

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, 2024

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
(State or other jurisdiction of
incorporation or organization)
825 Industrial Road, Suite 500
San Carlos, California
(Address of principal executive offices)

45-4798831
(I.R.S. Employer
Identification No.)

94070
(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 1, 2024, the registrant had 89,343,634 shares of common stock outstanding.

ALLAKOS INC.
Table of Contents

| | <u>Page</u> |
|-------------------|-------------|
| PART I. | |
| | <u>2</u> |
| Item 1. | <u>2</u> |
| | <u>2</u> |
| | <u>3</u> |
| | <u>4</u> |
| | <u>5</u> |
| | <u>6</u> |
| Item 2. | <u>16</u> |
| Item 3. | <u>25</u> |
| Item 4. | <u>25</u> |
| PART II. | <u>26</u> |
| Item 1. | <u>26</u> |
| Item 1A. | <u>26</u> |
| Item 2. | <u>27</u> |
| Item 3. | <u>27</u> |
| Item 4. | <u>27</u> |
| Item 5. | <u>28</u> |
| Item 6. | <u>29</u> |
| <u>Signatures</u> | <u>30</u> |

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (unaudited).

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

| | September 30, 2024 (unaudited) | December 31, 2023 |
|---|--------------------------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 10,449 | \$ 66,440 |
| Investments | 82,266 | 104,354 |
| Prepaid expenses and other current assets | 4,438 | 9,095 |
| Total current assets | 97,153 | 179,889 |
| Property and equipment, net | 15,733 | 33,369 |
| Operating lease right-of-use assets | 9,880 | 24,136 |
| Other long-term assets | 1,668 | 6,216 |
| Total assets | \$ 124,434 | \$ 243,610 |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 3,964 | \$ 1,764 |
| Accrued expenses and other current liabilities | 12,017 | 34,814 |
| Total current liabilities | 15,981 | 36,578 |
| Operating lease liabilities, net of current portion | 35,710 | 38,215 |
| Total liabilities | 51,691 | 74,793 |
| Contingencies (Note 8) | | |
| Stockholders' equity: | | |
| Preferred stock, \$0.001 par value per share; 20,000 shares authorized as of September 30, 2024 and December 31, 2023; no shares issued and outstanding as of September 30, 2024 and December 31, 2023 | — | — |
| Common stock, \$0.001 par value per share; 200,000 shares authorized as of September 30, 2024 and December 31, 2023; 89,344 and 87,750 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively | 89 | 88 |
| Additional paid-in capital | 1,306,991 | 1,287,156 |
| Accumulated other comprehensive gain (loss) | 334 | 50 |
| Accumulated deficit | (1,234,671) | (1,118,477) |
| Total stockholders' equity | 72,743 | 168,817 |
| Total liabilities and stockholders' equity | \$ 124,434 | \$ 243,610 |

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, | |
|---|-------------------------------------|--------------------|------------------------------------|---------------------|
| | 2024 | 2023 | 2024 | 2023 |
| Operating expenses | | | | |
| Research and development | \$ 10,874 | \$ 36,749 | \$ 65,120 | \$ 97,107 |
| General and administrative | 8,876 | 11,461 | 28,985 | 33,966 |
| Impairment of long-lived assets | — | — | 27,347 | — |
| Total operating expenses | <u>19,750</u> | <u>48,210</u> | <u>121,452</u> | <u>131,073</u> |
| Loss from operations | (19,750) | (48,210) | (121,452) | (131,073) |
| Interest income | 1,392 | 2,590 | 5,346 | 7,965 |
| Other expense, net | (14) | (6) | (88) | (42) |
| Net loss | (18,372) | (45,626) | (116,194) | (123,150) |
| Unrealized gain (loss) on investments | 325 | 87 | 284 | 212 |
| Comprehensive loss | <u>\$ (18,047)</u> | <u>\$ (45,539)</u> | <u>\$ (115,910)</u> | <u>\$ (122,938)</u> |
| Net loss per common share: | | | | |
| Basic and diluted | <u>\$ (0.21)</u> | <u>\$ (0.52)</u> | <u>\$ (1.31)</u> | <u>\$ (1.42)</u> |
| Weighted-average number of common shares outstanding: | | | | |
| Basic and diluted | <u>89,024</u> | <u>87,115</u> | <u>88,571</u> | <u>86,539</u> |

