UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(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, 2023

OR

☐ **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: 001-38582

Allakos Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**45-4798831**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
825 Industrial Road, Suite 500 San Carlos, California	**94070**
(Address of principal executive offices)	**(Zip Code)**

(650) 597-5002
Registrant's telephone number, including area code

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value $0.001	ALLK	The Nasdaq Global Select Market

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

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

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

As of November 7, 2023, the registrant had 87,476,338 shares of common stock outstanding.

ALLAKOS INC.
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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (unaudited).

ALLAKOS INC.
BALANCE SHEETS
(in thousands, except per share data)

	September 30, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 70,519	$ 87,217
Investments	123,389	192,569
Prepaid expenses and other current assets	24,371	29,057
Total current assets	218,279	308,843
Property and equipment, net	34,965	39,144
Operating lease right-of-use assets	24,167	30,225
Other long-term assets	6,084	8,208
Total assets	$ 283,495	$ 386,420
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 915	$ 4,832
Accrued expenses and other current liabilities	22,535	25,206
Total current liabilities	23,450	30,038
Operating lease liabilities, net of current portion	39,002	45,949
Total liabilities	62,452	75,987
Contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.001 par value per share; 20,000 shares authorized as of September 30, 2023 and December 31, 2022; no shares issued and outstanding as of September 30, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value per share; 200,000 shares authorized as of September 30, 2023 and December 31, 2022; 87,476 and 85,387 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	87	85
Additional paid-in capital	1,276,954	1,243,408
Accumulated other comprehensive loss	(72)	(284)
Accumulated deficit	(1,055,926)	(932,776)
Total stockholders' equity	221,043	310,433
Total liabilities and stockholders' equity	$ 283,495	$ 386,420

See accompanying notes to unaudited interim financial statements

ALLAKOS INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses				
Research and development	$ 36,749	$ 18,438	$ 97,107	$ 229,693
General and administrative	11,461	13,007	33,966	46,520
Total operating expenses	48,210	31,445	131,073	276,213
Loss from operations	(48,210)	(31,445)	(131,073)	(276,213)
Interest income	2,590	711	7,965	898
Other expense, net	(6)	(103)	(42)	(1,648)
Net loss	(45,626)	(30,837)	(123,150)	(276,963)
Unrealized gain on investments	87	196	212	89
Comprehensive loss	$ (45,539)	$ (30,641)	$ (122,938)	$ (276,874)
Net loss per common share:				
Basic and diluted	$ (0.52)	$ (0.53)	$ (1.42)	$ (4.95)
Weighted-average number of common shares outstanding:				
Basic and diluted	87,115	58,169	86,539	55,905

See accompanying notes to unaudited interim financial statements

ALLAKOS INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)
(unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2022	85,387	$ 85	$ 1,243,408	$ (284)	$ (932,776)	$ 310,433
Stock-based compensation expense	—	—	10,665	—	—	10,665
Issuance of common stock upon exercise of stock options	6	—	26	—	—	26
Issuance of common stock upon 2018 ESPP purchase	144	—	442	—	—	442
Issuance of common stock upon vesting of restricted stock units	881	1	(1)	—	—	—
Issuance of common stock under the ATM Offering, net of issuance costs	142	—	990	—	—	990
Unrealized gain on investments	—	—	—	296	—	296
Net loss	—	—	—	—	(42,404)	(42,404)
Balance at March 31, 2023	86,560	$ 86	$ 1,255,530	$ 12	$ (975,180)	$ 280,448
Stock-based compensation expense	—	—	9,821	—	—	9,821
Issuance of common stock upon vesting of restricted stock units	263	1	(1)	—	—	—
Unrealized loss on investments	—	—	—	(171)	—	(171)
Net loss	—	—	—	—	(35,120)	(35,120)
Balance at June 30, 2023	86,823	87	1,265,350	(159)	(1,010,300)	254,978
Stock-based compensation expense	—	—	10,534	—	—	10,534
Issuance of common stock upon exercise of stock options	200	—	647	—	—	647
Issuance of common stock upon 2018 ESPP purchase	137	—	423	—	—	423
Issuance of common stock upon vesting of restricted stock units	316	—	—	—	—	—
Unrealized gain on investments	—	—	—	87	—	87
Net loss	—	—	—	—	(45,626)	(45,626)
Balance at September 30, 2023	87,476	$ 87	$ 1,276,954	$ (72)	$ (1,055,926)	$ 221,043

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	54,622	$ 54	$ 1,058,399	$ (153)	$ (612,824)	$ 445,476
Stock-based compensation expense	—	—	11,392	—	—	11,392
Issuance of common stock upon exercise of stock options	34	—	104	—	—	104
Issuance of common stock upon 2018 ESPP purchase	42	—	243	—	—	243
Issuance of common stock upon vesting of restricted stock units	63	—	—	—	—	—
Unrealized loss on investments	—	—	—	(316)	—	(316)
Net loss	—	—	—	—	(197,023)	(197,023)
Balance at March 31, 2022	54,761	$ 54	$ 1,070,138	$ (469)	$ (809,847)	$ 259,876
Stock-based compensation expense	—	—	11,761	—	—	11,761
Issuance of common stock upon exercise of stock options	25	—	66	—	—	66
Issuance of common stock upon vesting of restricted stock units	58	—	—	—	—	—
Unrealized gain on investments	—	—	—	209	—	209
Net loss	—	—	—	—	(49,103)	(49,103)
Balance at June 30, 2022	54,844	$ 54	$ 1,081,965	$ (260)	$ (858,950)	$ 222,809
Stock-based compensation expense	—	—	10,732	—	—	10,732
Issuance of common stock upon exercise of stock options	346	1	492	—	—	493
Issuance of common stock upon 2018 ESPP purchase	62	—	195	—	—	195
Issuance of common stock upon vesting of restricted stock units	59	—	—	—	—	—
Issuance of common stock upon registered direct offering, net	29,882	30	140,561	—	—	140,591
Unrealized gain on investments	—	—	—	196	—	196
Net loss	—	—	—	—	(30,837)	(30,837)
Balance at September 30, 2022	85,193	$ 85	$ 1,233,945	$ (64)	$ (889,787)	$ 344,179

See accompanying notes to unaudited interim financial statements

ALLAKOS INC.
STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (123,150)	$ (276,963)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,594	5,560
Stock-based compensation	31,020	33,885
Net amortization (accretion) of premiums and discounts on investments	(4,324)	2,335
Noncash lease expense	1,106	2,459
Loss on disposal of property and equipment	3	28
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	4,790	12,569
Other long-term assets	2,124	(1,051)
Accounts payable	(3,709)	(8,820)
Accrued expenses and other current liabilities	(2,372)	157
Operating lease liabilities, net of current portion	(2,294)	(3,344)
Net cash used in operating activities	(92,212)	(233,185)
Cash flows from investing activities		
Purchases of investments	(139,388)	(139,958)
Proceeds from sales of investments	—	19,989
Proceeds from maturities of investments	213,000	270,000
Proceeds from sale of property and equipment	—	1,169
Purchases of property and equipment	(626)	(8,042)
Net cash provided by investing activities	72,986	143,158
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	990	140,591
Proceeds from exercise of stock options	673	663
Proceeds from issuance of common stock under the 2018 ESPP	865	438
Net cash provided by financing activities	2,528	141,692
Net increase (decrease) in cash, cash equivalents and restricted cash	(16,698)	51,665
Cash, cash equivalents and restricted cash, beginning of period	88,689	155,097
Cash, cash equivalents and restricted cash, end of period	$ 71,991	$ 206,762
Supplemental disclosures		
Noncash investing and financing items:		
Noncash adjustments to right-of-use assets	$ (5,617)	$ —
Right-of-use assets obtained in exchange for lease obligations	$ 665	$ 1,216
Decrease in payables related to purchase of property and equipment	$ (208)	$ (4,170)

See accompanying notes to unaudited interim financial statements

1. Organization and Business

Allakos Inc. ("Allakos" or the "Company") was incorporated in the State of Delaware in March 2012. Allakos is a clinical stage biopharmaceutical company focused on the development of lirentelimab (AK002) and AK006 for the treatment of eosinophil and mast cell related diseases. The Company's primary activities to date have included establishing its facilities, recruiting personnel, conducting research and development of its product candidates and raising capital. The Company's operations are located in San Carlos, California. The Company operates in one reportable segment.

Liquidity Matters

Since inception, the Company has incurred net losses and negative cash flows from operations. During the nine months ended September 30, 2023, the Company incurred a net loss of $123.2 million. At September 30, 2023, the Company had an accumulated deficit of $1,055.9 million and does not expect to experience positive cash flows from operating activities in the foreseeable future. The Company has financed its operations to date primarily through the sale of common stock. Management expects to incur additional operating losses in the future as the Company continues to further develop, seek regulatory approval for and, if approved, commence commercialization of its product candidates.

