) who attend and vote, either in person or by proxy, at a meeting (or meetings) convened for that purpose; or (ii) a scheme of arrangement proposed between a company and its creditors (or any class of creditors), a majority in number representing 75% in value of the creditors (or each class of creditors) who attend and vote, either in person or by proxy, at a meeting (or meetings) convened for that purpose. The convening of the meetings and subsequently the terms of the arrangement must be sanctioned by the Grand Court of the Cayman Islands. While a dissenting shareholder would have the right to express to the Cayman

Islands court the view that the scheme of arrangement should not be sanctioned, the Cayman Islands court may be expected to sanction the scheme of arrangement if it satisfies itself that:

- the company is not proposing to act illegally or beyond the scope of its corporate authority and the statutory provisions as to dual majority vote have been complied with;
- the shareholders have been fairly represented at the meeting in question;
- the arrangement is such as a businessman would reasonably approve; and
- the arrangement is not one that would more properly be sanctioned under some other provision of the Companies Act or that would amount to a "fraud on the minority."

If a scheme of arrangement is sanctioned by the Cayman Islands court, the scheme of arrangement will be binding on all of the shareholders (or each class of shareholder) or creditors (or each class of creditor).

If a scheme of arrangement or takeover offer (as described below) is sanctioned by the Cayman Islands court, any dissenting shareholder would have no rights comparable to appraisal rights (providing rights to receive payment in cash for the judicially determined value of the shares), which would otherwise ordinarily be available to dissenting shareholders of United States corporations.

Squeeze-out Provisions. When a takeover offer is made and accepted by holders of 90% of the shares to whom the offer relates within four months, the offeror may, within a two-month period following the expiration of the initial four month period, require the holders of the remaining shares to transfer such shares on the terms of the offer. An objection can be made to the Grand Court of the Cayman Islands, but this is unlikely to succeed unless there is evidence of fraud, bad faith, collusion or inequitable treatment of the shareholders.

No Appraisal Rights. Our shareholders have no rights comparable to appraisal rights, which might otherwise ordinarily be available to dissenting shareholders of United States corporations and allow such dissenting shareholders to receive payment in cash for the judicially determined value of the shares. However, appraisal rights would also not be available to shareholders of a Delaware target in a business combination transaction if the shares of the target were listed on a national securities exchange and target shareholders receive only shares of a corporation which shares are also listed on a national securities exchange.

Further, transactions similar to a merger, reconstruction and/or an amalgamation may in some circumstances be achieved through means other than these statutory provisions, such as a share capital exchange, asset acquisition or control, or through contractual arrangements of an operating business.

Shareholders' Suits. Walkers (Cayman) LLP, our Cayman Islands counsel, is not aware of any reported class action having been brought in a Cayman Islands court. Derivative actions have been brought in the Cayman Islands courts, and the Cayman Islands courts have confirmed the availability for such actions. In most cases, we will be the proper plaintiff in any claim based on a breach of duty owed to us, and a claim against (for example) our officers or directors usually may not be brought by a shareholder. However, based both on Cayman Islands authorities and on English authorities, which would in all likelihood be of persuasive authority and be applied by a court in the Cayman Islands, exceptions to the foregoing principle apply in circumstances in which:

- a company is acting, or proposing to act, illegally or beyond the scope of its authority;
- the act complained of, although not beyond the scope of the authority, could be effected if duly authorized by more than the number of votes which have actually been obtained; or
- those who control the company are perpetrating a "fraud on the minority."

A shareholder may have a direct right of action against us where the individual rights of that shareholder have been infringed or are about to be infringed.

Enforcement of Civil Liabilities. The Cayman Islands has a different body of securities laws as compared to the United States and provides less protection to investors. Additionally, Cayman Islands companies may not have standing to sue before the Federal courts of the United States.

