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

## **FORM 10-O**

## (MARK ONE)

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

## For the quarterly period ended September 30, 2022

#### □ 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)

(State or other jurisdiction of incorporation or organization) Dorfstrasse 29 6300 Zug Switzerland N/A (ZIP Code) (Address of principal executive offices) 41 415108022 (Registrant's telephone number, including area code)

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

**Cayman Islands** 

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 Stock Market LLC

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  $\boxtimes$  No  $\square$ 

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

As of November 14, 2022, there were 38,977,600 Class A Ordinary Shares, \$0.0001 par value (the "Class A Ordinary Shares"), and 13,723,511 Class C Ordinary Shares, \$0.0001 par value (the "Class C Ordinary Shares"), issued and outstanding.

N/A

(I.R.S. Employer Identification No.)

## FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2022

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## PART I. FINANCIAL INFORMATION

## MOONLAKE IMMUNOTHERAPEUTICS

## CONDENSED CONSOLIDATED BALANCE SHEETS

(Amounts in USD, except share data)

	September 30, 2022 (Unaudited)		December 31, 2021
Current assets		· · ·	
Cash and cash equivalents	\$ 41,204,667	\$	8,038,845
Short-term marketable debt securities	42,254,788		—
Other receivables	600,536		148,774
Prepaid expenses	4,479,194		1,449,096
Total current assets	88,539,185		9,636,715
Non-current assets			
Property and equipment, net	52,679		45,739
Total non-current assets	52,679		45,739
Total assets	\$ 88,591,864	\$	9,682,454
Current liabilities			
Trade and other payables	\$ 1,056,253	\$	1,569,290
Short-term loans	φ 1,000,200 	Ψ	15,000,000
Accrued expenses and other current liabilities	4,962,470		4,518,311
Total current liabilities	6,018,723		21,087,601
			21,007,001
Non-current liabilities			
Pension liability	4,985		239,860
Total non-current liabilities	4,985		239,860
Total liabilities	6,023,708		21,327,461
Commitments and contingencies (Note 15)			
Equity (deficit)			
Series A Preferred Shares, CHF 0.10 par value; 22,880,908 authorized; 22,880,908 shares issued and outstanding as of December 31, 2021 (liquidation preference of \$33.4 million);	_		72,466
Common Shares, CHF 0.10 par value; 13,119,092 authorized; 12,161,331 shares issued and 10,218,495 shares outstanding as of December 31, 2021	_		38,537
Treasury Shares, 1,942,837 as of December 31, 2021	_		(6,202)
Class A Ordinary Shares: \$0.0001 par value; 500,000,000 shares authorized; 36,925,639 shares issued and outstanding as of September 30, 2022	3,693		_
Class C Ordinary Shares: \$0.0001 par value; 100,000,000 shares authorized; 15,775,472 shares issued and outstanding as of September 30, 2022	1,578		_
Additional paid-in capital	123,825,896		42,061,984
Accumulated deficit	(68,788,276)		(53,643,615)
Accumulated other comprehensive income (loss)	245,283		(168,177)
Total shareholders' equity (deficit)	55,288,174		(11,645,007)
Noncontrolling interests	27,279,982		_
Total equity (deficit)	82,568,156		(11,645,007)
Total liabilities and equity (deficit)	\$ 88,591,864	\$	9,682,454

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

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Amounts in USD, except share and per share data)

## (Unaudited)

	Three Months Er	ided Se	ptember 30,	Nine Months En	ded Se	ptember 30,
	2022		2021 (As restated) <sup>1</sup>	2022		2021 (As restated) <sup>1</sup>
Operating expenses						
Research and development	(9,024,437)		(669,528)	(30,679,842)		(30,536,746)
General and administrative	 (5,746,064)		(5,597,688)	 (17,685,152)		(8,762,925)
Total operating expenses	(14,770,501)		(6,267,216)	(48,364,994)		(39,299,671)
Operating loss	 (14,770,501)		(6,267,216)	 (48,364,994)		(39,299,671)
Other income (expense), net	37,593		(20,840)	352,227		(25,839)
Loss before income tax	 (14,732,908)		(6,288,056)	 (48,012,767)		(39,325,510)
Income tax expense	(8,740)		_	(25,354)		_
Net loss	\$ (14,741,648)	\$	(6,288,056)	\$ (48,038,121)	\$	(39,325,510)
Of which: net loss attributable to controlling interests shareholders	 (10,110,452)		(6,288,056)	 (32,865,429)		(39,325,510)
Of which: net loss attributable to noncontrolling interests shareholders	(4,631,196)		_	(15,172,692)		-
Net unrealized gain on marketable securities and short term						
investments	77,006		—	77,006		—
Foreign currency Translation	—		—	567		_
Actuarial income (loss) on employee benefit plans	89,586		1,000	456,883		—
Other comprehensive income (loss)	166,592		1,000	534,456		_
Comprehensive loss	\$ (14,575,056)	\$	(6,287,056)	\$ (47,503,665)	\$	(39,325,510)
Comprehensive loss attributable to controlling interests shareholders	(9,998,892)		(6,287,056)	(32,507,526)		(39,325,510)
Comprehensive loss attributable to noncontrolling interests	(4,576,164)		—	(14,996,139)		_
Weighted-average number of Class A Ordinary Shares, basic and diluted <sup>2</sup>	36,925,639		—	25,830,560		-
Basic and diluted net loss per share attributable to controlling interests shareholders	\$ (0.27)	\$	_	\$ (1.27)	\$	_
Weighted-average number of Common Shares, basic and diluted <sup>2</sup>			2,390,587			9,689,627
Basic and diluted net loss per Common Share	\$ _	\$	(2.63)	\$ _	\$	(4.06)

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

<sup>1</sup> For additional details, refer to Note 3 - Basis of Presentation and Significant Accounting Policies - Restatement of Consolidated Financial Statements as of and for the Three and Nine-months Ended September 30, 2021.

 $^2$  As a result of the Business Combination, the Company has retroactively restated the weighted average number of shares outstanding prior to April 5, 2022 to give effect to the Exchange Ratio.

# **CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (DEFICIT)** (Amounts in USD, except share data)

(Unaudited)

		100nLake AG Series A Moo Preferred Shares		Common	MoonLake AG Shares Held In		Class A Ordina	y Shares	Class C Ordinar	y Shares	Additional Paid- In Capital	Accumulated Deficit	Accumulated Other Comprehensive	Total Shareholders' Equity (Deficit)	Noncontrolling Interests	Total Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			Income (Loss)	••• •		
Balance at March 10, 2021 (As previously reported)	— \$	_	1,000,000 \$	106,508	- \$	_	— \$	_	— \$	- 5	s — s	— \$	— s	106,508 \$	- \$	106,508
Retroactive application of the recapitalization due to the Business Combination (Note 2)	_	_	32,638,698	_	_	_	_	_	_	_	_	_	_	_	_	_
Balance at March 10, 2021, effect of Business Combination (Note 2)	— \$	-	33,638,698 \$	106,508	- \$	-	- \$	_	- \$	_ \$	s – s	- \$	— s	106,508 \$	- \$	106,508
Net loss for the period from March 10, 2021 to March 31, 2021	-	-	_	_	-	_	-	-	_	-	_	(351,673)	_	(351,673)	_	(351,673)
Balance at March 31, 2021, effect of Business Combination (Note 2)	— \$	_	33,638,698 \$	106,508	— <b>s</b>	-	- \$	_	- \$	_ \$	s – s	(351,673) \$	— s	(245,165) \$	— <b>s</b>	(245,165)
Share-based compensation expense through transfer of existing Common Shares (3,330,231) to Merck KGaA, Darmstadt, Germany, and conversion of transferred shares into Series A Preferred Shares	3,330,231	10,544	(3,330,231)	(10,544)	_	_	_	_	_	_	4,851,000	_	_	4,851,000	_	4,851,000
Share based compensation granted under the equity incentive plans ESPP, ESOP, and Restricted Founders Shares	_	_	-	_	_	_	-	_	_	_	1,250,365	-	_	1,250,365	_	1,250,365
Transfer of existing Common Shares (19,207,697) to new Shareholders, concurrent capital contribution by new shareholders net of share sisuance cost of \$279,364, and conversion of transferred shares into Series A Preferred Shares	19,207,697	60,816	(19,207,697)	(60,816)	_	_	_	_	_	_	27,659,237	_	_	27,659,237	_	27,659,237
Net loss for the three months ended June 30, 2021	_	_	_	_	_	_	_	_	_	_	-	(32,685,779)	_	(32,685,779)	_	(32,685,779)
Other comprehensive loss	_	_	_	_	_	_	_	_	_	_	_	_	(1,000)	(1,000)	—	(1,000)
Balance at June 30, 2021, effect of Business Combination (Note 2)	22,537,928 \$	71,360	11,100,770 \$	35,148	- \$	_	- \$	_	— <b>s</b>	_ \$	\$ 33,760,602 \$	(33,037,452) \$	(1,000) \$	828,658 \$	— <b>s</b>	828,658
Preferred Shares purchased by a director following his appointment as chairman of the board of directors (net of share issuance cost of \$4951)	342,980	1,106	_	_	_	_	_	_	_	_	493,944	_	_	495,050	_	495,050
Share based compensation granted under the equity incentive plans (ESPP and ESOP) and reverse vesting of Restricted Founder Shares	_	_	1,026,956	3,281	_	_	_	_	-	_	1,855,827	_	_	1,859,108	-	1,859,108
Net loss for the period from June 30, 2021 to September 30, 2021	_	_	_	_	_	_	_	_	_	_	_	(6,288,056)	_	(6,288,056)	-	(6,288,056)
Other comprehensive income	-	_	-	—	-	-	-	_	-	_	_	-	1,000	1,000	-	1,000
Balance at September 30, 2021, effect of Business Combination (Note 2)	22,880,908 S	72,466	12,127,726 \$	38,429	- \$	_	- \$	_	- \$	- 5	\$ 36,110,373 \$	(39,325,508) \$	— s	(3,104,240) \$	— <b>s</b>	(3,104,240)