Due to the clinical study results released in December 2021, our Board of Directors approved in February 2022 plans to reduce our contractual commitments and a reorganization plan (the "Reorganization Plan") to reduce operating costs and better align our workforce with the clinical development plans of our business.

The Company had $193.9 million of cash, cash equivalents and marketable securities at September 30, 2023. Management believes that this amount is sufficient to fund the Company's operations for at least the next 12 months from the issuance date of these financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited interim financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements and accompanying notes.

The interim balance sheet as of September 30, 2023, the statements of operations and comprehensive loss, statements of stockholders' equity for the three and nine months ended September 30, 2023 and 2022 and statements of cash flows for the nine months ended September 30, 2023 and 2022 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair presentation of the Company's financial position as of September 30, 2023 and its results of operations and comprehensive loss for the three and nine months ended September 30, 2023 and 2022 and its cash flows for the nine months ended September 30, 2023 and 2022. Certain information and note disclosures normally included in annual audited financial statements prepared in accordance with U.S. GAAP have been omitted. The financial data and the other financial information disclosed in these notes to the interim financial statements are also unaudited. The results of operations for any interim period are not necessarily indicative of the results to be expected for the entire year or for any other future annual or interim period. These interim financial statements should be read in conjunction with the Company's audited financial statements included in the Company's Annual Report on Form 10-K, which was filed with the U.S. Securities and Exchange Commission ("SEC") on March 6, 2023.

Use of Estimates

Management uses significant judgment when making estimates related to common stock valuation and related stock-based compensation expense, accrued research and development expense, and lease-related assets and liabilities. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates under different assumptions or conditions, and those differences could be material to the financial position and results of operations.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to credit risk principally consist of cash, cash equivalents and investments. These financial instruments are currently held in accounts in varying amounts at four separate financial institutions that management believes possess high credit quality. Amounts on deposit with these financial institutions have and will continue to exceed federally-insured limits. The Company has not experienced any losses on its cash deposits. Additionally, the Company's investment policy limits its investments to certain types of securities issued by or backed by the U.S. government and its agencies.

The Company is subject to a number of risks similar to that of other early stage biopharmaceutical companies, including, but not limited to, the need to obtain adequate additional funding, possible failure of current or future clinical trials, its reliance on third-parties to conduct its clinical trials, the need to obtain regulatory and marketing approvals for its product candidates, competitive developments, the need to successfully commercialize and gain market acceptance of the Company's product candidates, its right to develop and commercialize its product candidates pursuant to the terms and conditions of the licenses granted to the Company, protection of proprietary technology, the ability to make milestone, royalty or other payments due under licensing agreements, and the need to secure and maintain adequate manufacturing arrangements with third-parties. If the Company does not successfully commercialize or partner its product candidates, it will be unable to generate product revenue or achieve profitability.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the Company's balance sheets and which, in aggregate, represent the amounts reported in the accompanying statements of cash flows (in thousands):

	September 30, 2023	December 31, 2022
Cash and cash equivalents	$ 70,519	$ 87,217
Restricted cash in other long-term assets	1,472	1,472
Total	$ 71,991	$ 88,689

	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 205,290	$ 152,822
Restricted cash in other long-term assets	1,472	2,275
Total	$ 206,762	$ 155,097

Restricted cash at September 30, 2023 represents $1.5 million in security deposits for the lease of the Company's facility in San Carlos, California. The security deposit is in the form of a letter of credit secured by restricted cash and is recorded in other long-term assets on the Company's balance sheets.

Investments

The Company invests in marketable securities, primarily securities issued by the U.S. government and its agencies. The Company's investments are considered available-for-sale and are classified as current assets even when the stated maturities of the underlying securities exceed one year from the date of the current balance sheet being reported. This classification reflects management's ability and intent to utilize proceeds from the sale of such investments to fund ongoing operations. Unrealized gains and losses are excluded from earnings and are reported as a component of accumulated other comprehensive gain (loss). The cost of securities sold is determined using the specific-identification method. Interest earned and adjustments for the amortization of premiums and discounts on investments are included in interest income on the statements of operations and comprehensive loss. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on investments in marketable securities are included in other expense, net, on the statements of operations and comprehensive loss.

Operating Leases

The Company accounts for its leases in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 842, "Leases" ("ASC 842"). Right-of-use assets represent the Company's right to use an underlying asset over the lease term and include any lease payments made prior to the lease commencement date and are reduced by lease incentives. Lease liabilities represent the present value of the total lease payments over the lease term, calculated using the Company's incremental borrowing rate. In determining the Company's incremental borrowing rate, consideration is given to the term of the lease and the Company's credit risk. The Company recognizes options to extend a lease when it is reasonably certain that it will exercise such extension. The Company does not recognize options to terminate a lease when it is reasonably certain that it will not exercise such early termination options. Lease expense is recognized on a straight-line basis over the expected lease term.

Accrued Research and Development Expense

Service agreements with contract development and manufacturing organizations ("CDMOs"), clinical contract research organizations ("CROs") and clinical investigative sites comprise a significant component of the Company's research and development activities. External costs for these vendors are recognized as the services are incurred. The Company accrues for expenses resulting from obligations under agreements with its third-parties for which the timing of payments does not match the periods over which the materials or services are provided to the Company. Accruals are recorded based on estimates of services received and efforts expended pursuant to agreements established with CDMOs, clinical CROs, clinical investigative sites and other outside service providers. These estimates are typically based on contracted amounts applied to the proportion of work performed and determined through analysis with internal personnel and external service providers as to the progress or stage of completion of the services.

The Company makes judgements and estimates in determining the accrual balance in each reporting period. In the event advance payments are made to a CDMO, clinical CRO, clinical investigative site or other outside service provider, the payments are recorded within prepaid expenses and other current assets or other long-term assets, as appropriate, and subsequently recognized as research and development expense when the associated services have been performed. As actual costs become known, the Company adjusts its liabilities and assets. Inputs, such as the extent of services received and the duration of services to be performed, may vary from the Company's estimates, which will result in adjustments to research and development expense in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations. The Company's historical estimates have not been materially different from actual amounts recorded.

Research and Development Expense

Research and development costs are expensed as incurred. Research and development costs include, among others, consulting costs, salaries, benefits, travel, stock-based compensation, laboratory supplies and other non-capital equipment utilized for in-house research, allocation of facilities and overhead costs and external costs paid to third-parties that conduct research and development activities on the Company's behalf. Costs to terminate commitments with third-party suppliers performing research and development activities and amounts incurred in connection with license agreements, including milestone payments, are also included in research and development expense.

Advance payments for goods or services to be rendered in the future for use in research and development activities are deferred and included in prepaid expenses and other current assets or other long-term assets, as appropriate. The deferred amounts are expensed as the related goods are delivered or the services are performed.

Comprehensive Loss

Comprehensive loss is defined as the change in stockholders' equity during a period from transactions and other events and circumstances from non-owner sources. The differences between net loss and comprehensive loss for the three and nine months ended September 30, 2023 and 2022 are a result of unrealized gains and losses on the Company's investments included in current assets on the Company's balance sheets.

Net Loss per Share

The Company calculates basic net loss per share by dividing the net loss attributable to common stockholders by the weighted-average shares of common stock outstanding during the period. The Company calculates diluted net loss per share after giving consideration to all potentially dilutive securities outstanding during the period using the treasury-stock and if-converted methods, except where the effect of including such securities would be anti-dilutive. Because the Company has reported net losses since inception, the effect from potentially dilutive securities would have been anti-dilutive and therefore has been excluded from the calculation of diluted net loss per share.

The Company's weighted-average shares of common stock outstanding increased from 58.2 million shares during the third quarter of 2022 to a weighted-average of 87.1 million shares of common stock outstanding during the third quarter of 2023, and from 55.9 million shares of common stock outstanding to 86.5 million shares of common stock outstanding during the nine months ended September 30, 2022 and September 30, 2023, respectively, primarily as a result of the 29.9 million shares sold as part of an underwritten registered direct offering closed on September 21, 2022 (the "September 2022 Offering"). Refer to Note 8 "Stockholders' Equity" for additional details related to the offering.

Basic and diluted net loss per share was calculated as follows (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Numerator:				
Net loss	$ (45,626)	$ (30,837)	$ (123,150)	$ (276,963)
Denominator:				
Weighted-average shares of common stock outstanding, basic and diluted	87,115	58,169	86,539	55,905
Net loss per share, basic and diluted	$ (0.52)	$ (0.53)	$ (1.42)	$ (4.95)

The following table sets forth the potentially dilutive securities that have been excluded from the calculation of diluted net loss per share due to their anti-dilutive effect for the periods indicated (in thousands):

	Nine Months Ended September 30,	
	2023	2022
Options to purchase common stock	7,966	5,365
Unvested restricted stock units	5,902	4,996
Unvested performance stock units	2,851	3,559
Shares issuable under employee stock purchase plans	58	63
Total	16,777	13,983

Recently Issued and Adopted Accounting Pronouncements

The Company has reviewed recently issued accounting pronouncements and concluded they are either not applicable to the business or that no material effect is expected on the Company's financial statements as a result of future adoption.