We have been advised by Walkers (Cayman) LLP, our Cayman Islands legal counsel, that the courts of the Cayman Islands are unlikely (i) to recognize or enforce against us judgments of courts of the United States predicated upon the civil liability provisions of the federal securities laws of the United States or any state in the United States; and (ii) in original actions brought in the Cayman Islands, to impose liabilities against us predicated upon the civil liability provisions of the federal securities laws of the United States or any state in the United States, so far as the

liabilities imposed by those provisions are penal in nature. In those circumstances, although there is no statutory enforcement in the Cayman Islands of judgments obtained in the United States, the courts of the Cayman Islands will recognize and enforce a foreign money judgment of a foreign court of competent jurisdiction without retrial on the merits based on the principle that a judgment of a competent foreign court imposes upon the judgment debtor an obligation to pay the sum for which judgment has been given provided certain conditions are met. For a foreign judgment to be enforced in the Cayman Islands, such judgment must be final and conclusive and for a liquidated sum, and must not be in respect of taxes or a fine or penalty, inconsistent with a Cayman Islands judgment in respect of the same matter, impeachable on the grounds of fraud or obtained in a manner, and or be of a kind the enforcement of which is, contrary to natural justice or the public policy of the Cayman Islands (awards of punitive or multiple damages may well be held to be contrary to public policy). A Cayman Islands Court may stay enforcement proceedings if concurrent proceedings are being brought elsewhere.

Special Considerations for Exempted Companies. The Company is an exempted company with limited liability under the Companies Act. The Companies Act distinguishes between ordinary resident companies and exempted companies. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. "Limited liability" means that the liability of each shareholder is limited to the amount unpaid by the shareholder on the shares of the company (except in exceptional circumstances, such as involving fraud, the establishment of an agency relationship or an illegal or improper purpose or other circumstances in which a court may be prepared to pierce or lift the corporate veil).

Certain Anti-takeover Provisions of the MAA

The MAA provides that the Board be classified into three classes of directors, each to be elected for a three year term.

Our authorized but unissued ordinary shares and preference shares are available for future issuances without shareholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved ordinary shares and preference shares could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Transfer Agent

The Transfer Agent and Registrar for the Class A Ordinary Shares and Class C Ordinary Shares is Continental Stock Transfer & Trust Company.

Certain personally identifiable information contained in this document, marked by brackets as [***], has been omitted from this exhibit pursuant to Item 601(a)(6) under Regulation S-K.

INSIDER TRADING POLICY

(dated August 30, 2023)

I. INTRODUCTION

MoonLake Immunotherapeutics (the "**Company**" or "**MoonLake**") is listed on the Nasdaq Stock Market (the "Nasdaq"), and is subject to its rules, as well as the rules and regulations of the U.S. Securities and Exchange Commission (the "**SEC**"). U.S. federal and state laws prohibit buying, selling or making other transfers of securities by persons who have material information that is not generally known or available to the public ("**Material Nonpublic Information**"). These laws also prohibit persons with such Material Nonpublic Information from disclosing this information to others who trade.

The Company has adopted the following policy (this "**Policy**") regarding trading in securities by all of its directors, officers, employees, consultants and contractors (collectively, "**Company Personnel**") as well as their family members who reside with them, anyone else who lives in their household, and any family members who do not live in their household but whose transactions in Company securities (as defined below) are directed by them or are subject to their influence or control (collectively, "**Family Members**"), and corporations or other business entities controlled, influenced or managed by them or their Family Members, and trusts for which such persons are a trustee or in which they have a beneficial or pecuniary interest (collectively, "**Controlled Entities**", and together with Company Personnel and Family Members, "**Insiders**"). Unless otherwise indicated, all references to "you" in this Policy should be read to include all of your Family Members and Controlled Entities.

The principles discussed in this Policy also apply to non-public information that you obtain in the course of your employment or other involvement with the Company about another public company with which the Company has a preexisting or prospective relationship, such as the Company's customers, suppliers, or a company with which the Company is involved in a transaction, such as a joint venture, licensing transaction, contract research arrangement or other collaboration, or material acquisition or disposition (a "**Company Counterparty**" or "**Company Counterparties**"). If you obtain Material Nonpublic Information about a Company

Counterparty, then you must not trade in the securities of that Company Counterparty until the information has been publicly disseminated or is no longer material.

No Exceptions. The prohibition against trading while in possession of Material Nonpublic Information is absolute and unconditional. The securities laws do not recognize any mitigating circumstances, and in any event, even the appearance of an improper transaction must be avoided to preserve the Company's reputation for adhering to high standards of conduct . There is no exception for small transactions or transactions that may seem necessary or justifiable, such as the need to raise money for an emergency expenditure.

Individual Responsibility. You are responsible for ensuring that you (as well as your Family Members and Controlled Entities) do not violate U.S. federal or state securities laws or this Policy. The Company has designed this Policy to promote compliance with the federal securities laws and to protect the Company and you from the serious liabilities and penalties that can result from violations of these laws.