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

# **CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (DEFICIT)** (Amounts in USD, except share data)

(Unaudited)

	MoonLake AG Preferred S		MoonLake AG Shares	Common	MoonLake AG Shares Held In 7		Class A Ordinar	y Shares	Class C Ordinar	y Shares	Additional Paid- In Capital	Accumulated Deficit	Accumulated Other Comprehensive	Total Shareholders' Equity (Deficit)	Noncontrolling Interests	Total Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			Income (Loss)	1.1.1.1		
Balance at December 31, 2021 (As previously reported)	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 December 31, 2021, effect of Business Combination (Note 2)	22,880,908 \$	72,466	12,161,331 \$	38,537	(1,942,837) \$	(6,202)	— <b>s</b>	_	— <b>s</b>	— \$	5 42,061,984 <b>\$</b>	(53,643,615) \$	(168,177) \$	(11,645,007) \$	— <b>s</b>	(11,645,007)
Share-based compensation granted under the equity incentive plan ESPP, and reverse vesting of Restricted Founder Shares	_	_	_	_	1,177,354	3,791	_	_	_	_	1,988,871	_	_	1,992,662	_	1,992,662
Net loss for the three months ended March 31, 2022	_	_	_	_	_	_	_	_	_	_	_	(15,880,142)	_	(15,880,142)	_	(15,880,142)
Other comprehensive income	_	_	-	_	_	_	_	_	-	_	_	_	266,269	266,269	_	266,269
Balance at March 31, 2022, effect of Business Combination (Note 2)	22,880,908 \$	72,466	12,161,331 \$	38,537	(765,483) \$	(2,411)	— <b>s</b>	_	- \$	— \$	6 44,050,855 \$	(69,523,757) \$	98,092 \$	(25,266,218) \$	— \$	(25,266,218)
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	_	-	90,782,089	_	_	90,783,932	43,869,269	134,653,201
Share-based compensation granted under the equity incentive plan ESPP, ESOP, reverse vesting of Restricted Founder Shares and 2022 MoonLake Immunotherapeutics Equity Incentive Plan	_	_	_	_	_	_	_	_	_	_	1,701,614	_	_	1,701,614	782,609	2,484,223
Net loss for the three months ended June 30, 2022	_	_	_	_	_	_	_	_	_	-	_	(12,120,719)	_	(12,120,719)	(5,295,610)	(17,416,329)
Other comprehensive income	-	-	-	-	-	-	-	-	-	-	_	-	68,035	68,035	33,562	101,597
At June 30, 2022	— <b>s</b>	_	— \$	_	— \$	_	36,925,639 \$	3,693	15,775,472 \$	1,578 \$	5 122,053,558 <b>\$</b>	(58,677,824) \$	133,723 \$	63,514,728 \$	31,043,324 \$	94,558,052
Share-based compensation granted under the equity incentive plan ESPP, ESOP, reverse vesting of Restricted Founder Shares and 2022 MoonLake Immunotherapeutics Equity Incentive Plan	_	_	_	_	_	_	_	_	_	_	1,772,338	_	-	1,772,338	812,822	2,585,160
Net loss for the three months ended September 30, 2022	_	_	_	_	_	_	_	_	_	_	_	(10,110,452)	_	(10,110,452)	(4,631,196)	(14,741,648)
Other comprehensive income	_	_	-	_	-	_	-	_	-	_	_	-	111,560	111,560	55,032	166,592
At September 30, 2022	— <b>s</b>	_	— <b>s</b>	-	— \$	-	36,925,639 \$	3,693	15,775,472 \$	1,578 \$	5 123,825,896 <b>\$</b>	(68,788,276) \$	245,283 \$	55,288,174 \$	27,279,982 \$	82,568,156

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

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Amounts in USD, except share and per share data)

## (Unaudited)

	Nine Mon	ths Ended September 30, 2022	Nine Mo	ne Months Ended September 30, 2021 (As restated) <sup>3</sup>	
Cash flow from operating activities		-			
Net loss	\$	(48,038,121)	\$	(39,325,510)	
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation		9,069		2,484	
Share-based payment		7,058,255		3,106,192	
Share-based compensation for the in-licensing agreement		—		4,851,000	
Net periodic pension benefit cost for the qualified pension plan		227,691		150,000	
Other non-cash items		(5,504)		10,270	
Changes in operating assets and liabilities:					
Other receivables		(451,762)		(66,810)	
Prepaid expenses		(3,030,098)		(43,645)	
Trade and other payables		(513,037)		762,550	
Accrued expenses and other current liabilities		445,589		2,830,291	
Net cash flow used in operating activities		(44,297,918)		(27,723,178)	
Cash flow from investing activities					
Purchase of Short-term marketable debt securities		(42,226,022)			
Purchase of property and equipment		(16,008)		(32,332)	
Net cash flow used in investing activities		(42,242,030)		(32,332)	
8		(,,,		(,)	
Cash flow from financing activities					
Issuance of shares at incorporation		—		106,508	
Issuance of Series A Preferred Shares, net		—		28,154,287	
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		—		3,281	
Net cash flow provided by financing activities		119,688,944		28,264,076	
Effect of movements in exchange rates on cash held		16,826		(1,005)	
Net change in cash and cash equivalents		33,165,822		507,561	
		, ,			
Cash and cash equivalents, beginning of period		8,038,845		_	
Cash and cash equivalents, end of period	\$	41,204,667	\$	507,561	

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

<sup>&</sup>lt;sup>3</sup> For additional details, refer to Note 3 - Basis of Presentation and Significant Accounting Policies - Restatement of Consolidated Financial Statements as of and for the Three and Nine-months Ended September 30, 2021.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2022

(Amounts in USD, except share and per share data)

## (Unaudited)

## Note 1 — Overview of the Company

## **Corporate Information**

MoonLake Immunotherapeutics is a clinical-stage biotechnology company engaged in leveraging Nanobody® technology to develop next-level medicines for immunologic diseases, including inflammatory skin and joint diseases. MoonLake Immunotherapeutics focuses on developing its novel tri-specific Nanobody® Sonelokimab ("SLK"), an IL-17A and IL-17F inhibitor, in multiple inflammatory diseases in dermatology and rheumatology where the pathophysiology is known to be driven by IL-17A and IL-17F.

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 equity holders 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 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 existing 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.
- 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.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS SEPTEMBER 30, 2022

(Amounts in USD, except share and per share data)

#### (Unaudited)

- 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 11 Shareholders' Equity (Deficit) 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

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

**SEPTEMBER 30, 2022** 

(Amounts in USD, except share and per share data)

## (Unaudited)

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)							
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 unaudited condensed consolidated financial statements include those of the Company and its subsidiaries, MoonLake AG and MoonLake Immunotherapeutics Ltd., after elimination of all intercompany accounts and transactions. The accompanying unaudited condensed consolidated financial statements and notes hereto have been prepared in conformity with the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial reporting and, therefore, omit or condense certain footnotes and other information normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") as set forth by the Financial Accounting Standards Board ("FASB"). 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 FASB. In the opinion of management, all adjustments necessary for a fair statement of the financial information, which are of a normal and recurring nature, have

In the opinion of management, all adjustments necessary for a fair statement of the financial information, which are of a normal and recurring nature, have been made for the interim periods reported. Results of operations for the three and nine months ended September 30, 2022 and 2021 are not necessarily indicative of the results for the entire fiscal year or any other period. The unaudited condensed consolidated financial information for the three and nine months ended September 30, 2022 and 2021 have been prepared on the same basis as and should be read in conjunction with MoonLake AG's audited financial statements and notes thereto for the year ended December 31, 2021 included in the final prospectus filed with the SEC pursuant to Rule 424(b)(3) on August 2, 2022.

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



## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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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 11 — *Shareholders' Equity (Deficit)* for further details on the classes of ordinary shares). The number of shares, and the number of shares within the net income (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 condensed 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 continue 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, and "€" refers to euros.

## Restatement of Consolidated Financial Statements as of and for the Three and Nine-months Ended September 30, 2021

On April 28, 2021, a shareholders' agreement between MoonLake AG, its Series A investors, and its co-founders 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 vest on the 28th of each month at a rate of 4.166% over a period of two years until April 28, 2023. If, before the end of the vesting period, the contractual relationship of the relevant co-founders is terminated, MoonLake AG in first priority, or any third party designated by it, and the other shareholders in second priority pro rata to their shareholdings, shall have an option to purchase all or a pro rata portion of the leaver shares that are unvested on the day the termination becomes effective at nominal value of CHF 0.10 per share. The Restricted Founder Shares are legally outstanding and continue to have voting and dividend rights.