3. Fair Value Measurements

The Company measures and reports certain financial instruments as assets and liabilities at fair value on a recurring basis. The Company's financial assets measured at fair value on a recurring basis were as follows (in thousands):

	September 30, 2023			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 71,728	$ —	$ —	$ 71,728
Total cash equivalents	71,728	—	—	71,728
Short-term marketable securities				
U.S. treasuries	123,389	—	—	123,389
Total short-term marketable securities	123,389	—	—	123,389
Total cash equivalents and short-term marketable securities	$ 195,117	$ —	$ —	$ 195,117

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 86,270	$ —	$ —	$ 86,270
Total cash equivalents	86,270	—	—	86,270
Short-term marketable securities:				
U.S. treasuries	192,569	—	—	192,569
Total short-term marketable securities	192,569	—	—	192,569
Total cash equivalents and short-term marketable securities	$ 278,839	$ —	$ —	$ 278,839

The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of assets or liabilities between levels during the three and nine months ended September 30, 2023 and 2022.

4. Investments

All investments were considered available-for-sale at September 30, 2023. The amortized cost, gross unrealized holding gains or losses, and fair value of the Company's investments by major security type at September 30, 2023 and December 31, 2022 are summarized in the table below (in thousands):

	September 30, 2023			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Available-for-sale securities:				
U.S. treasuries classified as investments	$ 123,496	$ 2	$ (109)	$ 123,389
Total available-for-sale securities	$ 123,496	$ 2	$ (109)	$ 123,389

	December 31, 2022			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Available-for-sale securities:				
U.S. treasuries classified as investments	$ 192,853	$ 3	$ (287)	$ 192,569
Total available-for-sale securities	$ 192,853	$ 3	$ (287)	$ 192,569

The amortized cost of available-for-sale securities is adjusted for amortization of premiums and accretion of discounts to maturity. As of September 30, 2023 and December 31, 2022, the aggregate fair value of securities held by the Company in an unrealized loss position for less than twelve months was $108.5 million and $162.6 million, respectively. These securities had remaining maturities of less than one year. The Company has the intent and ability to hold such securities until recovery and has determined that there has been no material change to their credit risk. As a result, the Company determined it did not hold any investments with a credit loss at September 30, 2023 and December 31, 2022.

There were no material realized gains or losses recognized on the sale or maturity of available-for-sale securities during the three and nine months ended September 30, 2023 and 2022, and as a result, there were no material reclassifications out of accumulated other comprehensive gain (loss) for the same periods.

5. Balance Sheet Components and Supplemental Disclosures

Property and Equipment, Net

Property and equipment, net, consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Laboratory equipment	$ 6,993	$ 6,473
Furniture and office equipment	3,947	3,947
Leasehold improvements	32,457	32,457
Capitalized software	4,382	4,112
Construction-in-progress	46	422
	47,825	47,411
Less accumulated depreciation	(12,860)	(8,267)
Property and equipment, net	$ 34,965	$ 39,144

Depreciation and amortization expense for each of the three months ended September 30, 2023 and 2022 was $1.5 million. Depreciation and amortization expense for the nine months ended September 30, 2023 and 2022 was $4.6 million and $5.6 million, respectively.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Accrued contract research and development expense	$ 12,061	$ 13,950
Accrued compensation and benefits expense	7,106	7,039
Current portion of operating lease liabilities	2,766	3,161
Other current liabilities	602	1,056
Total	$ 22,535	$ 25,206

6. Leases

Operating Leases

The Company's lease obligations primarily relate to leased office and laboratory space under a noncancelable operating lease. In accordance with ASC 842, the Company has performed an evaluation of its other contracts with vendors and has determined that, except for the leases described below, none of its other contracts contain a material lease.

2019 San Carlos Lease

In December 2019, the Company entered into an operating lease agreement for office and laboratory space in San Carlos, California (the "2019 San Carlos Lease"). The contractual term of the 2019 San Carlos Lease is 10.25 years from August 2021 until October 2031. The 2019 San Carlos Lease provides rent abatements and includes a one-time option to extend the lease term for five years. This option to extend the lease term was not determined to be reasonably certain and therefore has not been included in the Company's calculation of the associated operating lease liability under ASC 842.

The 2019 San Carlos Lease includes monthly base rent amounts escalating over the term of the lease. In addition, the lessor provided for a tenant improvement allowance of up to $14.7 million, which was fully utilized and is recorded in lease obligations.

On March 27, 2023, the Company entered into an amendment for the 2019 San Carlos Lease, whereby rentable square feet was adjusted to 95,692 square feet and lease payments were reduced by approximately 2.5% per month, effective from January 1, 2022 through the end of the lease term. The Company accounted for these changes as a modification under ASC 842 and the operating right-of-use asset and lease liability were remeasured during the first quarter of 2023 utilizing an estimated incremental borrowing rate of 10.5%. Our estimated incremental borrowing rate was based on our estimated rate of interest for a fully collateralized borrowing over a similar term as the remaining lease payments while incorporating our credit risk. As a result of the modification, the right-of-use asset and lease liability decreased by approximately $5.6 million. No gain or loss was recognized upon the modification.

Classification of Operating Leases

The 2019 San Carlos Lease required a security deposit of $1.5 million, which the Company satisfied by establishing a letter of credit secured by restricted cash. As of September 30, 2023 and December 31, 2022, a security deposit of $1.5 million for the 2019 San Carlos Lease was recorded as restricted cash in other long-term assets on the Company's balance sheets.

Classification of the Company's operating lease liabilities included on the Company's balance sheets at September 30, 2023 and December 31, 2022 was as follows (in thousands):

	September 30, 2023	December 31, 2022
Operating lease liabilities		
Current portion included in accrued expenses and other current liabilities	$ 2,766	$ 3,161
Operating lease liabilities, net of current portion	39,002	45,949
Total operating lease liabilities	$ 41,768	$ 49,110

The components of lease costs included in operating expenses in the Company's statements of operations and comprehensive loss were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating lease costs	$ 1,407	$ 1,507	$ 4,283	$ 4,432
Variable costs	894	890	2,733	2,578
Total lease costs	$ 2,301	$ 2,397	$ 7,016	$ 7,010

Variable costs included in the table above represent amounts the Company pays related to property taxes, insurance, maintenance and repair costs.

Cash paid for amounts included in the measurement of the Company's operating lease liabilities and presented within cash used in operating activities in the statements of cash flows was $4.9 million and $5.1 million for the nine months ended September 30, 2023 and 2022, respectively.

Cash received for amounts related to tenant improvement allowances from lessors was $0.3 million and $1.0 million for the nine months ended September 30, 2023 and 2022, respectively.

Operating Lease Obligations

Future lease payments required under operating leases included on the Company's balance sheet at September 30, 2023 are as follows (in thousands):

Fiscal Year Ending December 31,	
2023 (remaining 3 months)	$ 1,751
2024	7,075
2025	7,287
2026	7,506
2027	7,731
Thereafter	31,834
Total future lease payments	63,184
Less:	
Present value adjustment	21,416
Operating lease liabilities	$ 41,768

Operating lease liabilities are based on the net present value of the remaining lease payments over the remaining lease term. In determining the present value of lease payments, the Company used its incremental borrowing rate based on the information available at the lease commencement date. As of September 30, 2023, the weighted-average remaining lease term of the Company's leases was 8.1 years and the weighted-average discount rate used to determine the operating lease liabilities included on the balance sheet was 10.5%.

As of September 30, 2023, the Company was not party to any lease agreements containing material residual value guarantees or material restrictive covenants.

7. Contingencies

In-Licensing Agreements

The Company has entered into exclusive and non-exclusive, royalty bearing license agreements with third-parties for certain intellectual property. Under the terms of the license agreements, the Company is obligated to pay milestone payments upon the achievement of specified clinical, regulatory and commercial milestones. Research and development expense associated with the Company's milestone payments are recognized when such milestone has been achieved. Actual amounts due under the license agreements will vary depending on factors including, but not limited to, the number of products developed and the Company's ability to further develop and commercialize the licensed product. The Company is also subject to future royalty payments based on sales of the licensed products.

The Company did not recognize any milestone expense for the three and nine months ended September 30, 2023 and 2022. As of September 30, 2023, the Company has not incurred any royalty liabilities related to its license agreements, as product sales have not yet commenced.

Exclusive License Agreement with The Johns Hopkins University

In December 2013, the Company entered into a license agreement with The Johns Hopkins University ("JHU") for a worldwide exclusive license to develop, use, manufacture and commercialize covered product candidates including lirentelimab, which was amended in September 2016. Under the terms of the agreement, the Company has made upfront and milestone payments of $0.7 million through September 30, 2023 and may be required to make aggregate additional milestone payments of up to $1.8 million. The Company also issued 88,887 shares of common stock as consideration under the JHU license agreement. In addition to milestone payments, the Company is also subject to low single-digit royalties to JHU based on future net sales of each licensed therapeutic product candidate by the Company and its affiliates and sublicensees, with up to a low six-digit dollar minimum annual royalty payment.