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, 2023 | 87,750 | \$ 88 | \$ 1,287,156 | \$ 50 | \$ (1,118,477) | \$ 168,817 |
| Stock-based compensation expense | — | — | 6,210 | — | — | 6,210 |
| Issuance of common stock upon exercise of stock options | 26 | — | 26 | — | — | 26 |
| Issuance of common stock upon 2018 ESPP purchase | 98 | — | 106 | — | — | 106 |
| Issuance of common stock upon vesting of restricted stock units | 670 | 1 | (1) | — | — | — |
| Unrealized gain (loss) on investments | — | — | — | (30) | — | (30) |
| Net loss | — | — | — | — | (71,146) | (71,146) |
| Balance at March 31, 2024 | 88,544 | \$ 89 | \$ 1,293,497 | \$ 20 | \$ (1,189,623) | \$ 103,983 |
| Stock-based compensation expense | — | — | 6,703 | — | — | 6,703 |
| Issuance of common stock upon vesting of restricted stock units | 307 | — | — | — | — | — |
| Unrealized gain (loss) on investments | — | — | — | (11) | — | (11) |
| Net loss | — | — | — | — | (26,676) | (26,676) |
| Balance at June 30, 2024 | 88,851 | \$ 89 | \$ 1,300,200 | \$ 9 | \$ (1,216,299) | \$ 83,999 |
| Stock-based compensation expense | — | — | 6,746 | — | — | 6,746 |
| Issuance of common stock upon 2018 ESPP purchase | 80 | — | 45 | — | — | 45 |
| Issuance of common stock upon vesting of restricted stock units | 413 | — | — | — | — | — |
| Unrealized gain (loss) on investments | — | — | — | 325 | — | 325 |
| Net loss | — | — | — | — | (18,372) | (18,372) |
| Balance at September 30, 2024 | 89,344 | \$ 89 | \$ 1,306,991 | \$ 334 | \$ (1,234,671) | \$ 72,743 |

| | 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 (loss) 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 gain (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 (loss) 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 |

See accompanying notes to unaudited interim financial statements

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

| | Nine Months Ended September 30, | |
|---|------------------------------------|--------------|
| | 2024 | 2023 |
| Cash flows from operating activities | | |
| Net loss | \$ (116,194) | \$ (123,150) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Impairment of long-lived assets | 27,347 | — |
| Depreciation and amortization | 2,818 | 4,594 |
| Stock-based compensation | 19,659 | 31,020 |
| Net amortization (accretion) of premiums and discounts on investments | (2,590) | (4,324) |
| Noncash lease expense | 1,846 | 1,106 |
| Loss on disposal of property and equipment | — | 3 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | 4,547 | 4,790 |
| Other long-term assets | 4,548 | 2,124 |
| Accounts payable | 2,190 | (3,709) |
| Accrued expenses and other current liabilities | (22,796) | (2,372) |
| Operating lease liabilities, net of current portion | (2,505) | (2,294) |
| Net cash used in operating activities | (81,130) | (92,212) |
| Cash flows from investing activities | | |
| Purchases of investments | (100,524) | (139,388) |
| Proceeds from maturities of investments | 125,595 | 213,000 |
| Purchases of property and equipment | (109) | (626) |
| Net cash provided by investing activities | 24,962 | 72,986 |
| Cash flows from financing activities | | |
| Proceeds from issuance of common stock, net of issuance costs | — | 990 |
| Proceeds from exercise of stock options | 26 | 673 |
| Proceeds from issuance of common stock under the 2018 ESPP | 151 | 865 |
| Net cash provided by financing activities | 177 | 2,528 |
| Net decrease in cash, cash equivalents and restricted cash | (55,991) | (16,698) |
| Cash, cash equivalents and restricted cash, beginning of period | 67,912 | 88,689 |
| Cash, cash equivalents and restricted cash, end of period | \$ 11,921 | \$ 71,991 |
| 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 |
| Increase (decrease) in payables related to purchase of property and equipment | \$ 10 | \$ (208) |

See accompanying notes to unaudited interim financial statements

ALLAKOS INC.
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 developing therapeutics which target immunomodulatory receptors present on immune effector cells involved in allergic, inflammatory and proliferative diseases. The Company’s most advanced product candidate is AK006 which targets mast cells. Inappropriately activated mast cells have been identified as key drivers in a number of severe diseases affecting the gastrointestinal tract, eyes, skin, lungs and other organs. 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, 2024, the Company incurred a net loss of \$116.2 million. At September 30, 2024, the Company had an accumulated deficit of \$1,234.7 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.