Management had initially determined that the reverse vesting condition was necessary to induce the sale of the Series A Preferred Shares and did not contain a compensatory element. However, on December 13, 2021 a termination agreement was reached between one of the co-founders and MoonLake AG to terminate the co-founder's contractual relationship and, as a result, 57,756 Common Shares (the equivalent of 1,942,837 Class C Ordinary Shares) were purchased by MoonLake AG. Management concluded that this termination agreement was reflective of the intention of the parties and therefore the substance of the previous agreement. As a result, management concluded that its accounting for the Restricted Founder Shares should have instead reflected a service condition and should be accounted for as a share-based compensation arrangement.

Accounting for the Restricted Founder Shares as share-based compensation increased general and administrative expenses to reflect the recognition of the non-cash expense of the fair value of the Restricted Founder Shares at the grant date of April 28, 2021 over the two-year vesting period, and led to a corresponding increase in additional paid in capital. The previously unrecognized share-based compensation expense amounts to \$1.8 million for three months ended September 30, 2021, and \$3.1 for the period from inception to September 30, 2021, causing an increase in net loss, general and administrative expenses and additional paid-in capital of the same amount in the respective periods. Net loss per share was previously \$(13.55) ((0.40), assuming the retroactive adjustment of the EPS denominator by multiplying MoonLake AG Common Shares by the Exchange Ratio) for the period from inception to September 30, 2021. The increase in net loss, and exclusion of unvested Restricted Founder Shares in the denominator leads to corrected values of \$(88.48) ((2.63), assuming the equivalent number of shares by applying the Exchange Ratio) for the three months ended September 30,

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS SEPTEMBER 30, 2022

(Amounts in USD, except share and per share data)

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2021, and \$(136.52) ((4.06), assuming the retroactive adjustment of the EPS denominator by multiplying MoonLake AG Common Shares by the Exchange Ratio) for the period from inception to September 30, 2021.

## 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. The significant judgments, estimates and assumptions relevant to the Company relate to:

- determining whether the in-process research and development expenditure ("IPR&D") has an alternative future use;
- estimating the fair value of the portion of the aggregate purchase price relating to its own shares in connection with the acquisition of the inlicense agreement;
- determining assumptions used in determining the fair value of share-based compensation; and
- · estimating the recoverability of the deferred tax asset.

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 September 30, 2022, the Company considers \$19.9 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, 2021, the Company did not have any 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 will assess 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 "Interest and dividend income." 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 (loss)" component of shareholder' equity (deficit) until realized. Realized gains and losses on available-forsale debt securities are computed based upon the historical cost of these securities, using the specific identification method.

A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to earnings and the corresponding establishment of a new cost basis for the security. Dividend and interest income are recognized when earned. Realized gains and losses are included in earnings and the cost of securities sold is determined using the specific-identification method.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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(Amounts in USD, except share and per share data)

## (Unaudited)

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

## **Concentration of Credit Risk**

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash accounts in a large financial institution which, at times, may exceed the CHF 100,000 deposit protection limit. 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. Further, the Company's investment strategy for cash (in excess of current business requirements) is set to invest in short-term 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 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, 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 September 30, 2022, property and equipment, net relates to IT and office equipment.

## **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

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS SEPTEMBER 30, 2022

(Amounts in USD, except share and per share data)

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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 Transaction

Goods or services received in a share-based payment transaction are measured using a fair value-based measure.

The Company measures and recognizes compensation expense for all share-based awards made to employees and directors based on estimated fair values. The fair value of employee share options is estimated on the date of grant using the Black-Scholes option pricing model. Share-based compensation expense is adjusted for forfeitures as they occur.

## 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 the daily exchange rate on the respective accounting date.

Gains or losses from foreign currency translation are included in the consolidated statement of operations. The Company recognized foreign currency transaction gain of \$344,914 for the nine months ended September 30, 2022 ("the period ended September 30, 2022"), and a gain of \$4,361 for the three months ended September 30, 2022. For the three and nine months ended September 30, 2021, MoonLake AG recognized a foreign currency transaction loss of \$19,853 and \$24,543 respectively.

#### 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 a deferred tax asset 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. The Company acquired the Sonelokimab program (the "SLK Program") during the period ended December 31, 2021 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.



## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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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** Accounting

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 September 30, 2022 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 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 statement of operations separately from the service cost component, in "other income (expenses), 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 (loss).

## **Recently Issued Accounting Pronouncements not yet Adopted**

The Company is an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). As such the Company is eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including reduced reporting and extended transition periods to comply with new or revised accounting standards for public business entities. The Company has elected to avail itself of this exemption and, therefore, will not be subject to the timeline for adopting new or revised accounting standards for public business entities that are not emerging growth companies, and will follow the transition guidance applicable to private companies.

In February 2016, the FASB issued ASU No. 2016-02, *Leases Topic 842 ("ASU 2016-02")*. The guidance in ASU 2016-02 supersedes the lease recognition requirements in ASC 840, *Leases*. ASU 2016-02 requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases, along with additional qualitative and quantitative disclosures. ASU 2016-02 is effective for fiscal years beginning after December 15, 2021, and for interim periods within fiscal years beginning after December 15, 2022, with early adoption permitted. The Company has continued to account for the open-ended office lease agreement as an operating lease under the guidance prior to ASU 2016-02 through the consolidated statement of operations for the period ended December 31, 2021.

In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which allows entities to elect a modified retrospective transition method where entities may continue to apply the existing lease guidance during the comparative periods and apply the new lease requirements through a cumulative effect adjustment in the period of adoptions rather than in the earliest period presented.

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## Note 4 – Risks and Liquidity

## Going Concern, Liquidity and Capital Resources

The Company incurred a loss of \$48.0 million for the nine months ended September 30, 2022. As of September 30, 2022, the Company's current assets exceeded its current liabilities by \$82.5 million.

The Company had \$41.2 million of cash and cash equivalents, of which \$19.9 million relate to investments in short-term marketable debt securities with an original maturity of three months or less at the date of purchase, and \$42.3 million of short-term marketable debt securities with an original maturity of more than three months at the date of purchase. Management believes that the Company has sufficient capital to fund its operations and capital expenditures into the second half of 2024.

#### **Coronavirus Pandemic**

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic which continues to evolve. To date, the impact of COVID-19 on the Company's business, operations and development timelines has been limited. However, the future impact of COVID-19 on the Company's business is uncertain. The Company will continue to actively monitor the evolving situation related to COVID-19 and may take further actions that alter its operations, including those that may be required by Switzerland state or local authorities, or that the Company determines are in the best interests of its employees and other third parties with whom the Company does business. At this point, the extent to which COVID-19 may affect the Company's future business, operations and development timelines and plans, including the resulting impact on our expenditures and capital needs, remains uncertain and the Company may experience disruptions.

## Note 5 - Fair Value Measurements

The following table presents the Company's short-term marketable debt securities by level within the fair value hierarchy:

		September 30, 2022		
	Level 1	Level 2	Level 3	Total
Eurocommercial Papers	\$ 32,407,888 \$	— \$	— \$	32,407,888
Certificates of Deposit	9,846,900	—	—	9,846,900
Total	\$ 42,254,788 \$	— \$	— \$	42,254,788

There were no Eurocommercial Papers, Certificates of Deposit or other assets measured at fair value as at December 31, 2021.

Cash, accounts payable and accrued liabilities approximate their fair values as of September 30, 2022 and December 31, 2021, due to their short-term nature. Pension plan assets fair value is determined based on Level 2 inputs.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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## (Unaudited)

## Note 6 – Investments

The fair value and amortized cost of investments in short-term marketable debt securities by major security type as of September 30, 2022 are as follows:

	 Amortized cost	 Gross unrealized gains	 Gross unrealized losses	-	Fair value
Eurocommercial Papers	\$ 52,287,157	\$ 80,994	\$ (16,263)	\$	52,351,888
Certificates of Deposit	9,834,625	12,275	—		9,846,900
Total	\$ 62,121,782	\$ 93,269	\$ (16,263)	\$	62,198,788
Of which classified within cash and cash equivalents	19,895,762	48,238	_		19,944,000
<i>Of which classified within short-term marketable debt securities</i>	42,226,020	45,031	(16,263)		42,254,788

The following table presents the changes in fair values of the Company's short-term marketable debt securities, classified as level 1 financial assets (in thousands):

Beginning balance, January 1, 2022	\$ _
Other comprehensive income before reclassifications	95,815
Amounts reclassified from accumulated other comprehensive income	(18,809)
Net current-period other comprehensive income	77,006
Ending balance, September 30, 2022	\$ 77,006

As of September 30, 2022, the Company's marketable debt securities maturities are all due within one year.