Non-exclusive License Agreement with BioWa Inc. and Lonza Sales AG

In October 2013, the Company entered into a tripartite agreement with BioWa Inc. ("BioWa"), and Lonza Sales AG ("Lonza Sales"), for the non-exclusive worldwide license to develop and commercialize product candidates including lirentelimab that are manufactured using a technology jointly developed and owned by BioWa and Lonza Sales. Under the terms of the agreement, the Company has made milestone payments of $3.4 million through September 30, 2023 and may be required to make aggregate additional milestone payments of up to $38.0 million. In addition to milestone payments, the Company is also subject to minimum annual commercial license fees of $40,000 per year to BioWa until such time as BioWa receives royalty payments, as well as low single-digit royalties to BioWa and to Lonza Sales. Royalties are based on future net sales by the Company and its affiliates and sublicensees.

Indemnification Agreements

The Company has entered into indemnification agreements with certain directors and officers that require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. To date, no such matters have arisen and the Company does not believe that the outcome of any claims under indemnification arrangements will have a material adverse effect on its financial positions, results of operations or cash flows. Accordingly, the Company has not recorded a liability related to such indemnifications at September 30, 2023.

8. Stockholders' Equity

September 2022 Offering

On September 21, 2022, the Company closed an underwritten registered direct offering (the "September 2022 Offering") under its shelf registration statement on Form S-3 (File No. 333-265085), supplemented by a prospectus supplement filed with the SEC on September 19, 2022 pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the "Securities Act"). In connection with the September 2022 Offering, the Company sold an aggregate of 29,882,000 shares of our common stock, par value $0.001 per share, at a public offering price of $5.02 per share. Aggregate net proceeds were approximately $140.6 million, after deducting the underwriting commissions and estimated offering expenses.

"At-the-Market" Equity Offering

On August 4, 2022, the Company entered into a sales agreement (the "2022 Sales Agreement") with Cowen and Company, LLC ("Cowen"). Pursuant to the 2022 Sales Agreement, the Company may sell, from time to time, up to an aggregate of $75.0 million in gross sales proceeds of its common stock through an "at-the-market" offering ("ATM Offering") as defined under the Securities Act.

The Company will pay a commission equal to 3% of the gross proceeds from the sale of shares of its common stock under the 2022 Sales Agreement. The $75.0 million of common stock that may be offered, issued and sold in the ATM Offering is included in the $250.0 million of securities that may be offered, issued and sold by the Company under its registration statement on Form S-3 (File No. 333-265085). The Company expects to use the net proceeds from sales under the 2022 Sales Agreement for general corporate purposes.

During the nine months ended September 30, 2023, the Company sold 0.1 million shares of its common stock at an average price of $7.20 per share through its ATM Offering, resulting in proceeds of $1.0 million net of commissions, with all sales occurring during the first quarter of 2023. Under its current ATM Offering program, $74.0 million of common stock remain available for future sales as of September 30, 2023; however, the Company is not obligated to make any sales under this program.

9. Stock-Based Compensation

Total stock-based compensation expense recognized is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	$ 4,408	$ 4,267	$ 13,171	$ 13,572
General and administrative	6,126	6,465	17,849	20,313
Total	$ 10,534	$ 10,732	$ 31,020	$ 33,885

No income tax benefits for stock-based compensation expense have been recognized for the three and nine months ended September 30, 2023 and 2022 as a result of the Company's full valuation allowance applied to net deferred tax assets and net operating loss carryforwards.

Equity Incentive Plans

In July 2018, the Board of Directors adopted the 2018 Equity Incentive Plan (the "2018 Plan"). The 2018 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units ("RSUs"), stock appreciation rights, performance units and performance shares. The number of shares of common stock that may be issued under the 2018 Plan will automatically increase on each January 1, beginning with the fiscal year ending December 31, 2019, equal to the least of (i) 5,000,000 shares, (ii) 5% of the outstanding shares of common stock as of the last day of the preceding fiscal year or (iii) such other amount as the Board of Directors may determine. Stock options and RSUs granted under the 2018 Plan generally vest over four years and expire no more than 10 years from the date of grant.

Following the IPO and upon the effectiveness of the 2018 Plan, the Company's 2012 Equity Incentive Plan, as amended, (the "2012 Plan"), terminated and no further awards will be granted thereunder. All outstanding awards under the 2012 Plan will continue to be governed by their existing terms. Any shares subject to awards granted under the 2012 Plan that, on or after the termination of the 2012 Plan, expire or terminate and shares previously issued pursuant to awards granted under the 2012 Plan that, on or after the termination of the 2012 Plan, are forfeited or repurchased by the Company will be transferred into the 2018 Plan. As of September 30, 2023, the maximum number of shares that may be added to the 2018 Plan pursuant to the preceding sentence is 2,546,977 shares.

Prior to its termination, the 2012 Plan provided for the grant of stock options, stock appreciation rights, restricted stock and RSUs to employees, directors and consultants. Stock options granted under the 2012 Plan generally vest over four years and expire no more than 10 years from the date of grant.

Stock Options

The following weighted-average assumptions were used to calculate the fair value of stock options granted during the periods indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Risk-free interest rate	4.31%	3.11%	3.88%	2.81%
Expected volatility	108.84%	74.33%	99.97%	73.81%
Expected dividend yield	—	—	—	—
Expected term (in years)	5.94	5.94	5.96	5.81

The Company's stock option activity during the nine months ended September 30, 2023 is summarized as follows (number of shares in thousands):

	Options Outstanding		Weighted-Average Exercise Price
Balance at December 31, 2022	5,423	$	15.41
Granted	3,451	$	5.79
Exercised	(206)	$	3.26
Expired	(266)	$	48.47
Forfeited	(436)	$	7.93
Balance at September 30, 2023	7,966	$	10.86
Options exercisable	4,073	$	13.55
Options vested and expected to vest	7,735	$	10.97

As of September 30, 2023, total unrecognized stock-based compensation expense relating to unvested stock options was $19.2 million. This amount is expected to be recognized over a weighted-average period of 2.6 years.

Time-based RSUs

RSU activity under the 2018 Plan during the nine months ended September 30, 2023 is summarized as follows (in thousands, except per share data):

	Shares		Weighted-Average Grant Date Fair Value
Balance at December 31, 2022	4,478	$	16.90
Granted	3,855	$	6.53
Vested	(1,460)	$	17.05
Forfeited	(971)	$	12.28
Balance at September 30, 2023	5,902	$	18.32

The weighted-average fair value of RSUs granted during the nine months ended September 30, 2023 and 2022 was $6.53 and $5.37, respectively.

As of September 30, 2023, total unrecognized stock-based compensation expense relating to unvested RSUs was $55.4 million and the weighted-average remaining vesting period was 2.4 years.

Performance-based Restricted Stock Units ("PSUs")

PSU activity under the 2018 Plan during the nine months ended September 30, 2023 is summarized as follows (in thousands, except per share data):

	Shares		Weighted-Average Grant Date Fair Value
Balance at December 31, 2022	3,276	$	6.21
Forfeited	(425)	$	5.58
Balance at September 30, 2023	2,851	$	8.85

As of September 30, 2023, total unrecognized stock-based compensation expense relating to unvested PSUs was $25.2 million and the weighted-average remaining vesting period was 0.5 year.

Employee Stock Purchase Plan

In July 2018, the Company's Board of Directors and stockholders approved the 2018 Employee Stock Purchase Plan (the "2018 ESPP"). The number of shares of common stock that may be issued under the 2018 ESPP shall automatically increase on each January 1, beginning with the fiscal year ending December 31, 2019, equal to the least of (i) 1,000,000 shares, (ii) 1% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year and (iii) such other amount determined by the 2018 ESPP administrator. As of September 30, 2023, the number of shares available for issuance under the 2018 ESPP was 2,781,902.

Under the 2018 ESPP, employees may purchase shares of the Company's common stock at a price per share equal to 85% of the lower of the fair market value of the common stock on the first trading day of the offering period or on the exercise date. The 2018 ESPP provides for consecutive, overlapping 24-month offering periods, each of which will include four 6-month purchase periods. The first offering period under the 2018 ESPP commenced on July 18, 2018.

During the three and nine months ended September 30, 2023, stock-based compensation expense related to the 2018 ESPP was $0.2 million and $0.6 million, respectively. During the three and nine months ended September 30, 2022, stock-based compensation expense related to the 2018 ESPP was $0.1 million and $0.6 million, respectively.