On January 16, 2024, the Company announced that due to unfavorable clinical trial results associated with the use of lirentelimab in its Phase 2 atopic dermatitis and Phase 2b chronic spontaneous urticaria trials, that the Company would halt lirentelimab-related activities across clinical, manufacturing, research and administrative functions. Accordingly, the Company’s Board of Directors approved a reorganization plan to reduce operating costs and better align the Company’s workforce with its current clinical development plans of its business (the “2024 Reorganization Plan”). Under the 2024 Reorganization Plan, the Company’s workforce was reduced by approximately 50% primarily during the first quarter of 2024.

The Company had \$92.7 million of cash, cash equivalents and investments at September 30, 2024. 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, 2024, the statements of operations and comprehensive loss, statements of stockholders’ equity for the three and nine months ended September 30, 2024 and 2023 and statements of cash flows for the nine months ended September 30, 2024 and 2023 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, 2024 and its results of operations and comprehensive loss for the three and nine months ended September 30, 2024 and 2023 and its cash flows for the nine months ended September 30, 2024 and 2023. 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 14, 2024.

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, valuation of long-lived assets 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, protection of proprietary technology, 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, 2024 | December 31, 2023 |
|---|-----------------------|----------------------|
| Cash and cash equivalents | \$ 10,449 | \$ 66,440 |
| Restricted cash in other long-term assets | 1,472 | 1,472 |
| Total | <u>\$ 11,921</u> | <u>\$ 67,912</u> |

| | 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 | <u>\$ 71,991</u> | <u>\$ 88,689</u> |

Restricted cash at September 30, 2024 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) unless the decline in fair value of the investments is attributable to expected credit losses and if it is more likely than not that the Company will be required or will intend to sell the investment before recovery of its amortized cost basis. 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 on the sale of investments are included in other expense, net, on the statements of operations and comprehensive loss.

Valuation of Long-lived Assets

Long-lived assets, including property and equipment and finite-lived intangible assets, are reviewed for possible impairment whenever events or circumstances indicate that the carrying amount of such assets may not be recoverable. The evaluation is performed at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities. Recoverability of these assets is measured by a comparison of the carrying amounts to the future undiscounted cash flows the assets are expected to generate from the use and eventual disposition. If such review indicates that the carrying amount of the long-lived assets is not recoverable, the carrying amount of such assets is reduced to fair value. The Company has recorded impairment charges during the nine months ended September 30, 2024. For a further description of the impairment, see Note 5 – *Impairment of Long-Lived Assets* in the accompanying notes.

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, 2024 and 2023 are a result of unrealized gains and losses on the Company's investments in marketable securities 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.

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, | |
|---|-------------------------------------|-------------|------------------------------------|--------------|
| | 2024 | 2023 | 2024 | 2023 |
| Numerator: | | | | |
| Net loss | \$ (18,372) | \$ (45,626) | \$ (116,194) | \$ (123,150) |
| Denominator: | | | | |
| Weighted-average shares of common stock outstanding, basic and diluted | 89,024 | 87,115 | 88,571 | 86,539 |
| Net loss per share, basic and diluted | \$ (0.21) | \$ (0.52) | \$ (1.31) | \$ (1.42) |

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, | |
|---|------------------------------------|--------|
| | 2024 | 2023 |
| Options to purchase common stock | 13,214 | 7,966 |
| Unvested restricted stock units | 5,714 | 5,902 |
| Unvested performance stock units | — | 2,851 |
| Shares issuable under employee stock purchase plans | 69 | 58 |
| Total | 18,997 | 16,777 |

Recently Issued and Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. This ASU requires entities to expand their existing income tax disclosures, specifically related to the rate reconciliation and income taxes paid. This authoritative guidance will be effective for us in fiscal year 2025, with early adoption permitted. The Company is currently evaluating the impact of the ASU, but does not expect any material impact upon adoption.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which requires all public entities, including public entities with a single reportable segment, to provide in interim and annual periods one or more measures of segment profit or loss used by the chief operating decision maker to allocate resources and assess performance. Additionally, the standard requires disclosures of significant segment expenses and other segment items as well as incremental qualitative disclosures. The guidance in this update is effective for the Company's fiscal year 2024 annual reporting period. The Company is currently in the process of evaluating the effects of this pronouncement on its related disclosures.