If you violate the insider trading laws, you may be subject to criminal charges, which may carry severe penalties, including imprisonment for up to 20 years. You may also have to pay civil fines for up to three times the profit gained or loss avoided by such trading, as well as criminal fines of up to $5 million. In addition, the Company may face civil penalties up to the greater of $1 million, or three times the profit gained or loss avoided as a result of your insider trading violations, as well as criminal fines of up to $25 million.

Both the SEC and Nasdaq are very effective at detecting and pursuing insider trading cases. The SEC has successfully prosecuted cases against employees trading through foreign accounts, trading by family members and friends, and trading involving only a small number of shares. Therefore, it is important that you understand the breadth of activities that constitute illegal insider trading. This Policy sets out the Company's policy in the area of insider trading and should be read carefully and complied with fully.

This Policy applies to transactions, whether direct or indirect, in MoonLake's securities, including its common stock, options to purchase common stock, restricted stock or restricted stock units, or any other type of securities that MoonLake may issue, including but not limited to preferred stock and convertible debentures, as well as derivative securities relating to MoonLake but that are not issued by MoonLake, such as exchange-traded put or call options or swaps relating to MoonLake's securities (collectively referred to as "**Company securities**"). Similarly, this Policy applies to all securities issued by a Company Counterparty, as well as any related derivative securities, such as puts, calls or swaps.

All Company Personnel will be required to certify their understandings of and intent to comply with this Policy by signing the Receipt and Acknowledgment attached hereto periodically.

The Company will review, evaluate and revise this Policy from time to time in light of regulatory changes, developments in the Company's business and other factors.

II. TRADING POLICIES AND PROCEDURES

A. No Trading on Material Nonpublic Information; No "Tipping" Others

1. *General prohibition.* You cannot, directly or indirectly, engage in transactions in Company securities when you have Material Nonpublic Information about MoonLake. For guidance on what is "material" or "nonpublic," see Section II.B.1 below.

   This prohibition against illegal "insider trading" also applies to transactions in the securities of Company Counterparties when you learn the Material Nonpublic Information about such entities as a result of your employment or other association with MoonLake.

2. *No tipping.* You must also not convey Material Nonpublic Information about the Company or a Company Counterparty to anyone else, including family members. You also must not recommend that anyone purchase or sell any company's securities while you are aware of Material Nonpublic Information about that company. These practices, known as "**tipping**", also violate the U.S. securities laws and can result in the same civil and criminal penalties that apply if you engage in insider trading directly, even if you do not receive any money or derive any benefit from trades made by persons to whom you passed Material Nonpublic Information. This Policy against "tipping" applies to information about the Company and its securities, as well as to information about Company Counterparties. Persons with whom you have a history, pattern or practice of sharing confidences—such as family members, close friends and financial and personal counselors—may be presumed to act on the basis of information known to the Insider; therefore, special care should be taken so that Material Nonpublic Information is not disclosed to such persons. This Policy does not restrict legitimate business communications on a "need to know" basis. Material Nonpublic Information, however, should not be disclosed to persons outside the Company unless you are specifically authorized to disclose such information and such disclosure is made in accordance with the Company's policies regarding the protection or authorized external disclosure of information regarding the Company.

3. *No short-term or speculative trading.* It is against Company policy for you to engage in short-term or speculative transactions in Company securities. As such, you may not engage in: (a) short-term trading (generally defined as selling Company securities within six months following a purchase); (b) short sales (selling Company securities you do not own); (c) transactions involving publicly traded options or other derivatives, such as trading in puts or calls with respect to Company securities; and (d) other hedging transactions (such as "cashless" collars, forward sales, equity swaps and other similar arrangements). Additionally, because securities held in a margin account or pledged as collateral may be sold without your consent, if you fail to meet a margin call or if you default on a loan,

a margin or foreclosure sale may result in unlawful insider trading. Because of this danger, you should exercise caution when including Company securities in a margin account or pledging Company securities as collateral for a loan, and the Company's directors and Section 16 Officers (as defined below) are prohibited from doing so.

As stated above, these restrictions also apply to your Family Members and Controlled Entities. The SEC and federal prosecutors may presume that trading by Family Members and Controlled Entities is based on information you supplied and may treat any such transactions as if you had traded yourself.