10. Defined Contribution Plans

In January 2018, the Company established a defined contribution plan under Section 401(k) of the Internal Revenue Code (the "401(k) plan"). The 401(k) plan covers all employees who meet defined minimum age and service requirements. Employee contributions are voluntary and are determined on an individual basis, limited to the maximum amount allowable under U.S. federal tax regulations. The Company makes matching contributions of up to 4% of the eligible employees' compensation to the 401(k) plan. During the three and nine months ended September 30, 2023, the Company made contributions to the 401(k) plan of $0.2 million and $0.8 million, respectively. During the three and nine months ended September 30, 2022, the Company made contributions to the 401(k) plan of $0.1 million and $0.8 million, respectively.

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 together with our financial statements and the other financial information appearing elsewhere in this Quarterly Report on Form 10-Q. These statements generally relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which 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. The following discussion and analysis contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Our actual results and the timing of events may differ materially from those discussed in our forward-looking statements as a result of various factors, including those discussed below and those discussed in the section entitled "Risk Factors" included in this Quarterly Report on Form 10-Q. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements. Additional information concerning these and other risks and uncertainties is contained in our other periodic filings with the SEC.

Forward-looking statements include, but are not limited to, statements about:

- *our plans to develop, manufacture and commercialize lirentelimab (AK002), AK006 and our other product candidates, including our targeted clinical indications, intellectual property strategy, sales and marketing objectives and infrastructure capabilities;*
- *the timing, focus and clinical indications of our preclinical studies and clinical trials, and the reporting of data from those trials;*
- *the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;*
- *the expected patient enrollment in our clinical trials;*
- *our work models;*
- *the impact that the adoption of new accounting pronouncements will have on our financial statements;*
- *the beneficial characteristics, safety, efficacy and therapeutic effects of lirentelimab, AK006 or our other product candidates;*
- *the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations, such as orphan drug designation, for lirentelimab, AK006 or our other product candidates for various diseases;*
- *our ability to obtain and maintain regulatory approval of lirentelimab, AK006 or our other product candidates;*
- *our continued reliance on third-parties to conduct additional clinical trials of lirentelimab and our other product candidates;*
- *our ability to obtain, maintain, or negotiate favorable terms of any collaboration, partnership, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize lirentelimab and our other product candidates;*
- *the need to hire additional personnel and our ability to attract and retain such personnel;*
- *the need for additional financing, and our ability to obtain such financing on terms that are favorable to the Company and its stockholders;*
- *our expectations regarding financial performance, including revenues, expenses and net losses, and impacts from our Reorganization Plan and manufacturing development efforts on the foregoing;*
- *the sufficiency of our existing cash, cash equivalents and marketable securities to fund our future operating expenses and capital expenditure requirements;*
- *the costs associated with being a public company; and*
- *our anticipated uses of our existing cash, cash equivalents and investments.*

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including, but not limited to, those described in "Risk Factors". In some cases, you can identify these statements by terms such as "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes. These forward-looking statements reflect our beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this

Quarterly Report on Form 10-Q and are subject to risks and uncertainties. We discuss many of these risks in greater detail in the section entitled "Risk Factors" included in Part II, Item 1A and elsewhere in this Quarterly Report on Form 10-Q. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible to predict all risks, nor can we assess the impact of all factors 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 we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We qualify all of the forward-looking statements in this Quarterly Report on Form 10-Q by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

Overview

We are a clinical stage biotechnology company developing therapeutics which target immunomodulatory receptors present on immune effector cells involved in allergic, inflammatory and proliferative diseases. Activating these immunomodulatory receptors allows us to directly target cells involved in disease pathogenesis and, in the setting of allergy and inflammation, has the potential to result in broad inhibition of inflammatory cells. In the setting of proliferative diseases, blocking the inhibitory function of the receptors could restore the immune cells' ability to identify and kill proliferative cells. Our most advanced therapeutics are lirentelimab (AK002) and AK006.

Lirentelimab targets Siglec-8, an inhibitory receptor expressed selectively on mast cells and eosinophils, two types of white blood cells that are widely distributed in the body and play a central role in the inflammatory response. Binding of lirentelimab (AK002) to Siglec-8 results in rapid and sustained depletion of eosinophils via antibody dependent cellular cytotoxicity and inhibition of mast cells via multiple stimuli including interleukin-33 ("IL-33"), thymic stromal lymphopoietin ("TSLP"), immunoglobulin E ("IgE"), mass-related G protein-coupled receptor-X2 ("MRGPR-X2"), toll-like receptor ("TLR") and others. Inappropriately activated mast cells and eosinophils have been identified as key drivers in a number of severe diseases affecting the skin, lungs, gastrointestinal tract, eyes and other organs. We are currently developing lirentelimab for the treatment of atopic dermatitis, chronic spontaneous urticaria and potentially other indications.

Lirentelimab has completed an open label Phase 2a chronic urticaria trial that included patients with chronic spontaneous urticaria ("CSU") including patients with omalizumab refractory CSU. CSU is a debilitating skin condition characterized by frequent and unpredictable eruption of hives, severe itching and swelling. Based on the promising symptom improvements reported in the Phase 2a study we initiated a randomized, double-blind, placebo-controlled Phase 2b trial of subcutaneous ("SC") lirentelimab in patients with CSU. We have completed enrollment in the Phase 2b study of SC lirentelimab in patients with CSU and topline data from that study is expected in the latter half of the fourth quarter of 2023 to the first quarter of 2024.

Lirentelimab has also completed clinical studies in severe allergic conjunctivitis, indolent systemic mastocytosis, eosinophilic gastritis ("EG") and/or eosinophilic duodenitis ("EoD"), and eosinophilic esophagitis ("EoE"). Based on promising observations in these studies in patients with comorbid atopic dermatitis, we initiated a randomized, double-blind, placebo-controlled Phase 2 clinical trial of SC lirentelimab in adult patients with moderate-to-severe atopic dermatitis. Atopic dermatitis is a chronic pruritic inflammatory condition that is characterized by dry, red, itchy patches of skin. We have completed enrollment in the Phase 2 study of SC lirentelimab in patients with atopic dermatitis and topline data from that study is expected in the latter half of the fourth quarter of 2023 to the first quarter of 2024.

In addition to our clinical development efforts with lirentelimab, we have initiated clinical development of AK006. AK006 targets Siglec-6, an inhibitory receptor expressed selectively on mast cells. Binding of AK006 to Siglec-6 activates the native inhibitory function of the receptor which in turn reduces mast cell activation. In preclinical studies, AK006 inhibited multiple modes of mast cell activation, including targeting IgE, IL-33, tyrosine kinase receptor ("KIT"), complement component 5a ("C5a"), and MRGPR-X2, resulting in the deep suppression of mast cell activation. In addition to mast cell inhibition, AK006 reduced human tissue mast cells via antibody-dependent cellular phagocytosis ("ADCP"). AK006 appears to have the potential to provide broader and deeper mast cell inhibition than lirentelimab and, in addition to its inhibitory activity, reduce mast cell numbers. The Investigational New Drug ("IND") application for AK006 was accepted by the U.S. Food and Drug Administration and we dosed our first healthy adult volunteers in the third quarter of 2023.

The Phase 1, first-in-human, study of AK006 consists of single and multiple ascending doses administered via infusion in healthy adult volunteers. In addition, following the single and multiple ascending dose portions, the Phase 1 study will explore the activity of AK006 in a randomized, double-blind, placebo-controlled cohort of patients with CSU. The CSU cohort is expected to be initiated in the second quarter of 2024.

In addition to our clinical programs, we are continuing our preclinical research efforts with AK007 and additional preclinical programs directed at generating antibodies to novel immunomodulatory receptors. AK007 targets Siglec-10, a myeloid inhibitory checkpoint receptor that is selectively expressed on tumor associated macrophages and dendritic cells. AK007 is designed to block all known ligand interaction with Siglec-10, including the "don't eat me" signal CD24. "Don't eat me" signals such as CD47 and CD24,

have been identified to be overexpressed in tumors and allow cancer cells to avoid destruction by macrophages and other myeloid cells of the innate immune system. In preclinical research, AK007 polarizes tumor-associated myeloid cells and promotes anti-tumor immunity.

Since our inception in 2012, we have devoted substantially all of our resources and efforts towards the research and development of our product candidates. Our lead product candidate, lirentelimab, a monoclonal antibody targeting Siglec-8, entered clinical trials in 2016. In addition to activities conducted internally at our facilities, we have utilized significant financial resources to engage contractors, consultants and other third parties to conduct various preclinical and clinical development activities on our behalf.

To date, we have not had any products approved for sale and have not generated any revenue nor been profitable. Further, we do not expect to generate revenue from product sales until such time, if ever, that we are able to successfully complete the development and obtain marketing approval for one of our product candidates. We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We have incurred significant operating losses to date and expect to incur significant operating losses for the foreseeable future. Our net losses were $123.2 million and $277.0 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, we had an accumulated deficit of $1,055.9 million.