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, 2024 | | | |
|---|--------------------|---------|---------|------------|
| | Level 1 | Level 2 | Level 3 | Total |
| Cash equivalents: | | | | |
| Money market funds | \$ 10,747 | \$ — | \$ — | \$ 10,747 |
| Total cash equivalents | 10,747 | — | — | 10,747 |
| Short-term marketable securities | | | | |
| U.S. treasuries | 72,290 | — | — | 72,290 |
| U.S. government agency bonds | 9,976 | — | — | 9,976 |
| Total short-term marketable securities | 82,266 | — | — | 82,266 |
| Total cash equivalents and short-term marketable securities | \$ 93,013 | \$ — | \$ — | \$ 93,013 |
| | December 31, 2023 | | | |
| | Level 1 | Level 2 | Level 3 | Total |
| Cash equivalents: | | | | |
| Money market funds | \$ 67,070 | \$ — | \$ — | \$ 67,070 |
| Total cash equivalents | 67,070 | — | — | 67,070 |
| Short-term marketable securities: | | | | |
| U.S. treasuries | 96,705 | — | — | 96,705 |
| U.S. government agency bonds | 7,649 | — | — | 7,649 |
| Total short-term marketable securities | 104,354 | — | — | 104,354 |
| Total cash equivalents and short-term marketable securities | \$ 171,424 | \$ — | \$ — | \$ 171,424 |

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, 2024 and 2023.

4. Investments

All investments were considered available-for-sale at September 30, 2024. The amortized cost, gross unrealized holding gains or losses, and fair value of the Company's investments by major security type at September 30, 2024 and December 31, 2023 are summarized in the table below (in thousands):

| | September 30, 2024 | | | |
|---|----------------------|------------------|-------------------|------------|
| | Amortized Cost Basis | Unrealized Gains | Unrealized Losses | Fair Value |
| Available-for-sale securities: | | | | |
| U.S. treasuries classified as investments | \$ 71,993 | \$ 297 | \$ — | \$ 72,290 |
| U.S. government agency bonds | 9,974 | 2 | — | 9,976 |
| Total available-for-sale securities | \$ 81,967 | \$ 299 | \$ — | \$ 82,266 |
| | December 31, 2023 | | | |
| | Amortized Cost Basis | Unrealized Gains | Unrealized Losses | Fair Value |
| Available-for-sale securities: | | | | |
| U.S. treasuries classified as investments | \$ 96,688 | \$ 39 | \$ (22) | \$ 96,705 |
| U.S. government agency bonds | 7,652 | — | (3) | 7,649 |
| Total available-for-sale securities | \$ 104,340 | \$ 39 | \$ (25) | \$ 104,354 |

The amortized cost of available-for-sale securities is adjusted for amortization of premiums and accretion of discounts to maturity. As of September 30, 2024, the Company held no securities in an unrealized loss position. As of December 31, 2023, the aggregate fair value of securities held by the Company in an unrealized loss position for less than twelve months was \$53.7 million. 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, 2024 and December 31, 2023.

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, 2024 and 2023, and as a result, there were no material reclassifications out of accumulated other comprehensive gain (loss) for the same periods.