For purposes of this Policy, references to "trading" and "transactions" include, among other things:

- purchases and sales of Company securities in public markets;
- sales of Company securities obtained through the exercise of employee stock options granted by the Company;
- making gifts of Company securities; and
- using Company securities to secure a loan.

Transactions in mutual funds that are invested in Company securities are not transactions subject to this Policy as long as (a) the Insider does not control the investment decisions on individual stocks within the fund and (b) Company securities do not represent a substantial portion of the assets of the fund.

In addition, transactions pursuant to a Rule 10b5-1 Trading Plan (as defined below) are subject to certain exceptions and requirements set forth below.

Insiders should consult the Chief Financial Officer (the "**CFO**") if they have any questions. At any time when the Company does not have an active CFO, the duties and responsibilities under this Policy shall be fulfilled by the principal financial officer.

4. *Company transactions.* From time to time, the Company may engage in transactions in its own securities. It is the Company's policy to comply with all applicable securities and state laws (including appropriate approvals by the Board of Directors or appropriate committee, if required) when engaging in transactions in Company securities.

B. What is "Material Nonpublic Information"? When is Information "Public"?

1. *Material Information*

Material information generally means information that a reasonable investor would consider important in making an investment decision to buy, hold, or sell securities. Either positive or negative information may be material. Any information that could reasonably be expected to affect the Company's stock price should be considered material.

- Depending on the circumstances, common examples of information that may be material include:
- significant new product developments, innovations or discoveries;
- pending U.S. Food and Drug Administration, European Medicines Agency or other regulatory action;
- clinical data or significant interactions, approval or rulings by a regulatory agency relating to the Company or a Company product;
- status of pre-clinical or clinical studies;
- earnings, revenue, or similar financial information;
- unexpected financial results;
- unpublished financial reports or projections;
- extraordinary borrowing or liquidity problems;
- changes in control or sale of all or part of the Company's business;
- changes in directors, senior management or auditors;
- information about current, proposed, or contemplated transactions, business plans, financial restructurings, acquisition targets or significant expansions or contractions of operations;
- changes in dividend policies or the declaration of a stock split or the proposed or contemplated issuance, redemption, or repurchase of securities;
- negotiations regarding an important license, distribution agreement, joint venture or collaboration agreement;
- material defaults under agreements or actions by creditors, clients, or suppliers relating to a company's credit rating;
- information about major contracts;

- significant cybersecurity incidents, events or risks that affect the Company or third-party providers that support the Company's business operations, including computer system or network compromises, viruses or other destructive software, and data breach incidents that may disclose personal, business or other confidential information;
- product recalls;
- impending financial problems;
- the interruption of production or other aspects of a company's business as a result of an accident, fire, natural disaster, or breakdown of labor negotiations;
- major environmental incidents;
- institution of, or developments in, major litigation, investigations, or regulatory actions or proceedings;
- any of the information described above to the extent applicable to Company affiliates or a Company Counterparty; and
- the imposition of a trading "blackout" on transactions in Company securities or the securities of a Company Counterparty.

Federal and Nasdaq investigators will scrutinize a questionable trade after the fact with the benefit of hindsight, so you should always err on the side of deciding that the information is material and not trade. The mere fact that a person is aware of Material Nonpublic Information is a bar to trading. It is no excuse that such person's reasons for trading were not based on the Material Nonpublic Information. If you have questions regarding specific transactions, please contact the CFO.

2. *Non-public Information*

Nonpublic information is information that is not generally known by or available to the public. We consider information to be available to the public only when:

- it has been released to the public by the Company through appropriate channels, such as by means of a press release distributed through a widely circulated news or wire service, such as Dow Jones or Bloomberg, or a filing with the SEC; and
- two full trading days have lapsed following the time of public disclosure.

The fact that rumors, speculation, or statements attributed to unidentified sources are public is insufficient to be considered "generally available to the public" even when the information is accurate.

C. Unauthorized Disclosure; Prohibition on Certain Public Speaking

All Company Personnel must maintain the confidentiality of Company information for competitive, security and other business reasons, as well as to comply with securities laws. All information you learn about the Company or its business plans is potentially nonpublic information until it is publicly disclosed by the Company. You should treat this information as confidential and proprietary to the Company. You may not disclose it to others, such as family members, other relatives, or business or social acquaintances.