In February 2022, we implemented a reorganization plan to reduce operating costs, contractual commitments and better align our workforce with the clinical development plans of our business (the "Reorganization Plan"). As a result, we entered into a termination agreement (the "Termination Agreement") with Lonza AG, Lonza Sales Ltd and Lonza Sales AG (collectively, "Lonza AG") regarding all outstanding manufacturing service agreements and reduced our workforce by approximately 35%. While this resulted in increased costs in the first and second quarters of 2022, our overall spending in subsequent quarters was significantly reduced as compared to the first and second quarters of 2022. Future expenses are subject to periodic fluctuations particularly due to the timing of ongoing manufacturing development efforts.

As of September 30, 2023, we had cash, cash equivalents and marketable securities of $193.9 million, which we believe will be sufficient to fund our planned operations for at least the next 12 months from the issuance of our financial statements.

Vendor Termination Agreement

Approximately $231.2 million of noncancellable purchase obligations as of December 31, 2021, related to various manufacturing services agreements with Lonza AG or affiliates (such agreements, the "MSAs"). On February 14, 2022 (the "Effective Date"), we entered into the Termination Agreement with Lonza AG regarding all outstanding MSAs. Lonza AG will continue to provide certain services to us, including completion of select batches that were then already underway and subsequently completed by the third quarter of 2022 and will continue to provide certain other specified services to assist with the transition post-termination. The Termination Agreement provides that we pay 126 million Swiss Francs, approximately USD $136.5 million (the "Termination Amount") to Lonza AG, as a result of such termination. In accordance with the terms of the Termination, we paid 95% of the Termination Amount (approximately USD $130 million) during the first quarter of 2022. The remaining 5% (approximately USD $6.5 million) was paid during the third quarter of 2022. The Termination Agreement contains mutual releases by all parties thereto, for all claims known and unknown, relating and arising out of, or connected with, the MSAs and the subject matter(s) thereof, subject to certain exceptions.

As the agreement was terminated on February 14, 2022, we recognized the costs associated with the Termination Agreement during the first quarter of 2022 in accordance with ASC 420 except for approximately $6.0 million attributed to services that were remaining to be rendered by Lonza AG and to be expensed during the periods in which the services are performed.

Reorganization Plan

Under the Reorganization Plan, we reduced our workforce by approximately 35%. Impacted employees were informed on February 16, 2022. At the time of departure, impacted employees were eligible to receive severance benefits and we funded COBRA premiums, contingent upon an impacted employee's execution (and non-revocation) of a customary separation agreement, which includes a general release of claims against us.

In connection with the Reorganization Plan, we recognized restructuring charges of approximately $5.2 million during the first quarter of 2022, related to severance payments and other employee-related separation costs.

In addition, the Board determined that it was in the best interests of us and our stockholders to put in place arrangements designed to promote the continued dedication and commitment of those employees, including executives, determined to be key to the planned go-forward operations. The Board approved, and management implemented, a retention program for employees remaining which included cash retention bonuses totaling $3.1 million for certain retained employees and grants of RSUs totaling 8.2 million awards in aggregate to all employees. Half of these RSUs are time-based RSUs with four-year vesting and half are performance-based with full vesting occurring only if we achieve all primary endpoints in any of our Phase 2/3 clinical studies other than the Phase 3 Eosinophilic Duodenitis study that was completed in the third quarter of 2022. The cash retention bonuses are required to be repaid in full if the

employee leaves prior to January 1, 2024. As a result, these cash retention bonuses are amortized over the requisite service period with $0.3 million remaining in prepaid expenses and other current assets as of September 30, 2023.

Components of Operating Results

Revenue

We have not generated any revenue from product sales or otherwise, and do not expect to generate any revenue for at least the next several years.

Operating Expenses

We classify operating expenses into two categories: (i) research and development and (ii) general and administrative.

Research and Development Expenses

Research and development expenses represent the following costs incurred by us for the discovery, development and manufacturing of our product candidates:

- consultant and personnel-related costs including consulting fees, employee salaries and benefits, travel and stock-based compensation expense;
- costs incurred under service agreements with contract research organizations ("CROs") that conduct nonclinical research and development activities on our behalf;
- costs incurred under service agreements with clinical CROs and clinical investigative sites to conduct our clinical studies;
- costs incurred under service agreements with contract development and manufacturing organizations ("CDMOs") for the manufacture and fill finish of our product candidates, as well as any costs required to cancel any related purchase obligations;
- costs related to in-house research and development activities conducted at our facilities including laboratory supplies, non-capital laboratory equipment and depreciation of capital laboratory equipment and leasehold improvements;
- costs incurred under exclusive and non-exclusive license agreements with third-parties; and
- allocated facility and other costs including the rent and maintenance of our facilities, insurance premiums, depreciation of shared-use leasehold improvements and general office supplies.

We expense research and development costs as incurred. We recognize costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as clinical site activations, patient enrollment or information provided to us by our clinical CROs and clinical investigative sites, along with analysis by our in-house clinical operations personnel. Advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized as prepaid expenses, even when there is no alternative future use for the research and development. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

Prior to the regulatory approval of our product candidates, we recognize expenses incurred with our CDMOs for the manufacture of product candidates that could potentially be available to support future commercial sales, if approved, in the period in which they have occurred. To date, we have not yet capitalized any costs to inventory as we are unable to determine if these costs will provide a future economic benefit, given the unapproved nature of our product candidates.

The successful development of our product candidates is highly uncertain. Accordingly, it is difficult to estimate the nature, timing and extent of costs necessary to complete the remainder of the development of our product candidates. We are also unable to predict when, if ever, we will be able to generate revenue from our product candidates. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty surrounding:

- demonstrating sufficient safety and tolerability profiles of product candidates;
- successful enrollment and completion of clinical trials;
- requisite clearance and approvals from applicable regulatory authorities;
- establishing and maintaining commercial manufacturing capabilities with CDMOs;

- obtaining and maintaining protection of intellectual property; and
- commercializing product candidates, if and when approved, alone or in collaboration with third-parties.

A change pertaining to any of these variables would significantly impact the timing and extent of costs incurred with respect to the development and commercialization of our product candidates.

External costs incurred from CDMOs, clinical CROs and clinical investigative sites have comprised a significant portion of our research and development expenses since inception. We track these costs on a program-by-program basis following the advancement of a product candidate into clinical development. Consulting and personnel-related costs, laboratory supplies and non-capital equipment utilized in the conduct of in-house research, in-licensing fees and general overhead, are not tracked on a program-by-program basis, nor are they allocated, as they commonly benefit multiple projects, including those still in our pipeline.

We anticipate that our research and development expenses will fluctuate from quarter-to-quarter in the future, primarily driven by the timing of costs associated with the manufacturing of our lead product candidate, lirentelimab, as we refine the frequency and increase the scale of our manufacturing batches, including raw material costs. Additionally, we expect costs to fluctuate from quarter-to-quarter associated with our ongoing and future early, mid and late-stage clinical trials for various indications.

General and Administrative Expenses

General and administrative expenses consist of fees paid to consultants, salaries, benefits and other personnel-related costs, including stock-based compensation, for our personnel in executive, finance, accounting and other administrative functions, legal costs, fees paid for accounting and tax services, costs associated with pre-commercialization activities and facility costs not otherwise included in research and development expenses. Legal costs include general corporate and patent legal fees and related costs.

We anticipate that our general and administrative expenses will fluctuate from quarter-to-quarter in the future to support our continued research and development activities, as well as progress on our preliminary commercial development activities, including costs related to personnel, outside consultants, attorneys and accountants, stock-based compensation, among others. Additionally, we expect to incur costs associated with continuing to operate as a public company, including expenses related to maintaining compliance with the rules and regulations of the U.S. Securities and Exchange Commission ("SEC"), and those of any national securities exchange on which our securities are traded, additional insurance premiums, investor relations activities and other ancillary administrative and professional services.

Interest Income

Interest income primarily consists of interest and investment income earned on our cash, cash equivalents and investments included on the balance sheets.

Other Expense, Net

Other expense, net, primarily consists of amounts realized from gains and losses related to fluctuations in foreign currencies.

In-Licensing Agreements

We have entered into a number of exclusive and nonexclusive, royalty bearing license agreements with third-parties for certain intellectual property. Under the terms of the license agreements described below, we are obligated to pay milestone payments upon the achievement of specified clinical, regulatory and commercial milestones. Research and development expense associated with our milestone payments are recognized when such milestone has been achieved. Actual amounts due under the license agreements vary depending on factors including, but not limited to, the number of product candidates we develop and our ability to successfully develop and commercialize our product candidates covered under the respective agreements. In addition to milestone payments, we are also subject to future royalty payments based on sales of our product candidates covered under the agreements, as well as certain minimum annual royalty and commercial reservation fees. Because the achievement of milestones and the timing and extent of future royalties is not probable, these contingent amounts have not been included on our balance sheets or as part of Contractual Obligations and Commitments discussion below.

We did not incur any milestone expense for the three and nine months ended September 30, 2023 and 2022. As of September 30, 2023, we have not incurred any royalty liabilities related to our license agreements, as product sales have not yet commenced.