## Note 7 — Prepaid Expenses

	September 30, 2022	December 31, 2021
Advances on non-clinical research and clinical development services	\$ 2,208,728	\$ 547,586
Advances on insurances	2,042,275	23,141
Advances on supply and manufacturing services	83,559	750,622
Other prepayments	144,632	127,747
Total	\$ 4,479,194	\$ 1,449,096

Prepaid expenses as of September 30, 2022 primarily relate to services expected to be received within the next 12 months.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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(Amounts in USD, except share and per share data)

## (Unaudited)

## Note 8 — Trade and Other Payables

	September 30, 2022	December 31, 2021
Supply and manufacturing fees payable	\$ 523,991	\$ 183,298
Legal and intellectual property ("IP") advisory fees payable	155,532	1,233,070
Research and development services	149,161	50,088
Other consulting and advisory services	77,741	71,938
Other payables	149,828	30,896
Total	\$ 1,056,253	\$ 1,569,290

## Note 9 — Accrued Expenses and Other Current Liabilities

	September 30, 2022	December 31, 2021
Research and development services	\$ 3,281,331	\$ _
Bonuses and related employees compensation expenses	865,882	1,419,137
License fees	520,948	2,055,687
Consultant and other fees	154,806	49,211
Legal fees	77,895	930,354
Tax liabilities	61,608	63,922
Total	\$ 4,962,470	\$ 4,518,311

## Note 10 — 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 September 30, 2022 the Plan covers the Company's employees in Switzerland with benefits in the event of death, disability, retirement, or termination of employment.

## Components of Net Periodic Benefit Cost under the Plan

	 e months ended tember 30, 2022	Three months ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Service cost	\$ 112,222	\$ 11,423	\$ 338,173	\$ 11,423
Interest cost	1,258	—	3,791	—
Expected return on plan assets	(3,862)	—	(11,637)	_
Amortization of unrecognized loss	451	—	1,361	—
Total Net Periodic Benefit Cost	\$ 110,069	\$ 11,423	\$ 331,688	\$ 11,423

The components of net periodic benefit cost other than the service cost component are included in general and administrative expense in the Company's unaudited condensed consolidated statements of operations.

## Employer Contributions under the Plan

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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(Amounts in USD, except share and per share data)

#### (Unaudited)

For the nine months ended September 30, 2022, \$103,873 (CHF 98,806) of contributions were made to the Plan. The Company presently anticipates contributing an additional estimated amount of \$33,757 (CHF 32,609) to fund the Plan in 2022 for a total of \$137,630 (CHF 131,415).

## Note 11 — Shareholders' Equity (Deficit)

As a result of the Business Combination, the Company has retroactively restated the share numbers prior to April 5, 2022 to give effect to the Exchange Ratio.

	Series A Prefer	red Shares <sup>(1)</sup>	Common	Shares <sup>(1)</sup>	Common Shares Held In Treasury <sup>(2)</sup>	eld In Class A Ordinary Shares <sup>(3)</sup>		ass A Ordinary Shares <sup>(3)</sup> Class C Ordinary Shares <sup>(3)</sup>			Total Number of Shares		
	Authorized	Issued	Authorized	Issued	Issued	Authorized	Issued	Authorized	Issued	Authorized	Issued and Outstanding		
Balance - December 31, 2021	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 equity incentive plan ESPP	—	_	_	—	1,177,354	—	_	—	_	_	1,177,354		
Balance - March 31, 2022	22,880,908	22,880,908	13,119,092	12,161,331	(765,483)	_	_	_	_	36,000,000	34,276,756		
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)	_		
Balance - June 30, 2022	_	—		_		500,000,000	36,925,639	100,000,000	15,775,472	600,000,000	52,701,111		
Balance - September 30, 2022	_	—	_	—	_	500,000,000	36,925,639	100,000,000	15,775,472	600,000,000	52,701,111		

 $^{(1)}$  Fully paid-in registered shares with a par value of CHF 0.10

 $^{(2)}$  Registered shares with a par value of CHF 0.10 held in treasury

<sup>(3)</sup> Fully paid-in registered shares with a par value of \$0.0001

As of September 30, 2022, the Company had the following classes of shares:

## **Class A Ordinary Shares**

On April 6, 2021, the Company's Class A Ordinary Shares began trading on the Nasdaq Stock Market under the symbol "MLTX." As of September 30, 2022, there were 36,925,639 Class A Ordinary Shares issued or 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**

On the Closing Date, the Company issued 15,775,472 Class C Ordinary Shares to the ML Parties (other than the BVF Shareholders) in an amount equivalent to the ML Parties' (other than the BVF Shareholders) 468,968 MoonLake AG Common Shares multiplied by the Exchange Ratio. As of September 30, 2022, there were 15,775,472 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.



## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

**SEPTEMBER 30, 2022** 

(Amounts in USD, except share and per share data)

## (Unaudited)

At the Closing, 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. Subsequent to September 30, 2022, a number of MoonLake AG Common Shares and Class C Ordinary Shares were converted into MoonLake Immunotherapeutics Class A Ordinary Shares (please see Note 16 - *Subsequent Events* for additional information). The foregoing description of the A&R Shareholders' Agreement is not complete and is qualified in its entirety by reference to the full text of the A&R Shareholders' Agreement.

## Note 12 — Net Loss per Share

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

The following table sets forth the loss per share calculations for the three and nine months ended September 30, 2022 compared to the three and nine months ended September 30, 2021:

	Three Months En	ded	September 30,	Nine Months Ended September 30,				
	2022		2021	2022		2021		
Numerator								
Net loss attributable to controlling interests shareholders	\$ (10,110,452)	\$	(6,288,056)	\$ (32,865,429)	\$	(39,325,510)		
Denominator								
Total weighted average number of outstanding shares	36,925,639		2,390,587	25,830,560		9,689,627		
Net loss per share – basic and diluted	\$ (0.27)	\$	(2.63)	\$ (1.27)	\$	(4.06)		

The weighted average number of shares used to calculate the net loss per share – basic for the three months and the nine months ended September 30, 2022 excludes 15,775,472 Class C Ordinary Shares as they do not carry economic rights.

In the event that ML Parties (other than the BVF Shareholders) elected to convert their 468,968 MoonLake AG Common Shares into 15,775,472 Class A Ordinary Shares on the Closing Date, the weighted average number of shares outstanding would have been 52,701,111 and 36,116,399 for the three and nine months ended September 30, 2022, resulting in a respective net loss per share of \$(0.28) and \$(1.33). Upon conversion, 15,775,472 Class C Ordinary Shares would be forfeited and there would no longer be any noncontrolling interests.

Upon conversion, the Company's number of Class A Ordinary Shares outstanding would be 52,701,111 as of November 14, 2022, the date the unaudited condensed consolidated financial statements were issued.

## Note 13 — Share-based Compensation

As at September 30, 2022 the Company had the following share-based compensation arrangements:

- a. Restricted Founder Shares created in April 2021 by MoonLake AG;
- b. The Employee Share Participation Plan ("ESPP") created in July 2021 by MoonLake AG;

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

**SEPTEMBER 30, 2022** 

(Amounts in USD, except share and per share data)

## (Unaudited)

c. The Employee Stock Option Plan ("ESOP") – created in July 2021 by MoonLake AG;

d. MoonLake Immunotherapeutics 2022 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.

As a result of the Business Combination, the Company has adjusted the share numbers related to the Restricted Founder Shares and Common Shares (under the ESPP and ESOP) prior to the Business Combination by the Exchange Ratio. The assumptions used in the valuation of the awards granted prior to Closing of the Business Combination have not been adjusted. The reference to "Common Shares" in this Note 13 refers to shares in MoonLake AG.

MoonLake AG's compensation plans are settled with Common Shares, and with a number of Class C Ordinary Shares determined multiplying the 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 (please see Note 11 — *Shareholders' Equity (Deficit) - Class C Ordinary Shares*).

For the three and nine months ended September 30, 2022, the Company has recognized an increase in equity in the condensed consolidated balance sheet, and share-based compensation expense in the condensed consolidated statement of operations of \$2.6 million and \$7.1 million respectively. The share-based compensation expense was driven by the following share-based compensation plans and programs:

Compensation Plan	Three months ended September 30, 2022	Three months ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
MoonLake AG Restricted Founder Shares	\$ 1,210,191	\$ 1,815,078	\$ 3,618,226	\$ 3,065,443
ESPP	1,080,441	39,436	2,829,635	39,436
ESOP	169,907	1,313	370,634	1,313
MoonLake Immunotherapeutics 2022 Equity Incentive Plan	124,621	—	239,760	_
Total share-based compensation expense <sup>1</sup>	\$ 2,585,160	\$ 1,855,827	\$ 7,058,255	\$ 3,106,192
Of which: included in R&D expense	 161,987	5,461	380,917	5,461
Of which: included in G&A expense	2,423,173	1,850,366	6,677,338	3,100,731

(1) In order to acquire the in-licensing agreement, the Company transferred to Merck KGaA, Darmstadt, Germany on April 28, 2021: (i) a cash consideration of \$25.0 million; and (ii) an equity consideration of 99,000 Common Shares (the equivalent of 3,330,231 Class C Ordinary Shares) for a total payment of \$1. The fair value of the equity consideration of \$4,851,000 was recorded as share-based portion for the in-licensing agreement for the IPR&D asset ("In-licensing Agreement") and does not belong to any compensation plan.