5. Impairment of Long-Lived Assets

During the first quarter of 2024, as a result of the significant sustained decline observed in the Company's stock price and related market capitalization following the Company's decision to halt the development of lrentelimab, the Company performed an impairment assessment of long-lived assets. The Company determined that the long-lived assets held and used did not have identifiable cash flows that were largely independent of the cash flows of other assets and liabilities. Therefore, the Company evaluated its long-lived assets for impairment on an entity-wide level. The Company concluded that the carrying value of the entity-wide asset group was not recoverable as it exceeded the future net undiscounted cash flows. To measure, allocate and recognize the impairment loss, the Company determined individual fair values of its long-lived assets. The Company utilized the income approach for estimating the fair value of right of use assets and related leasehold improvements by estimating the potential cash flows from a hypothetical fully-furnished sublease and applying a discount rate. The cost replacement method was used to estimate the fair value of laboratory and office equipment, capitalized software, and assets to be placed into service or in the process of construction. These represented Level 3 nonrecurring fair value measurements. Based on this analysis, the Company recorded a \$27.3 million charge to Impairment of long-lived assets in the Statement of Operations and Comprehensive Loss during the nine months ended September 30, 2024, of which \$12.4 million was attributed to right-of-use assets, \$13.9 million to leasehold improvements, and \$1.0 million to furniture. No impairment was recognized on the remaining long-lived assets as their carrying values were not in excess of their fair values.

6. Balance Sheet Components and Supplemental Disclosures

Property and Equipment, Net

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

| | September 30, 2024 | December 31, 2023 |
|--------------------------------|-----------------------|----------------------|
| Laboratory equipment | \$ 7,005 | \$ 6,993 |
| Furniture and office equipment | 1,468 | 3,947 |
| Leasehold improvements | 12,135 | 32,386 |
| Capitalized software | 4,437 | 4,382 |
| Construction-in-progress | 86 | 69 |
| | <u>25,131</u> | <u>47,777</u> |
| Less accumulated depreciation | (9,398) | (14,408) |
| Property and equipment, net | <u>\$ 15,733</u> | <u>\$ 33,369</u> |

Depreciation and amortization expense for the three months ended September 30, 2024 and 2023 was \$0.9 million and \$1.5 million, respectively. Depreciation and amortization expense for the nine months ended September 30, 2024 and 2023 was \$2.8 million and \$4.6 million, respectively. As discussed in Note 5 – *Impairment of Long-Lived Assets*, the Company recognized long-lived asset impairment charges of \$13.9 million for its leasehold improvements and \$1.0 million on furniture during the nine months ended September 30, 2024.

Accrued Expenses and Other Current Liabilities

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

| | September 30, 2024 | December 31, 2023 |
|---|-----------------------|----------------------|
| Accrued contract research and development expense | \$ 3,513 | \$ 22,262 |
| Accrued compensation and benefits expense | 4,552 | 8,674 |
| Current portion of operating lease liabilities | 3,292 | 3,250 |
| Other current liabilities | 660 | 628 |
| Total | <u>\$ 12,017</u> | <u>\$ 34,814</u> |

7. 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 \$14.4 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%. The estimated incremental borrowing rate was based on the Company's estimated rate of interest for a fully collateralized borrowing over a similar term as the remaining lease payments while incorporating the Company's 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. As discussed in Note 5 – *Impairment of Long-Lived Assets*, the Company recognized long-lived asset impairment charges of \$12.4 million on the right-of-use assets relating to the 2019 San Carlos Lease during the nine months ended September 30, 2024.

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, 2024 and December 31, 2023, 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, 2024 and December 31, 2023 was as follows (in thousands):

| | September 30, 2024 | December 31, 2023 |
|--|-----------------------|----------------------|
| Operating lease liabilities | | |
| Current portion included in accrued expenses and other current liabilities | \$ 3,292 | \$ 3,250 |
| Operating lease liabilities, net of current portion | 35,710 | 38,215 |
| Total operating lease liabilities | <u>\$ 39,002</u> | <u>\$ 41,465</u> |

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 | | Nine Months Ended | |
|-----------------------|--------------------|-----------------|-------------------|-----------------|
| | September 30, | | September 30, | |
| | 2024 | 2023 | 2024 | 2023 |
| Operating lease costs | \$ 1,385 | \$ 1,407 | \$ 4,257 | \$ 4,283 |
| Variable costs | 926 | 894 | 2,716 | 2,733 |
| Total lease costs | <u>\$ 2,311</u> | <u>\$ 2,301</u> | <u>\$ 6,973</u> | <u>\$ 7,016</u> |

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 \$5.6 million and \$4.9 million for the nine months ended September 30, 2024 and 2023, respectively. Cash received for amounts related to tenant improvements from lessors was \$0.0 million and \$0.3 million for the nine months ended September 30, 2024 and 2023, respectively.