In addition, you are prohibited from participating as an "expert", consultant, advisor, and/or in any capacity for an "expert network" and/or any other outside firm which compensates individuals for speaking with investors and other investment professionals. This prohibition is designed to protect the Company, its shareholders, and you.

Indeed, U.S. criminal authorities and the SEC have prosecuted numerous public company employees who received monetary compensation by expert networks to speak with investors and disclose confidential company information which investors then used for trading purposes.

Also, legal rules govern the timing and nature of our disclosure of material information to outsiders or the public. Violation of these rules could result in substantial liability for you, the Company and its management. For this reason, we permit only specifically designated representatives of the Company to discuss the Company with the news media, securities analysts and investors and only in accordance with the Company's "Guidelines For Public Disclosures and Communications With The Investment Community". If you receive inquiries of this nature, refer them to the CFO.

D. When and How to Trade Company Stock

1. *Overview*

   Directors, officers, as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended (the "**Exchange Act**") (such officers, "**Section 16 Officers**", and together with directors, "**Section 16 Persons**"), employees (including officers other than Section 16 Officers) and consultants (such employees and consultants, together with Section 16 Persons, and each of their respective Family Members and Controlled Entities, "**Restricted Persons**") are for purposes of this Policy required to comply with the restrictions covered below, except for any employee or consultant specifically exempted from compliance therewith by the CFO in writing (which exemption may be revoked by the CFO at any time).

2. *Blackout Periods*

   From time to time due to certain developments relating to Material Nonpublic Information (such as a significant event or transaction) about the Company or a Company

Counterparty, the Company may implement special blackout periods during which the Company may notify particular individuals that they should not engage in any transactions involving the purchase, sale, gift or other transaction in Company securities or the securities of a Company Counterparty. If you are subject to a special blackout period, you should not trade in the applicable company's securities during such time and you should not disclose to others the fact that you are prohibited from trading. These blackout periods, which may vary in length, will be determined by the CFO, and will be communicated to the appropriate personnel via e-mail. Termination of a blackout period will also be communicated to the appropriate personnel via e-mail.

However, it is not the Company's policy to impose special blackout periods every time that Material Nonpublic Information exists, or every time that an Insider may be in the possession of Material Nonpublic Information. Thus, the absence of a special blackout period should not be interpreted as permission to trade. In addition, if you are subject to the Company's pre-clearance policy (described below), you must pre-clear transactions even if you initiate them while a special blackout period is not in place.

Even if a special blackout period is in place, you may exercise Company stock options if no shares are to be sold – you may not, however, effect sales of stock issued upon the exercise of stock options (including same-day sales and cashless exercises). Generally, all pending purchase and sale orders regarding Company securities that could be executed while a special blackout period is not in place must be cancelled before a special blackout period is implemented so as to avoid any purchases and sales during such period.

In light of these restrictions, if you expect a need to sell Company stock at a specific time in the future, you may wish to consider entering into a prearranged Rule 10b5-1 Trading Plan, as discussed below.

3. *Pre-clearance*

The Company requires all Restricted Persons to contact the CFO in advance of effecting any purchase, sale, gift or other trading of Company securities, other than transactions made under an approved Rule 10b5-1 Trading Plan or non-Rule 10b5-1 trading arrangement pursuant to Section II.E below. All requests must be submitted to the CFO at least two business days in advance of the proposed transaction. For the avoidance of doubt, there should be no presumption that the CFO will grant any or all pre-clearance requests and there shall be no obligation to inform Restricted Persons of the reasons for any request approval or denial. **This pre-clearance policy applies to Restricted Persons even if they are initiating a transaction while a blackout period is not in place.**

If a transaction is approved under the pre-clearance policy, the transaction must be executed by the end of the second full trading day after the approval is obtained, but regardless may not be executed if you acquire Material Nonpublic Information concerning the Company during that time. If a transaction is not completed within the

period described above, the transaction must be approved again by the CFO before it may be executed.

If a proposed transaction is not approved under the pre-clearance policy, you may not transact in Company securities, and you should not inform anyone within or outside of the Company of the restriction. Any transaction under a Rule 10b5-1 Trading Plan or non-Rule 10b5-1 trading arrangement (discussed below) will not require pre-clearance at the time of the transaction, but the adoption, amendment, modification or termination of such plan or arrangement is subject to the pre-clearance and other restrictions set forth in Section II.E below and/or Appendix A, "Guidelines for Rule 10b5-1 Trading Plans.," as applicable.