Exclusive License Agreement with The Johns Hopkins University

In December 2013, we entered into a license agreement with JHU for a worldwide exclusive license to develop, use, manufacture and commercialize covered product candidates including lirentelimab, which was amended in September 2016. Under the terms of the agreement, we have made upfront and milestone payments of $0.7 million through September 30, 2023. We may be required to make aggregate additional milestone payments of up to $1.8 million. We also issued 88,887 shares of common stock as consideration under the JHU license agreement. In addition to milestone payments, we are also subject to low single-digit royalties to JHU based on future net sales of each licensed therapeutic product candidate by us and our affiliates and sublicensees, with up to a low six-digit dollar minimum annual royalty payment.

Non-exclusive License Agreement with BioWa Inc. and Lonza Sales AG

In October 2013, we entered into a tripartite agreement with BioWa and Lonza Sales for the non-exclusive worldwide license to develop and commercialize product candidates including lirentelimab that are manufactured using a technology jointly developed and owned by BioWa and Lonza Sales. Under the terms of the agreement, we have made milestone payments of $3.4 million through September 30, 2023 and we may be required to make aggregate additional milestone payments of up to $38.0 million. In addition to milestone payments, we are also subject to minimum annual commercial license fees of $40,000 per year to BioWa until such time as BioWa receives royalty payments, as well as low single-digit royalties to BioWa and to Lonza Sales. Royalties are based on future net sales by us and our affiliates and sublicensees.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts and experience. During the three and nine months ended September 30, 2023, there were no other changes to our critical accounting policies and estimates as disclosed in our 2022 Annual Report on Form 10-K.

Recent Accounting Pronouncements

See Note 2 to our unaudited financial statements for recently issued accounting pronouncements, including the respective effective dates of adoption and effects on our results of operations and financial condition.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations for the periods indicated (in thousands):

	Three Months Ended September 30,	
	2023	2022
Operating expenses		
Research and development	$ 36,749	$ 18,438
General and administrative	11,461	13,007
Total operating expenses	48,210	31,445
Loss from operations	(48,210)	(31,445)
Interest income	2,590	711
Other expense, net	(6)	(103)
Net loss	(45,626)	(30,837)
Unrealized gain (loss) on investments	87	196
Comprehensive loss	$ (45,539)	$ (30,641)

Research and Development Expenses

Research and development expenses were $36.7 million for the three months ended September 30, 2023 compared to $18.4 million for the three months ended September 30, 2022, an increase of $18.3 million. The increase is primarily attributed to a $16.7 million increase in manufacturing costs as the third quarter of 2022 included a $12.2 million benefit from refunds for previously expensed raw materials and the third quarter of 2023 included increased manufacturing costs relating to our lirentelimab (AK002) and AK006 programs, and a $1.6 million increase in other research and development expenses.

General and Administrative Expenses

General and administrative expenses were $11.5 million for the three months ended September 30, 2023 compared to $13.0 million for the three months ended September 30, 2022, a decrease of $1.5 million. The decrease was due to decreases in professional expenses, employee compensation and other administrative expenses.

Interest Income

Interest income was $2.6 million and $0.7 million for the three months ended September 30, 2023 and 2022, respectively, with the increase attributed primarily to higher interest rates.

Other Expense, Net

Changes in other expense, net were minimal for the three months ended September 30, 2023 compared to the three months ended September 30, 2022, and primarily attributed to changes in foreign exchange gains and losses.

Net Loss

Net loss was $45.6 million for the three months ended September 30, 2023 compared to net loss of $30.8 million for the three months ended September 30, 2022. Total combined stock-based compensation and depreciation expense for the three months ended September 30, 2023 and 2022 was $12.1 million and $12.2 million, respectively.

Comparison of the Nine Months Ended September 30, 2023 and 2022

	Nine Months Ended September 30,	
	2023	**2022**
Operating expenses		
Research and development	$ 97,107	$ 229,693
General and administrative	33,966	46,520
Total operating expenses	131,073	276,213
Loss from operations	(131,073)	(276,213)
Interest income	7,965	898
Other expense, net	(42)	(1,648)
Net loss	(123,150)	(276,963)
Unrealized gain (loss) on investments	212	89
Comprehensive loss	$ (122,938)	$ (276,874)

Research and Development Expenses

Research and development expenses were $97.1 million for the nine months ended September 30, 2023 compared to $229.7 million for the nine months ended September 30, 2022, a decrease of $132.6 million. The decrease was attributed to a $130.5 million charge related to the Lonza Termination agreement and $4.6 million of costs as a result of the Reorganization Plan recognized during the first quarter of the prior year, as well as a benefit of $2.7 million relating to payroll tax credit claims recognized during the nine months ended September 30, 2023, offset by an increase of $3.3 million in other contract research and development costs and clinical costs primarily relating to lirentelimab (AK002) and AK006 and a $1.9 million increase in other research and development expenses.

General and Administrative Expenses

General and administrative expenses were $34.0 million for the nine months ended September 30, 2023 compared to $46.5 million for the nine months ended September 30, 2022, a decrease of $12.5 million. The decrease included $4.3 million of costs as a result of the Reorganization Plan recognized during the first quarter of the prior year. Additionally, the nine months ended September 30, 2023

included a benefit of $1.2 million relating to payroll tax credit claims. The remaining decrease was primarily due to decreases of $3.9 million in other employee compensation and $3.1 million in other general and administrative expenses.

Interest Income

Interest income was $8.0 million and $0.9 million for the nine months ended September 30, 2023 and September 30, 2022, respectively, with the increase attributed primarily to higher interest rates.

Other Expense, Net

Change in other expense, net, for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022, were primarily attributed to changes in foreign exchange gains and losses.

Net Loss

Net loss was $123.2 million for the nine months ended September 30, 2023 compared to net loss of $277.0 million for the nine months ended September 30, 2022. Total combined stock-based compensation and depreciation expense for the nine months ended September 30, 2023 and September 30, 2022 was $35.6 million and $39.4 million, respectively.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2023, we had cash, cash equivalents and investments of $193.9 million. Based on our existing business plan, we believe that our current cash, cash equivalents and investments will be sufficient to fund our anticipated level of operations through at least the next 12 months from the issuance of our financial statements.

We are a clinical stage biotechnology company with a limited operating history. As a result of our significant research and development expenditures, we have generated net losses since our inception. We have financed our operations primarily through equity offerings.

September 2022 Offering

On September 21, 2022, we closed an underwritten registered direct offering (the "September 2022 Offering") under our shelf registration statement on Form S-3 (File No. 333-265085) pursuant to which we sold an aggregate of 29,882,000 shares of our common stock, at a public offering price of $5.02 per share. We received aggregate net proceeds of $140.6 million, after deducting the underwriting commissions and offering expenses.

"At-the-Market" Equity Offering

On August 4, 2022, we entered into a sales agreement (the "2022 Sales Agreement") with Cowen and Company, LLC ("Cowen"). Pursuant to the 2022 Sales Agreement we may sell, from time to time up to an aggregate of $75.0 million in gross sales proceeds of our common stock through an ATM Offering. We will pay Cowen a commission equal to 3.0% of the gross proceeds from the sale of shares of our common stock under the 2022 Sales Agreement. The $75.0 million of common stock that may be offered, issued and sold in the ATM Offering is included in the $250.0 million of securities that may be offered, issued and sold by us under our registration statement on Form S-3 (File No. 333-265085). We expect to use the net proceeds from sales under the 2022 Sales Agreement for general corporate purposes.

During the nine months ended September 30, 2023, we sold 0.1 million shares of our common stock at an average price of $7.20 per share through our ATM Offering, resulting in proceeds of $1.0 million net of commissions, with all sales occurring during the first quarter of 2023. Under our current ATM Offering program, $74.0 million of common stock remain available for future sales as of September 30, 2023; however, we are not obligated to make any sales under this program.

Summary Cash Flows

Comparison of the nine months ended September 30, 2023 and 2022

The following table summarizes the primary sources and uses of our cash, cash equivalents, and restricted cash for the periods indicated (in thousands):

	Nine Months Ended September 30,	
	2023	2022
Net cash used in operating activities	$ (92,212)	$ (233,185)
Net cash provided by investing activities	72,986	143,158
Net cash provided by financing activities	2,528	141,692
Net decrease in cash, cash equivalents and restricted cash	$ (16,698)	$ 51,665

Cash Used in Operating Activities

Net cash used in operating activities was $92.2 million for the nine months ended September 30, 2023, which was primarily attributable to our net loss of $123.2 million adjusted for net noncash charges of $32.4 million and net changes in operating assets and liabilities of $1.4 million. Noncash charges included approximately $31.0 million in stock-based compensation expense, $4.6 million in depreciation and amortization expense, $4.3 million in net accretion of premiums and discounts on investments and $1.1 million in noncash lease expense.