As of September 30, 2022, 22,756 treasury shares (the equivalent of 765,482 Class C Ordinary Shares) and 14,596 Common Shares (the equivalent of 490,990 Class C Ordinary Shares) issuable from the authorized conditional capital shares remain available for future grants under the ESPP and the ESOP by MoonLake AG.

MoonLake AG - Restricted Founder Shares

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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(Amounts in USD, except share and per share data)

## (Unaudited)

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 vest on the 28th of each month at a rate of 4.166% over a period of two years until April 28, 2023. If, before the end of the vesting period, the contractual relationship of the relevant co-founders is terminated, MoonLake AG in first priority, or any third party designated by it, and the other shareholders in second priority pro rata to their shareholdings, shall have an option to purchase all or a pro rata portion of the leaver shares that are unvested on the day the termination becomes effective at nominal value of CHF 0.10 (equivalent of \$0.0001) per share.

The assumptions used in the valuation of the Restricted Founder Shares awarded are summarized below:

Grant date	4/28/2021				
Estimated fair value per share of Restricted Founder Shares on the grant date (\$) <sup>(1)</sup>	49				
Estimated fair value of Restricted Founder Shares on the resignation date of one of the co-founders of MoonLake AG () <sup>(2)</sup>	336.39				
Purchase price (CHF)	0.10				
(1) MoonLake AG estimated the fair value of the Restricted Founder Shares with reference to the market-based transaction with the other Series A Preferred Shares Investors (refer to Note 9 of the audited consolidated					

<sup>(1)</sup>MoonLake AG estimated the fair value of the Restricted Founder Shares with reference to the market-based transaction with the other Series A Preferred Shares Investors (refer to Note 9 of the audited consolidated financial statements for the year ended December 31, 2021).

<sup>(2)</sup> MoonLake AG estimated the fair value of the Restricted Founder Shares at co-founder's resignation date 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).

Grants awarded	
Program	<b>Restricted Founder Shares</b>
Awards outstanding at January 1, 2022	4,440,309
Awards vested for the nine months ended September 30, 2022	(2,497,673)
Awards outstanding at September 30, 2022	1,942,634

As of September 30, 2022, MoonLake AG had \$2.8 million of total unrecognized compensation expense related to the Restricted Founder Shares that will be recognized by April 28, 2023 with a monthly compensation expense of \$403,416.

## 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 the grants will be deemed fully vested on the earlier of (i) 12 months (or such shorter period determined by the board of directors) after the occurrence of a "change of control" or (ii) the date after the occurrence of the change of control on which a termination notice is served to the participant by MoonLake AG (other than a bad leaver termination, described below) or by the participant for good cause (as defined under Swiss law or any other applicable foreign law). For awards made after September 30, 2021, the Closing of the Business Combination between MoonLake AG and Helix does not qualify as a Change of Control.

The assumptions used in the valuation of the grants awarded under the ESPP for the nine months ended September 30, 2022 are summarized below:

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

**SEPTEMBER 30, 2022** 

(Amounts in USD, except share and per share data)

## (Unaudited)

## **ESPP 2021**

Assumptions for the awards issued during the nine months ended September 30, 2022					
01/18/2022					
336.39					
0.10					

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 share: (1,070,196)

Grants awarded	
Program	ESPP
Awards outstanding at January 1, 2022	1,060,561
Awards granted for the nine months ended September 30, 2022	1,177,354
Awards outstanding at September 30, 2022	2,237,915
Awards vested at September 30, 2022	265,241

As of September 30, 2022, MoonLake AG had \$10.6 million of total unrecognized compensation expense related to the ESPP that will be recognized over the weighted average period of 2.02 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 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 MonLake AG or the Company, as the case may be, where the grants will be deemed fully vested on the earlier of (i) 12 months (or such shorter period determined by the board of directors) after the occurrence of a "change of control" or (ii) the date after the occurrence of the change of control on which a termination notice is served to the participant by MonLake AG (other than a bad leaver termination, described below) or by the participant for good cause (as defined under Swiss law or any other applicable foreign law). For awards made after September 30, 2021, the Closing of the Business Combination between MoonLake AG and Helix does not qualify as a Change of Control.

## Weighted average assumptions for the awards issued during the nine months ended September 30, 2022

Grant dates	5/1/2022, 6/22/2022
Estimated fair value of the option on the grant date using Black-Scholes model (\$) <sup>(1)</sup>	172.57
Exercise price (CHF)	27.25
Expected term of the award on the grant date (years) <sup>(2)</sup>	6
Expected volatility of the share price <sup>(3)</sup>	0.75
Risk-free interest rate <sup>(4)</sup>	3%
Expected dividend rate	0

(1) MoonLake AG estimated the fair value of the Common Shares multiplying the MoonLake Immunotherapeutics closing date trading share price on the grant date by the Exchange Ratio

(2) The expected term represents the period that share-based awards are expected to be outstanding.
 (3) The expected volatility was derived from the historical stock volatilities of comparable peer public companies within the Company's industry

(4) 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

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2022

(Amounts in USD, except share and per share data)

## (Unaudited)

Grants awarded	
Program	ESOP
Awards outstanding at January 1, 2022	224,033
Awards granted for the nine months ended September 30, 2022	242,737
Awards outstanding at September 30, 2022	466,770
Awards exercisable at September 30, 2022	23,311

As of September 30, 2022, MoonLake AG had \$2.0 million of total unrecognized compensation expense related to the ESOP that will be recognized over the weighted average period of 2.89 years.

## MoonLake Immunotherapeutics 2022 Equity Incentive Plan

On April 5, 2022 (the "Effective Date") the Company created the "MoonLake Immunotherapeutics 2022 Equity Incentive Plan" (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.

On April 6, 2022, the Company granted 180,000 options under the Equity Incentive Plan, each option representing the right to acquire one Class A Ordinary Share, par value \$0.0001 per share, of MoonLake. The options will vest one-third on each April 6, 2023, April 6, 2024 and April 6, 2025.

During the nine months ended September 30, 2022, no other grants were awarded under the Equity Incentive Plan.

Grant date	4/6/2022
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)	6
Expected volatility of the share price	75%
Risk-free interest rate	3%
Expected dividend rate	-

Grants awarded	
Program	MoonLake Immunotherapeutics 2022 Equity Incentive Plan
Awards outstanding at January 1, 2022	—
Awards granted for the nine months ended September 30, 2022	180,000
Awards outstanding at September 30, 2022	180,000
Awards exercisable at September 30, 2022	_

As of September 30, 2022, the Company had \$1.2 million of total unrecognized compensation expense related to the Equity Incentive Plan that will be recognized over the weighted average period of 2.52 years.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

**SEPTEMBER 30, 2022** 

(Amounts in USD, except share and per share data)

## (Unaudited)

#### Note 14 — Income Taxes

The Company's effective tax rate ("ETR") was 0.1% and 0.1% for each of the three and nine months ended September 30, 2022, respectively, and 0.0% for each of the three and nine months ended September 30, 2021. The Company is not aware of any items that would cause the quarterly or period-to-date ETR to be significantly different from the Company's annual ETR. The difference between the income tax provision that would be derived by applying the statutory rate to the Company's loss before income taxes and the income tax provision recorded was primarily attributable to the change in the valuation allowance. The Company continues to incur losses for the Cayman Island and Swiss entity and its ability to utilize the deferred tax asset related to the tax losses is not considered more likely than not.

## Note 15 — Commitments and Contingencies

#### **Commitments**

The Company has entered into agreements as of September 30, 2022 primarily in regard to advancement of clinical and non-clinical research program expenses, production of drug substance and technology transfer of the drug product process for SLK.

As of September 30, 2022, the total committed amount under these agreements not yet recognized amounted to \$37.4 million.

On April 2021, MoonLake AG acquired the SLK program, which 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 and royalty payments based on net sales. Subject to the terms of the license, additional milestone payments of up to  $\in$ 302.1 million (\$295.5 million using a September 30, 2022 exchange rate) are potentially payable, of which less than 1 percent being due upon initiation of the next clinical trial and the remainder being due 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. In addition, the In-licensing Agreement requires the Company to pay royalties within the range of low to mid-teen percent of net sales. Royalties will be recognized in the consolidated statement of operations when net sales are recognized.

The Company has committed to a lease contract with a term that commenced on November 1, 2021. We have accounted for this open-ended office lease arrangement as an operating lease under the guidance prior to ASU 2016-02, Leases Topic 842 through the consolidated statement of operations for the three and nine months period ended June 30, 2022. The future lease commitments in the amount of \$0.3 million relate to office contract for our headquarters in Zug, Switzerland and reflects minimum payments due.