4. *Exceptions*

The restrictions contained in this Policy shall not apply to the following transactions:

- the exercise of Company stock options or exchange of profits interests or other units into Company common stock if (1) no shares are to be sold to third parties or (2) there is only a "net exercise" (defined as the Company withholding shares to satisfy your tax obligations or to cover the exercise price or equivalent);
- "sell to cover" transactions involving a sale of shares of common stock directed by the Company in its sole discretion in order to cover the Company's or such individual's or entity's withholding tax obligations in connection with the grant, vesting or settlement of equity awards pursuant to the Company's equity incentive plans and agreements, for example, from the vesting or settlement of restricted stock units under such plans or exchange of units into shares of Common Stock;
- the vesting of Company stock options, restricted stock, restricted stock units or profits interests, phantom units or other equity incentive awards according to their terms;
- the withholding of shares to satisfy the exercise price or a tax withholding obligation upon the grant, vesting or settlement of equity awards pursuant to the Company's equity incentive plans and agreements, for example, from the vesting or settlement of restricted stock units under such plans or exchange of units into shares of the Company's common stock;
- the exchange of profits interests or other units into the Company's common stock (without selling the common stock);
- transferring shares to an entity that does not involve a change in the beneficial ownership of the shares (for example, transferring shares from one brokerage account to another brokerage that you control);

- sales of Company securities as a selling stockholder in a registered public offering, including a "synthetic secondary" offering, in accordance with applicable securities laws; or
- any other purchase of Company securities from the Company or sale of Company securities to the Company in accordance with applicable securities and state laws.

To the extent applicable and such elections are permitted, elections regarding participation in "net exercise" or "sell to cover" transactions, including changes from any defaults established by the Company, may only be made when you are not subject to a blackout period and are not in possession of Material Nonpublic Information.

E. Rule 10b5-1 Trading Plans and Non-Rule 10b5-1 Trading Arrangements

SEC Rule 10b5-1 provides an affirmative defense from insider trading liability if trades occur pursuant to a prearranged trading plan that meets specified conditions. Such plan (referred to herein as a "**Rule 10b5-1 Trading Plan**") is a written trading plan between you and your broker and must either specify the number of securities to be bought or sold, along with the price and the date, or provide a written formula for determining this information. Alternatively, such plan can delegate investment discretion to a third party, such as a broker, who then makes trading decisions without further input from the person implementing the plan. A Rule 10b5-1 Trading Plan must be established at a time when you are not aware of any Material Nonpublic Information and must not permit you to exercise any subsequent control or influence over how, when or whether the purchases or sales are made. Under this Policy, the adoption, amendment, modification or termination of a Rule 10b5-1 Trading Plan must meet the requirements set forth in Appendix A, "Guidelines for Rule 10b5-1 Trading Plans," including applicable pre-clearance procedures. In addition, the adoption, amendment, modification or termination of a "non-Rule 10b5-1 trading arrangement" within the meaning of SEC rules must be approved in advance by the CFO (or, in the case of the CFO, by the CEO) at least five trading days prior to such action. Because the SEC rules on trading plans are complex, you should consult with your broker and be sure you fully understand the limitations and conditions of the rules before you establish a Rule 10b5-1 Trading Plan (or a transaction that is intended to constitute a "non-Rule 10b5-1 trading arrangement" within the meaning of SEC rules).

F. Noncompliance

Anyone subject to this Policy who fails to comply with this Policy will be subject to appropriate disciplinary action, up to and including termination of employment.

G. Post-Termination Transactions

This Policy will continue to apply to your transactions in Company securities after your employment or service with the Company has terminated until such time as you are no longer aware of Material Nonpublic Information or until that information has been publicly disclosed or is no longer material.

Questions about this policy should be directed to the Company's CFO, at [***].

Adopted on August 30, 2023

RECEIPT AND ACKNOWLEDGMENT

I, _____, hereby acknowledge that I have received and read a copy of the Insider Trading Policy (this "Policy") of MoonLake Immunotherapeutics ("MoonLake"). I agree to comply with this Policy. I understand that violation of SEC regulations may subject me to severe civil and/or criminal penalties, and that violation of this Policy may subject me to discipline by MoonLake, up to and including termination for cause.