Net cash used in operating activities was $233.2 million for the nine months ended September 30, 2022, which was primarily attributable to our net loss of $277.0 million adjusted for net noncash charges of $44.3 million and net changes in operating assets and liabilities of $0.5 million. Noncash charges included approximately $33.9 million in stock-based compensation expense, $5.6 million in depreciation and amortization expense, $2.3 million in amortization of premiums and discounts on investments and $2.5 million in noncash lease expense.

Cash Provided by Investing Activities

Net cash provided by investing activities was $73.0 million for the nine months ended September 30, 2023, which consisted of $213.0 million in proceeds from maturities of investments, partially offset by $139.4 million for the purchases of investments and $0.6 million for the purchases of property and equipment.

Net cash provided by investing activities was $143.2 million for the nine months ended September 30, 2022, which consisted of $270.0 million in proceeds from maturities of investments, $20.0 million in proceeds from sales of investments and $1.2 million in proceeds from the sale of property and equipment, partially offset by $140.0 million for the purchases of investments and $8.0 million for the purchases of property and equipment.

Cash Provided by Financing Activities

Net cash provided by financing activities was $2.5 million for the nine months ended September 30, 2023, which consisted of $1.0 million in net proceeds from the issuance of common stock in connection with the ATM Offering, $1.5 million in proceeds received from employees for the purchase of common stock through the 2018 ESPP and for the exercise of stock options.

Net cash provided by financing activities was $141.7 million for the nine months ended September 30, 2022, which consisted of $140.6 million in net proceeds from the issuance of common stock in connection with the September 2022 Offering and $1.1 million in proceeds received from employees for the exercise of stock options and the purchase of common stock through the 2018 ESPP.

Funding Requirements

As of September 30, 2023, we had cash, cash equivalents and investments, excluding restricted cash, of $193.9 million, which we believe will be sufficient to fund our planned operations for at least the next 12 months from the issuance date of our unaudited interim financial statements included elsewhere in this Quarterly Report on Form 10-Q. We will continue to require additional capital to develop our product candidates, achieve commercial approval and fund operations for the foreseeable future. We intend to seek and have sought to raise funding from time to time through private or public equity or debt financings, or other sources such as strategic collaborations. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies.

The timing and amount of our capital expenditures will depend on many factors, including:

- the number and scope of clinical indications and clinical trials we decide to pursue;
- the scope and costs of manufacturing activities;
- the extent to which we acquire or in-license other product candidates and technologies, if any;
- the cost, timing and outcome of regulatory review of our product candidates, and if successful, the cost and time necessary to bring product candidates to market;

- the cost and timing of establishing sales and marketing capabilities for product candidates receiving marketing approval, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates; and
- the costs associated with being a public company.

If we are unable to raise additional funds when needed, we may be required to delay, reduce or terminate some or all of our development efforts. We may also be required to sell or license to others rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves.

The issuance of additional equity securities may cause our stockholders to experience dilution. Future equity or debt financings may contain terms that are not favorable to us or our stockholders including debt instruments imposing covenants that restrict our operations and limit our ability to incur liens, issue additional debt, pay dividends, repurchase our common stock, make certain investments or engage in certain merger, consolidation, licensing or asset sale transactions.

Contractual Obligations and Commitments

Our contractual obligations and commitments relate primarily to our operating leases and non-cancelable purchase obligations under agreements with various research and development organizations and suppliers in the ordinary course of business.

In the normal course of business, we enter into contracts with clinical CROs, clinical investigative sites and other counterparties assisting with our preclinical studies and clinical trials. Such contracts are generally cancellable, with varying provisions regarding termination. In the event of a contract being terminated, we would only be obligated for services received as of the effective date of the termination, along with cancellation fees, as applicable. Additionally, we have entered into agreements with certain vendors for the provision of goods and services, which includes development and manufacturing services with CDMOs. These agreements may include certain provisions for purchase obligations and termination obligations that could require payment for the cancellation of committed purchase obligations or for early termination of the agreements. The amounts of the cancellation or termination payments may vary and are based on the timing of the cancellation or termination and the specific terms of the agreements. We expect to enter into additional collaborative research, contract research, clinical and commercial manufacturing, and supplier agreements in the future, which may require significant upfront payments and long-term commitments of capital resources. Additionally, see Note 6, Leases, and Note 7, Contingencies, to our unaudited interim financial statements for further information relating to lease commitments, indemnification obligations and other commitments.

Off-Balance Sheet Arrangements

Since our inception, we have not entered into any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, we are not required to provide this disclosure.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures. As of September 30, 2023, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended September 30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Many of our employees, including some of those responsible for financial reporting, work remotely a significant amount of time. As part of our Company's transition to a hybrid/remote workforce, we took precautionary actions to re-evaluate our financial reporting process to provide assurance that we could report our financial results accurately and timely. We will continue to monitor and assess new potential impacts of having hybrid/remote workforce on the design and operating effectiveness of our internal controls going forward.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Item 1A. Risk Factors.

Except as set forth below, our risk factors have not materially changed from those previously disclosed in Part 1, Item 1A "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022.

We have incurred significant net losses since inception and we expect to continue to incur significant net losses for the foreseeable future.

We have incurred net losses in each reporting period since our inception, have not generated any revenue to date and have financed our operations principally through the sale and issuance of common stock and preferred stock. Our net losses were $320.0 million for the year ended December 31, 2022 and $123.2 million for the nine months ended September 30, 2023. As of September 30, 2023, we had an accumulated deficit of $1,055.9 million. We have devoted substantially all of our resources and efforts to research and development. One of our lead compounds, lirentelimab, is in clinical development, and our other product candidates are in preclinical development. As a result, we expect that it will be several years, if ever, before we generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to develop and market additional potential products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter-to-quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on our manufacturing and clinical activities, the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital and our ability to achieve and maintain profitability.

We will require substantial additional capital to finance our operations. 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 research and drug development programs or future commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for, lirentelimab and our other product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution. We have also incurred and expect to continue to incur significant costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we may need to reevaluate our operating plan and may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

As of September 30, 2023, we had $193.9 million in cash, cash equivalents and investments. We filed: (i) on August 4, 2022, a prospectus supplement to such shelf registration statement that covers the offering, issuance and sale of up to $75.0 million of our common stock from time to time through an "at-the-market" program under the Securities Act of 1933, as amended, and (ii) on September 19, 2022, a prospectus supplement to our shelf registration statement on Form S-3 (File No. 333-265085) that covered the offering, issuance and sale of 29,882,000 shares of our common stock, at a public offering price of $5.02 per share. We received aggregate net proceeds of $140.6 million, after deducting the underwriting commissions and offering expenses from the September 19, 2022 follow-on offering and as of September 30, 2023 received aggregate net proceeds of $1.0 million under the "at-the-market" program. We believe that our existing cash, cash equivalents and investments will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months. Our estimate as to how long we expect our existing cash, cash equivalents and investments to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We plan to use our existing cash, cash equivalents and investments to fund our development of lirentelimab, AK006 and for other research and development activities, working capital and other general corporate purposes. This may include additional research, hiring

additional personnel, capital expenditures and the costs of operating as a public company. Advancing the development of lirentelimab, AK006 and any other product candidates will require a significant amount of capital. Our existing cash, cash equivalents and investments will not be sufficient to fund all of the actions that are necessary to complete the development and commercial approval of lirentelimab, AK006 or any of our other product candidates. We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. Additionally, our ability to raise additional capital may be adversely impacted by potential worsening of global economic conditions and volatility of financial markets in the United States and worldwide. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

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

Not applicable.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

EXHIBIT INDEX

Exhibit Number	Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Number	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-38582	3.1	7/24/2018	
3.2	Amended and Restated Bylaws of the Registrant.	8-K	001-38582	3.1	8/21/2023	
10.1+	Outside Director Compensation Policy.	10-Q	001-38582	10.1	8/9/2023	
31.1	Certification of Principal Executive Officer 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.					X
31.2	Certification of Principal Financial Officer 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.					X
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 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 - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	The cover page for the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, has been formatted in Inline XBRL and is contained in Exhibit 101.					X

+ Indicated management contract or compensatory plan.

* The certifications attached as Exhibit 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

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.

Allakos Inc.

Date: November 13, 2023

By: /s/ Robert Alexander

Robert Alexander, Ph.D.
Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 13, 2023

By: /s/ H. Baird Radford, III

H. Baird Radford, III
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Robert Alexander, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Allakos Inc.;

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.

Date: November 13, 2023

By: /s/ Robert Alexander

Robert Alexander, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, H. Baird Radford, III, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Allakos Inc.;

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.

Date: November 13, 2023

By: /s/ H. Baird Radford, III

H. Baird Radford, III
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 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

In connection with the Quarterly Report of Allakos Inc. (the "Company") on Form 10-Q for the period ending September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 13, 2023

By: /s/ Robert Alexander

Robert Alexander, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Allakos Inc. (the "Company") on Form 10-Q for the period ending September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 13, 2023

By: /s/ H. Baird Radford, III

H. Baird Radford, III
Chief Financial Officer
(Principal Financial and Accounting Officer)