## Note 16 — Subsequent Events

## Partial Share Conversion

On October 6, 2022, pursuant to the A&R Shareholders' Agreement, an ML Party submitted an Exchange Notice to the Company, pursuant to which such ML Party effected the conversion of 61,000 MoonLake AG Common Shares and 2,051,961 Class C Ordinary Shares into 2,051,961 Class A Ordinary Shares using the Exchange Ratio. Please refer to Note 11 – Shareholders' Equity (Deficit) – Class C Ordinary Shares for more information regarding the conversion mechanics.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements as of and for the three and nine months ended September 30, 2022, appearing elsewhere in this quarterly report ("Quarterly Report") on Form 10-Q, and with MoonLake AG's audited financial statements and notes thereto for the year ended December 31, 2021 included in the Form S-1/A filed with the SEC on July 26, 2022, declared effective on August 2, 2022. Our unaudited condensed consolidated financial statements as of and for the three and nine months ended September 30, 2022 were prepared in accordance with U.S. GAAP and presented in United States dollars (\$).

References to "we," "us", "our", "MoonLake" or the "Company" refer to MoonLake Immunotherapeutics, and references to our "management" refer to our officers and directors.

The following discussion has been presented to give effect to the restatement disclosed in Note 3 within the Notes to the Unaudited Condensed Consolidated Financial Statements of this Quarterly Report.

## Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q 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 (the "Securities Act") 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 Quarterly Report on Form 10-Q, 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, and the plans and objectives of management for future operations and capital expenditures. 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 Quarterly Report on Form 10-Q 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 Quarterly Report contains forward-looking statements that reflect our plans and strategy for our business and related financing. Our actual results and the timing of events could differ materially from those anticipated in the forward-looking statements. Factors that could cause or contribute to these differences include but are not limited to those discussed below and elsewhere in the Quarterly Report, particularly in the section titled "Risk Factors". These forward-looking statements are subject to a number of important risks and uncertainties that could cause actual results to differ materially from those in the forward-looking statements, including but not limited to:

- our ability to:
  - realize the benefits expected from the Business Combination (as defined below in the section entitled "Business Combination"); and
  - maintain the listing of our Class A Ordinary Shares on The Nasdaq Capital Market ("Nasdaq");
- 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:
  - our limited operating history;
  - while we have initiated a clinical trial, we have not completed any clinical trials, and we have no products approved for commercial sale;

- 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;
- 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;
- we are substantially dependent on the success of our novel tri-specific nanobody, sonelokimab, 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 renew existing contracts;
- our ability to obtain regulatory approval for our products, and any related restrictions or limitations of any approved products;
- our ability to respond to general economic conditions;
- our ability to manage our growth effectively;
- the impact of the COVID-19 pandemic;
- the impact of adverse business and economic conditions including inflationary pressures, general economic slowdown or a recession, increasing interest rates, and changes in monetary policy;
- competition and competitive pressures from other global companies in the industries in which we operate;
- · litigation and the ability to adequately protect our intellectual property rights; and
- the other factors described under the caption "Risk Factors" in our final prospectus filed with the Securities and Exchange Commission (the "SEC") pursuant to Rule 424(b)(3) on August 2, 2022, (the "Final Prospectus"), as updated in this Quarterly Report on Form 10-Q, and our other filings with the SEC.

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.

You should read this Quarterly Report on Form 10-Q 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.

## **Overview**

We are a clinical-stage biotechnology company advancing transformative therapies to address significant unmet needs in inflammatory skin and joint diseases. Our novel tri-specific Nanobody® Sonelokimab, ("SLK") is an IL-17A and IL-17F inhibitor that has the potential, based on high response levels in clinical trials, to drive disease modification in dermatology and rheumatology patients.

The terms "Nanobody" and "Nanobodies" used herewith are registered trademarks of Ablynx, a Sanofi company ("Ablynx"). SLK is a proprietary Nanobody exclusively licensed from MHKDG. Nanobodies are able to bind selectively to a specific antigen with high affinity. Nanobodies have the same or higher affinity and specificity compared to traditional antibodies yet have a fraction of the molecular weight. They offer a number of potential advantages including an easier manufacturing process, a higher thermostability, and the potential to create multivalent molecules with enhanced ability to penetrate inflamed tissue, especially when containing an additional albumin binding domain such as SLK. We are developing a portfolio of therapeutic indications for SLK, and are focused on demonstrating its efficacy, safety and dosing convenience, initially in hidradenitis suppurativa ("HS") and psoriatic arthritis ("PsA"). We believe that SLK has a differentiated mechanism of action and potential to penetrate into deep skin and joint tissue. We envision SLK as a key therapeutic alternative in our initial target indications, and potentially in multiple other IL-17 driven inflammatory conditions. Building on the robust clinical data generated to date, we intend to further pursue the clinical development of SLK.

SLK was discovered by MHKDG and by Ablynx, and was previously studied by Avillion LLP under a 2017 co-development agreement with MHKDG in a Phase 2b clinical trial in over 300 moderate-to-severe psoriasis ("PsO") patients. In addition, Phase 1 single ascending and multiple ascending dosing trials were previously completed, bringing the total number of patients in SLK-related trials to more than 400. In the Phase 2b study, SLK showed a significant improvement in the primary end point as compared with placebo and numerically outperformed the control group treated with the current standard of care, secukinumab (also known as Cosentyx). In the highest dosage group, 57% of patients achieved total skin clearance (Psoriasis Area Severity Index, or PASI 100 response) after 24 weeks. 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. This study highlights SLK's promise as a treatment for inflammatory diseases and underscores the importance of the cytokines IL-17A and IL-17F by showing differentiated clinical outcomes between treatment with SLK (an inhibitor of IL17A and IL-17F) and secukinumab (an inhibitor of IL-17A). We believe this study demonstrates how critical both IL17A and IL17F are in optimizing the balance between inflammatory response and infection defense.

We plan to 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 initial target diseases (HS and PsA) among several other inflammatory conditions (including radiographic axial spondyloarthritis and moderate-to-severe PsO). Our initial target diseases affect millions of people worldwide, and we believe there is a need for improved treatment options. SLK's purposefully designed molecular characteristics, including its albumin binding site are intended to facilitate deep tissue penetration in the skin and joints. In April 2022, we commenced Phase 2 trials for the therapeutic indications of HS, in both the United States and Europe. Patient enrollment is progressing as planned and the primary end point data readout is expected in mid-2023. Our Phase 2 clinical trial in PsA has recently been cleared by the U.S. Food and Drug Administration and the protocol was approved by the central Institutional Review Board. We expect to commence enrollment of patients across the United States and Europe before the end of 2022 and to read out primary end point data towards the end of 2023. There are several additional indications that we could choose to explore, if warranted. Currently, we do not plan to initiate Phase 3 clinical trials in PsO, but we will continue to evaluate this options in the fuure.

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.

On April 5, 2022, we completed the Business Combination and the total funding raised amounted to \$134.7 million (net of transaction related expenses). As of September 30, 2022, we had \$41.2 million of cash and cash equivalents, of which \$19.9 million relate to investments in short-term marketable debt securities with an original maturity of three months or less at the date of purchase, and \$42.3 million of short-term marketable debt securities with an original maturity of more than three months at the date of purchase. Based on our current operating plans, we believe that our existing cash, cash equivalents and short-term marketable securities, together amounting to \$83.5 million, will be sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2024.

We expect to continue to incur significant expenses and operating losses for at least the next five years as we continue the development of SLK. 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.

#### **Business Combination**

We were originally incorporated on August 13, 2020 in the Cayman Islands as a special purpose acquisition company under the name Helix Acquisition Corp. ("Helix"), formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, recapitalization, reorganization or similar business combination with one or more businesses. Helix completed its initial public offering on October 22, 2020. 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, 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 equity holders of MoonLake AG set forth on the signature pages to the Business Combination Agreement and the equityholders of MoonLake AG that executed joinders to the Business Combination Agreement (collectively, the "ML Parties"), Helix Holdings LLC, a Cayman Islands limited liability company and the sponsor of Helix, and the representative of the ML Parties (such transactions contemplated by the Business Combination Agreement, collectively, the "Business Combination"). Pursuant to the Business Combination Agreement, MoonLake AG merged with and into Helix, with MoonLake AG as the surviving company in the Business Combination and, after giving effect to such Business Combination, MoonLake AG became our subsidiary. In connection with the consummation of the Business Combination, we changed our name from Helix Acquisition Corp. to MoonLake Immunotherapeutics.

The Business Combination was accounted for as a reverse recapitalization, in accordance with U.S. GAAP. 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.

## **COVID-19** Pandemic

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. To date, the impact of COVID-19 on our business, operations and development timelines has been limited.

We will continue to actively monitor the evolving situation related to COVID-19 and may take further actions that alter our operations, including those that may be required by Switzerland state or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business. At this point, the extent to which COVID-19 may affect our future business, operations and development timelines and plans, including the resulting impact on our expenditures and capital needs, remains uncertain and we may experience disruptions, including interruption of or delays in receiving supplies from the third parties that we rely on; limitations on our business operations by the Swiss federal, cantonal and/or local authorities; limitations on our ability to progress with the clinical studies; business disruptions caused by workplace, laboratory and office closures and an increased reliance on employees working from home, travel limitations, cybersecurity and data accessibility limits, or communication disruptions; and limitations on the conduct of our activities, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.

## **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. 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, 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. Our clinical development costs are expected to increase significantly when we progress into Phase 3 clinical trials.