Operating Lease Obligations

Future lease payments required under operating leases included on the Company's balance sheet at September 30, 2024 are as follows (in thousands):

| <u>Fiscal Year Ending December 31,</u> | |
|---|------------------|
| 2024 (remaining 3 months) | \$ 1,804 |
| 2025 | 7,287 |
| 2026 | 7,506 |
| 2027 | 7,731 |
| 2028 | 7,963 |
| Thereafter | 23,871 |
| Total future lease payments | <u>56,162</u> |
| Less: | |
| Present value adjustment | 17,160 |
| Operating lease liabilities | <u>\$ 39,002</u> |

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, 2024, the weighted-average remaining lease term of the Company's leases was 7.1 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, 2024, the Company was not party to any lease agreements containing material residual value guarantees or material restrictive covenants.

8. Contingencies

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 as of September 30, 2024.

9. Stockholders' Equity

“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.

No shares were sold during the nine months ended September 30, 2024 through the Company's ATM Offering. 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. Under the ATM Offering, \$74.0 million of common stock remain available for future sales as of September 30, 2024; however, the Company is not obligated to make any sales under this program.

10. Stock-Based Compensation

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|----------------------------|-------------------------------------|-----------|------------------------------------|-----------|
| | 2024 | 2023 | 2024 | 2023 |
| Research and development | \$ 2,269 | \$ 4,408 | \$ 5,719 | \$ 13,171 |
| General and administrative | 4,477 | 6,126 | 13,940 | 17,849 |
| Total | \$ 6,746 | \$ 10,534 | \$ 19,659 | \$ 31,020 |

Stock Options

The Company's stock option activity during the nine months ended September 30, 2024, is summarized as follows (number of shares in thousands):

| | Options Outstanding | Weighted- Average Exercise Price |
|-------------------------------------|------------------------|---|
| Balance at December 31, 2023 | 7,968 | \$ 10.85 |
| Granted | 5,933 | \$ 1.26 |
| Exercised | (26) | \$ 0.97 |
| Expired | (304) | \$ 41.23 |
| Forfeited | (357) | \$ 14.35 |
| Balance at September 30, 2024 | 13,214 | \$ 5.77 |
| Options exercisable | 5,434 | \$ 10.39 |
| Options vested and expected to vest | 12,684 | \$ 5.92 |

Time-based RSUs

RSU activity under the 2018 Plan during the nine months ended September 30, 2024, is summarized as follows (in thousands, except per share data):

| | Shares | | Weighted-Average Grant Date Fair Value |
|-------------------------------|--------------|----|--|
| Balance at December 31, 2023 | 5,621 | \$ | 10.16 |
| Granted | 4,118 | \$ | 1.23 |
| Vested | (1,390) | \$ | 12.45 |
| Forfeited | (2,635) | \$ | 7.44 |
| Balance at September 30, 2024 | <u>5,714</u> | \$ | 4.42 |

Performance-based Restricted Stock Units (“PSUs”)

As of September 30, 2024, there were no outstanding PSUs.

Determining Fair Value

The Company estimates the fair value of share options granted using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the input of certain assumptions that involve judgment, for which changes can materially affect the resulting estimates of fair value. Starting January 1, 2024, the Company estimated the expected term based on historical exercise patterns and its expectation of the time that it will take for employees to exercise options still outstanding. Prior to 2024, due to limited trading history, the Company did not believe that its historical employee exercise data provided reasonable data for estimating its expected term for use in determining the fair value of options. Therefore, for the period prior to 2024, the expected term of options was estimated based on the “simplified method” described by SEC Staff Accounting Bulletin No. 107, Share-Based Payment. There were no other changes to the assumptions and estimates related to determining the fair value of share options disclosed in the Company’s 2023 Annual Report on Form 10-K.

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”). As of September 30, 2024, the number of shares available for issuance under the 2018 ESPP was 3,481,174.

During the three and nine months ended September 30, 2024, stock-based compensation expense related to the 2018 ESPP was immaterial. 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.

11. 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, 2024, the Company made contributions to the 401(k) plan of \$0.1 million and \$0.7 million, respectively. 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.