_____ _____

Signature Date

Appendix A

MoonLake Immunotherapeutics Guidelines for Rule 10b5-1 Trading Plans

As discussed in the Policy, Rule 10b5-1 provides an affirmative defense from insider trading liability. In order to be eligible to rely on this affirmative defense, Insiders must enter into a Rule 10b5-1 Trading Plan for transactions in Company securities that meets certain conditions specified in Rule 10b5-1, including the guidelines set forth below. These guidelines generally do not apply to any transactions that are intended to constitute "non-Rule 10b5-1 trading arrangements" within the meaning of SEC rules. Capitalized terms used in these guidelines without definition have the meaning set forth in the Policy.

These guidelines are in addition to, and not in lieu of, the requirements and conditions of Rule 10b5-1. The CFO will interpret and administer these guidelines for compliance with Rule 10b5-1 and the Policy. No personal legal or financial advice is being provided by the CFO or other members of the Company regarding any Rule 10b5-1 Trading Plan or proposed trades. Insiders remain ultimately responsible for ensuring that their Rule 10b5-1 Trading Plans and contemplated transactions fully comply with applicable securities laws. It is recommended that Insiders consult with their own attorneys, brokers, or other advisors about any contemplated Rule 10b5-1 Trading Plan. **Note that for any Section 16 Person, the Company is required to disclose the material terms of his or her Rule 10b5-1 Trading Plan (and may be required to disclose the material terms of Rule 10b5-1 Trading Plans of Family Members and Controlled Entities of such persons), other than with respect to price, in its periodic report for the quarter in which the Rule 10b5-1 Trading Plan is adopted or terminated or modified (as described below).**

1. **Pre-Clearance Requirement.** The Rule 10b5-1 Trading Plan must be reviewed and approved in advance by the CFO (or, in the case of the CFO, by the CEO) at least five trading days prior to the entry into the plan in accordance with the procedures set forth in the Policy and these guidelines. The Company may require that Insiders use a standardized form of Rule 10b5-1 Trading Plan.

2. **Time of Adoption.** Subject to pre-clearance requirements described above, the Rule 10b5-1 Trading Plan must be adopted at a time:

    - When the Insider is not aware of any Material Nonpublic Information; and
    - When the Insider is not subject to a blackout period.

3. **Plan Instructions.** Any Rule 10b5-1 Trading Plan must be in writing, signed, and either:

    - specify the amount, price and date of the sales (or purchases) of Company securities to be effected;

- provide a formula, algorithm or computer program for determining when to sell (or purchase) the Company's securities, the quantity to sell (or purchase) and the price; or

- delegate decision-making authority with regard to these transactions to a broker or other agent without any Material Nonpublic Information about the Company or its securities.

For the avoidance of doubt, Insiders may not subsequently influence how, when, or whether to effect purchases or sales with respect to the securities subject to an approved and adopted Rule 10b5-1 Trading Plan.

4. **No Hedging.** Insiders may not have entered into or alter a corresponding or hedging transaction or position with respect to the securities subject to the Rule 10b5-1 Trading Plan and must agree not to enter into any such transaction while the Rule 10b5-1 Trading Plan is in effect.

5. **Good Faith Requirements.** Insiders must enter into the Rule 10b5-1 Trading Plan in good faith and not as part of a plan or scheme to evade the prohibitions of Rules 10b-5 and 10b5-1. Insiders must act in good faith with respect to the Rule 10b5-1 Trading Plan for the entirety of its duration.

6. **Certifications for Section 16 Persons.** Section 16 Persons and their Family Members and Controlled Entities that enter into Rule 10b5-1 Trading Plans must certify that they are: (1) not aware of any Material Nonpublic Information about the Company or the Company securities; and (2) adopting the Rule 10b5-1 Trading Plan in good faith and not as part of a plan or scheme to evade the prohibitions of Rules 10b-5 and 10b5-1 under the Exchange Act.

7. **Cooling Off Periods.** The first trade under the Rule 10b5-1 Trading Plan may not occur until the expiration of a cooling-off period as follows:

    - For Section 16 Persons (as well as their Family Members and Controlled Entities), the later of (1) two business days following the filing of the Company's Form 10-Q or Form 10-K for the completed fiscal quarter in which the Rule 10b5-1 Trading Plan was adopted and (2) 90 calendar days after adoption of the Rule 10b5-1 Trading Plan; provided, however, that the required cooling-off period shall in no event exceed 120 days.