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 Food and Drug Administration, the European Medicine Agency, 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:

- Building the leading efficacy and safety profile of SLK for patients We expect to incur significant research and development expenses, and G&A expenses as we: (i) conduct and initiate further clinical trials for SLK; (ii) seek regulatory approvals for SLK; (iii) make milestone and commercial payments under the License Agreement, dated April 29, 2021, by and between MoonLake AG and MHKDG (based on initiation of various clinical trials, regulatory filing acceptance, first commercial sales, and aggregate annual net sales); (iv) establish a sales, marketing and distribution infrastructure to commercialize SLK; (v) attract, hire and retain additional clinical, scientific, quality control, and administrative personnel; and (vi) add clinical, operational, financial and management information systems and personnel.
- Strengthening the differentiation elements for future SLK patients In parallel with our Phase 2 program, 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.
- 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 contract manufacturing organizations for both drug substance and finished drug product. We obtain our supplies from these manufacturers based on purchase orders. Therefore, we expect to incur research and development costs for the purchase of our supplies on an as needed basis to conduct our clinical trials. We pursue technology transfers into commercial scale contract manufacturing organizations. This is designed to allow us to scale-up while SLK is in clinical development and advance potential Phase 3 and 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.
- 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.
- Licensing/broadening our portfolio 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 AG's Employee Stock Option Plan ("ESOP"), MoonLake AG's Employee Share Participation Plan ("ESPP"), and MoonLake Immunotherapeutics 2022 Equity Incentive Plan. Further, we expect to continue to incur share-based compensation charges in connection with the above-mentioned plans and with the Restricted Founder Shares which have been granted to the cofounders.

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 will require substantial additional funding to continue the development of SLK 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 proceeds received in connection with the Business Combination, the sale of equity, debt financings, or other capital sources, which could include income from collaborations, strategic partnerships, or marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. Our business strategy includes the exploration of out-licensing opportunities with respect to commercial rights in non-U.S. geographies where we may not be the best party to pursue the commercialization of SLK, including in China. Any such arrangements would provide for up-front payments and/or royalty and milestone payments that could be used to help finance our operations. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all. Our ability to raise additional funds 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 resulting from geopolitical events, the COVID-19 pandemic and otherwise. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to have to delay, reduce or eliminate our product development or future commercialization efforts. Insufficient liquidity may also require us to relinquish rights to SLK at an earlier stage of development or on less favorable terms than we would otherwise choose. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our development efforts.

## 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. Revenue and expenses are translated at the daily exchange rate on the respective transaction date.

Gain or losses from foreign currency translation are included in other expenses in the unaudited condensed consolidated statement of operations. The Company recognized foreign currency transaction gain of \$344,914 for the nine months ended September 30, 2022, and a gain of \$4,361 for the three months ended September 30, 2022. For the three and nine months ended September 30, 2021, MoonLake AG recognized a foreign currency transaction loss of \$19,853 and \$24,543 respectively.

## **Results of Operations**

## Comparison of the three months ended September 30, 2022 and 2021

	 Three Months Ended September 30, 2022	 Three Months Ended September 30, 2021	 Change	Change %
Operating expenses			 	
Research and development	\$ (9,024,437)	\$ (669,528)	\$ (8,354,909)	1,247.9 %
General and administrative	(5,746,064)	(5,597,688)	(148,376)	2.7 %
Total operating expenses	 (14,770,501)	\$ (6,267,216)	 (8,503,285)	135.7 %
Operating loss	(14,770,501)	\$ (6,267,216)	 (8,503,285)	135.7 %
Other income (expense), net	37,593	\$ (20,840)	58,433	280.4 %
Loss before income tax	(14,732,908)	\$ (6,288,056)	(8,444,852)	134.3 %
Income tax expense	(8,740)	\$ —	(8,740)	-
Net loss	 (14,741,648)	\$ (6,288,056)	 (8,453,592)	134.4 %
Net unrealized gain on marketable securities and short term investments	77,006	_	77,006	
Actuarial income (loss) on employee benefit plans	89,586	\$ 1,000	88,586	8,858.6 %
Other comprehensive income (loss)	 166,592	\$ 1,000	 165,592	16,559.2 %
Comprehensive loss	\$ (14,575,056)	\$ (6,287,056)	\$ (8,288,000)	131.8 %

## Research and Development

Research and development expenses were \$9.0 million for the three months ended September 30, 2022, compared to \$0.7 million for the three months ended September 30, 2021. The increase of \$8.4 million compared to three months ended September 30, 2021, was primarily due to \$5.5 million in contracted clinical and non-clinical research services, \$1.9 million in supply and logistic services, \$0.5 million in consulting fees, and \$0.5 million in personnel related expense.

## General and Administrative

General and administrative expenses were \$5.7 million for the three months ended September 30, 2022, in line with \$5.6 million for the three months ended September 30, 2021. The expense recorded for the three months ended September 30, 2022 is primarily related to share-based compensation in the amount of \$2.4 million, personnel related expense in the amount of \$1.1 million, consulting and communication fees in the amount of \$1.0 million, \$0.7 million of insurance expenses, and \$0.5 million related to other G&A.

Other Income (Expense), Net

For the three months ended September 30, 2022, we recognized \$37,593 in other income, compared to an expense of \$20,840 for the three months ended September 30, 2021. The increase of \$58,433 is primarily due to foreign currency exchange gains.

## Income Tax Expense

For the three months ended September 30, 2022, we recognized income tax expense of \$8,740 which was related to the corporate income tax of our U.K. subsidiary. No income tax was recorded for the three months ended September 30, 2021.

## Other Comprehensive Income

The change in the actuarial income (loss) on employee benefit plans is related to an increase in the discount rates used to measure the present value of the liabilities, which has reduced the net liability position as of September 30, 2022. The net unrealized gain on marketable securities and short term investments relates to cash investments in short term marketable debt securities during the three months ended September 30, 2022.

## Comparison of the nine months ended September 30, 2022 and 2021

	ne Months Ended ptember 30, 2022	 ine Months Ended eptember 30, 2021	 Change	Change %
Operating expenses				
Research and development	\$ (30,679,842)	\$ (30,536,746)	\$ (143,096)	0.5 %
General and administrative	(17,685,152)	(8,762,925)	(8,922,227)	101.8 %
Total operating expenses	 (48,364,994)	 (39,299,671)	 (9,065,323)	23.1 %
Operating loss	(48,364,994)	 (39,299,671)	(9,065,323)	23.1 %
Other income (expense), net	352,227	(25,839)	378,066	1,463.2 %
Loss before income tax	(48,012,767)	(39,325,510)	(8,687,257)	22.1 %
Income tax expense	(25,354)	_	(25,354)	-
Net loss	(48,038,121)	 (39,325,510)	 (8,712,611)	22.2 %
Net unrealized gain on marketable securities and short term investments	77,006	_	77,006	-
Foreign currency Translation	567	_	567	-
Actuarial income (loss) on employee benefit plans	456,883	—	456,883	-
Other comprehensive income (loss)	 534,456	 	 534,456	-
Comprehensive loss	\$ (47,503,665)	\$ (39,325,510)	\$ (8,178,156)	20.8 %



## Research and Development

Research and development expenses were \$30.7 million for the nine months ended September 30, 2022, compared to \$30.5 million for the nine months ended September 30, 2022 primarily related to the set up and conduct of clinical development trials in the amount of \$15.0 million, supply and logistic services in the amount of \$5.6 million, consulting fees in the amount of \$1.2 million, personnel related expense in the amount of \$1.3 million, an IPR&D milestone payment to MHKDG in the amount of \$5.4 million (€5.0 million), and \$2.0 million related to other research and development services from MHKDG. The research and development expenditures incurred during the nine months ended September 30, 2021 primarily related to the one-off cost of \$25.0 million related to the purchase of the licenses for the SLK IPR&D program, \$4.9 million recorded as share-based portion for the in-licensing agreement, and \$0.6 million related to other research and development services from MHKDG.

## General and Administrative

G&A expenses were \$17.7 million for the nine months ended September 30, 2022, compared to \$8.8 million for the nine months ended September 30, 2021. The increase of \$8.9 million was due to an increase of: \$3.6 million in the share-based compensation, \$1.3 million in personnel-related costs to support of organizational growth, \$1.5 million of professional and other fees sustained in anticipation of the Business Combination in connection with operating as a public company, \$0.3 million in professional fees (legal, accounting, consulting, tax and audit fees), \$1.5 million of insurance expenses, and \$0.7 million related to other G&A.

## Other Income (Expense), Net

For the nine months ended September 30, 2022, we recognized \$352,227 in other income, compared to an expense of \$25,839 for the nine months ended September 30, 2021. The increase of \$378,066 is primarily due to foreign currency exchange gains.

## Income Tax Expense

For the nine months ended September 30, 2022, we recognized an income tax expense of \$25,354 which was related to corporate income tax of the U.K. subsidiary. No income tax was recorded for the nine months ended September 30, 2021.

## Other Comprehensive Income

The change in the actuarial income (loss) on employee benefit plans is related to an increase in the discount rates used to measure the present value of the liabilities, which has reduced the net liability position as of September 30, 2022. The net unrealized gain on marketable securities and short term investments relates to cash investments in short term marketable debt securities during the three months ended September 30, 2022.

## 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 to support clinical trials related to SLK;
- · conduct our research and development activities related to SLK;
- attract, hire and retain additional management, scientific and administrative personnel;

- · maintain, protect and expand our intellectual property portfolio, including patents, trade secrets and know how;
- · implement operational, financial and management information systems; and
- operate as a public company.

We anticipate a significant future increase in our expenses and capital requirements when proceeding to potential Phase 3 clinical trials and the build-up of our commercialization capabilities; however, based on our current development plans, this is not expected to occur within the next twelve months.

We incurred a loss of \$48.0 million for the nine month period ended September 30, 2022 and had a total of \$83.5 million in cash, cash equivalents and short-term marketable debt securities as of September 30, 2022. 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 into the second half of 2024. We expect to incur significant expenses and operating losses for at least the next five years, assuming we commence and 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 and efforts to achieve regulatory approval. We will require substantial additional funding to develop our product candidate 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 operating, 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 the Final Prospectus 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.

	For the nine months ended				
	September 30, 2022	September 30, 2021			
Net cash used in operating activities	\$ (44,297,918)	\$ (27,723,178)			
Net cash used in investing activities	(42,242,030)	(32,332)			
Net cash provided by financing activities	119,688,944	28,264,076			
Effect of movements in exchange rates on cash held	16,826	(1,005)			
Net increase in cash and cash equivalents	\$ 33,165,822	\$ 507,561			

## 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 and infrastructure efforts.

Net cash used in operating activities was \$44.3 million for the nine months ended September 30, 2022, and was primarily related to clinical development research, compensation and personnel-related expenses, legal, and consulting expenses. During the nine months ended September 30, 2021, we used cash in operating activities of \$27.7 million, of which \$25.0 million related to the cash consideration for the acquisition of the In-licensing Agreement, dated April 28, 2021, by and between us and Merck Healthcare KGaA, Darmstadt, Germany (the "In-licensing Agreement").

## Cash Flows from Investing Activities

During the nine months ended September 30, 2022, \$42.2 of net cash used in investing activities related to the purchase of short-term marketable debt securities, and \$16,008 related to purchases of office equipment. During the nine months ended September 30, 2021, net cash used in investing activities of \$32,332 related to purchases of office equipment.

## Cash Flows from Financing Activities

During the nine months ended September 30, 2022, net cash provided by financing activities was \$119.7 million consisting of \$134.7 million of net proceeds from the Business Combination offset by the \$15.0 million loan repayment to the BVF Shareholders. During the nine months ended September 30, 2021, net cash provided by financing activities was \$28.3 million consisting of \$28.2 million of net proceeds from the issuance of MoonLake AG Series A Preferred Shares and \$0.1 million of net proceeds from the issuance of MoonLake AG Common Shares.

#### **Contractual Obligations and Commitments**

The following summarizes our significant contractual obligations and other obligations as of September 30, 2022:

	Total		Less than 1 year		1 to 5 Years	More than 5 years	
Purchase obligations <sup>(1)</sup>	\$	37,394,665	\$ 27,129,947	\$	10,264,718		_
Lease commitments <sup>(2)</sup>		305,202	146,497		158,705		_
Total contractual obligations	\$	37,699,867	\$ 27,276,444	\$	10,423,423		

(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 relate to contractual commitments towards contract manufacturing and contract research organizations.

(2) We have committed ourselves to a lease contract, with a term that commenced on November 1, 2021. We have accounted for the open-ended office lease arrangement as an operating lease under the guidance prior to ASU 2016-02, *Leases Topic 842* through the consolidated statement of operations for the three and nine months ended September 30, 2022. The future lease commitments relate to office contract for our headquarters in Zug, Switzerland and reflects minimum payments due.

# **Critical Accounting Policies and Estimates**

The preparation of the 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-Licensing 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 MoonLake under the In-licensing Agreement and substantially all of the fair value of the gross assets acquired related to the 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 three months period ended June 30, 2021.

### Share-based Transaction

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.

## Determination of Fair Value – Common Shares and Class A Ordinary Shares

Prior to the completion of the Business Combination, given that there had been no public market for our 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.

All of our share-based compensation arrangements contain service and performance conditions that, depending on the relevant equity plan, are settled with shares of MoonLake or MoonLake AG, as applicable and meet the definition of a share-based compensation arrangements. All awards granted under our various share-based compensation plans were classified as equity-settled share-based arrangements.

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.

#### **Determination of Fair Value – Share Option Awards**

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 term used by other publicly traded peer companies. 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.

# Accrued Research and Development Expenses

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. To date, our estimated accruals have not differed materially from actual costs incurred.

## **Recently Issued Accounting Pronouncements**

Refer to Note 3 — *Basis of Presentation and Significant Accounting Policies* to the unaudited condensed consolidated financial statements included elsewhere in this Form 10-Q for more information about recent accounting pronouncements, the timing of their adoption, and our assessment, to the extent it has made one, of their potential impact on our financial condition and our results of operations and cash flows.

# **Emerging Growth Company Status**

The Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to use this extended transition period under the JOBS Act until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult. In addition, our independent

registered public accounting firm is not required to formally attest to the effectiveness of our internal control over financial reporting until the date we are no longer an emerging growth company and reach accelerated filer status.

We will cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of \$1.235 billion or more, (ii) the last day of our fiscal year following the fifth anniversary of the date of the closing of Helix's initial public offering, (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Further, even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our Common Shares less attractive because we may rely on these exemptions. If some investors find our Common Shares less attractive as a result, there may be a less active trading market for our Common Shares and our share price may be more volatile.

#### Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company, as defined by Rule 12b-2 under the Exchange Act and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

# **Item 4. 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.

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 such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2022. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of September 30, 2022, due to the unremediated material weakness in our internal controls over financial reporting described below, our disclosure controls and procedures were not effective to provide assurance at a reasonable level.

## Limitations on Effectiveness of Controls and Procedures

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.

#### **Remediation of Previously Identified Material Weakness**

As previously disclosed, in the course of preparing the consolidated financial statements for the year ended December 31, 2021, our management identified an error resulting from our failure to correctly account for a vesting condition imposed on certain founder shares pursuant to the shareholders' agreement that we entered into with our shareholders on April 28, 2021. Following the identification of the aforementioned error, our management performed a root cause analysis and identified that the error related to a deficiency in the design and implementation of effective controls

relating to our management's review of complex and bespoke transactions. As such, our management determined that a material weakness in internal control over financial reporting existed at that time.

During the six months ended June 30, 2022, management completed a comprehensive review of our controls over our accounting conclusions involving significant contracts, including revisiting such transactions with input from relevant subject matter experts as determined necessary, reassessing the understanding of each transaction, evaluating the application of the underlying accounting standards to the transactions, and verifying the completeness, accuracy and reasonableness of the final accounting conclusions. Management has also updated the design of our controls to evaluate the need to involve relevant subject matter experts as part of the review controls associated with complex and bespoke accounting transactions. The material weakness will not be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

#### **Changes in Internal Control over Financial Reporting**

Other than the remedial measures discussed above, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three month period ended September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### PART II. OTHER INFORMATION

#### **Item 1. Legal Proceedings**

We are not currently subject to any material legal proceedings.

## Item 1A. Risk Factors

Any of the risks described in the Final Prospectus are factors that could cause our actual results to differ materially from those in this Quarterly Report. Any of these factors could result in a significant or material adverse effect upon our business, results of operations or financial condition. Additional risk factors not presently known to us or that we currently deem immaterial may also impair our business, results of operations or financial condition. Except as described below, there have been no material changes to the risk factors that we included in the Final Prospectus. We may make changes to such risk factors or disclose additional risk factors from time to time in our future filings with the SEC.

# 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. Most recently, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 ("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.

#### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

#### Item 3. Defaults Upon Senior Securities

None.

#### Item 4. Mine Safety Disclosures

Not applicable.

#### **Item 5. Other Information**

None.



# Item 6. Exhibits

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

No.	Description of Exhibit						
	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)						
3.1							
10.1+	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).						
10.2+	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).						
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						
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.

+ Indicates a management contract or compensatory plan.

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# SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

# MOONLAKE IMMUNOTHERAPEUTICS

			/s/ Dr. Jorge Santos da Silva		
Date:	November 14, 2022	Name:	Dr. Jorge Santos da Silva		
		Title:	Chief Executive Officer		
			(Principal Executive Officer)		
			/s/ Matthias Bodenstedt		
Date:	November 14, 2022	Name:	Matthias Bodenstedt		
		Title:	Chief Financial Officer		
			(Principal Financial and Accounting Officer)		

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# 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 Quarterly Report on Form 10-Q 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 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: November 14, 2022

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

# 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 Quarterly Report on Form 10-Q 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: November 14, 2022

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

# 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 Quarterly Report on Form 10-Q of MoonLake Immunotherapeutics (the "Company") for the period ended September 30, 2022 (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: November 14, 2022

By: <u>/s/ Jorge Santos Da Silva</u> 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.

# 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 Quarterly Report on Form 10-Q of MoonLake Immunotherapeutics (the "Company") for the period ended September 30, 2022 (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: November 14, 2022

By: <u>/s/ Matthias Bodenstedt</u> 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.