    - For other Insiders, 30 days after adoption of the Rule 10b5-1 Trading Plan.

8. **No Overlapping Rule 10b5-1 Trading Plans.** An Insider may not enter into overlapping Rule 10b5-1 Trading Plans (subject to certain exceptions). Please consult with the CFO for any questions regarding overlapping Rule 10b5-1 Trading Plans.

9. **Single Transaction Plans.** An Insider may not enter into more than one Rule 10b5-1

Trading Plan designed to effect the open-market purchase or sale of the total amount of securities as a single transaction during any rolling 12-month period (subject to certain exceptions). A single-transaction plan is "designed to effect" the purchase or sale of securities as a single transaction when the terms of the plan would, for practical purposes, directly or indirectly require execution in a single transaction.

10. Modifications and Terminations. Modifications/amendments and terminations of an existing Rule 10b5-1 Trading Plan are strongly discouraged due to legal risks, and can affect the validity of trades that have taken place under the plan prior to such modification/amendment or termination. Under Rule 10b5-1 and these guidelines, any modification/amendment to the amount, price, or timing of the purchase or sale of the securities underlying the Rule 10b5-1 Trading Plan (a "Material Modification") will be deemed to be a termination of the current Rule 10b5-1 Trading Plan and creation of a new Rule 10b5-1 Trading Plan.

As such, the modification/amendment of an existing Rule 10b5-1 Trading Plan must be reviewed and approved in advance by the CFO in accordance with the pre-clearance procedures set forth in the Policy and these guidelines, and any Material Modification will be subject to all the other requirements set forth in these guidelines regarding the adoption of a new Rule 10b5-1 Trading Plan.

The termination (other than through an amendment or modification) of an existing Rule 10b5-1 Trading Plan must be reviewed and approved in advance by the CFO in accordance with the pre-clearance procedures set forth in the Policy and these guidelines. Except in limited circumstances, the CFO will not approve the termination of a Rule 10b5-1 Trading Plan unless:

- The Insider is not aware of any Material Nonpublic Information; and
- The Insider is not subject to a blackout period.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-267673) and on Form S-3 (No. 333-274286 and 333-262643) of MoonLake Immunotherapeutics of our report dated February 26, 2025, relating to the consolidated financial statements and the effectiveness of internal control over financial reporting of MoonLake Immunotherapeutics, appearing in this Annual Report on Form 10-K of MoonLake Immunotherapeutics for the year ended December 31, 2024.

/s/ BAKER TILLY US, LLP

San Jose, CA
February 26, 2025

Exhibit 31.1

Certification Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Jorge Santos Da Silva, certify that:

1. I have reviewed this Annual Report on Form 10-K of MoonLake Immunotherapeutics;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: February 26, 2025

By: /s/ Jorge Santos Da Silva
Name: Jorge Santos Da Silva
Title: Chief Executive Officer
(*principal executive officer*)

Exhibit 31.2

Certification Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Matthias Bodenstedt, certify that:

1. I have reviewed this Annual Report on Form 10-K of MoonLake Immunotherapeutics;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: February 26, 2025

By: /s/ Matthias Bodenstedt
Name: Matthias Bodenstedt
Title: Chief Financial Officer
(*principal financial and accounting officer)*

Exhibit 32.1

Certification Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, Jorge Santos Da Silva, to the best of my knowledge certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report on Form 10-K of MoonLake Immunotherapeutics (the "Company") for the year ended December 31, 2024 (the "Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 26, 2025

By: /s/ Jorge Santos Da Silva
Name: Jorge Santos Da Silva
Title: Chief Executive Officer
(*principal executive officer*)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Note: A signed original of this written statement required by Section 906 has been provided to MoonLake Immunotherapeutics and will be retained by MoonLake Immunotherapeutics and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

Certification Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, Matthias Bodenstedt, to the best of my knowledge certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report on Form 10-K of MoonLake Immunotherapeutics (the "Company") for the year ended December 31, 2024 (the "Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 26, 2025

By: /s/ Matthias Bodenstedt
Name: Matthias Bodenstedt
Title: Chief Financial Officer
(*principal financial and accounting officer*)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Note: A signed original of this written statement required by Section 906 has been provided to MoonLake Immunotherapeutics and will be retained by MoonLake Immunotherapeutics and furnished to the Securities and Exchange Commission or its staff upon request.