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 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;
- the impact that the adoption of new accounting pronouncements will have on our financial statements;
- the beneficial characteristics, safety, efficacy and therapeutic effects of 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 AK006 or our other product candidates for various diseases;
- our ability to obtain and maintain regulatory approval of AK006 or our other product candidates;
- our continued reliance on third-parties to manufacture our product candidates and conduct additional clinical trials of AK006;
- 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 AK006 and our other product candidates;
- our intentions with respect to future sales and marketing plans;
- 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 plans and manufacturing development efforts of the foregoing;
- the sufficiency of our existing cash, cash equivalents and investments 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 inhibitory 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. Our most advanced product candidate, AK006, is currently in a Phase 1 clinical trial.

AK006 has shown activity in preclinical studies including a broad array of animal disease models of mast cell diseases. In June 2024, we announced positive results from our Phase 1 trial of intravenous (IV) AK006 in healthy volunteers, with AK006 demonstrating high receptor occupancy on mast cells and a favorable safety profile. In October 2024, we announced positive results from our Phase 1 trial of subcutaneous (SC) AK006 in healthy volunteers, with AK006 demonstrating good bioavailability, high and prolonged receptor occupancy on mast cells, and a favorable safety profile. We have prioritized our AK006 development efforts based on our assessment of the probability of clinical and regulatory success, unmet medical need and potential market opportunity. We have assembled a team with a proven track record and deep experience in antibody discovery and in clinical development, operations and finance.

The key elements of our strategy are to:

- **Obtain POC with AK006 in chronic spontaneous urticaria (CSU) and other mast cell driven conditions.** We are testing AK006 in a randomized, double-blind, placebo-controlled cohort of patients with CSU. We expect to report initial data from over 30 subjects with CSU in early Q1 of 2025. CSU is an inflammatory skin disease believed to be caused by the inappropriate activation of mast cells in the skin. We believe there is a need for additional treatments for patients with CSU that are refractory to antihistamines.
- **Develop Subcutaneous formulation of AK006.** We have also developed a formulation of AK006 for SC administration. As part of the Phase 1 study, we reported SC AK006 safety, PK, and PD data, including bioavailability, as well as Siglec-6 receptor occupancy in skin biopsy samples, in October 2024. We plan to use the SC formulation in subsequent AK006 clinical development.
- **Build therapeutic pipeline.** Our research is focused on 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. Following this approach, we have developed AK006 and have research programs directed at other immunomodulatory targets.

AK006 targets Siglec-6, an inhibitory receptor expressed selectively on mast cells, a type of white blood cell that is widely distributed in the body and plays a central role in the inflammatory response. 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 IgE, IL-33, KIT, 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 ADCP in the presence of activated macrophages. AK006 is currently being evaluated in a randomized, double-blind, placebo-controlled cohort of patients with CSU. We expect to report initial data from over 30 patients with CSU in early Q1 of 2025.

Chronic spontaneous urticaria is an inflammatory skin disease believed to be caused by the inappropriate activation of mast cells via IgE-dependent and IgE-independent pathways in the skin. Symptoms of chronic spontaneous urticaria include frequent and unpredictable eruption of hives, severe itching and swelling. First-line treatment consists of H1 antihistamine medication; however, a significant number of patients do not receive adequate benefit even at up to four times the labeled dose. In the United States, it is estimated that there are 800 thousand adults with moderate-to-severe CSU whose disease is refractory to antihistamines. There is only one FDA approved therapy for patients who are refractory to antihistamines, omalizumab, which binds IgE. Because AK006 inhibits both IgE-dependent and IgE-independent modes of mast cell activation, it has the potential to treat a broad CSU population or show greater symptom improvement.

AK006 is being studied in an ongoing Phase 1 clinical trial that consists of IV and subcutaneous (SC) single ascending dose (SAD) cohorts and IV multiple ascending dose (MAD) cohorts in healthy volunteers, as well as a cohort in patients with CSU who will be

administered AK006 via intravenous infusion. We have completed and reported data from the SAD and MAD IV and SC AK006 cohorts in healthy volunteers. We expect initial data from over 30 CSU cohort patients to be available in early Q1 of 2025.

In June 2024, we announced that, in the ongoing Phase 1 study in healthy volunteers, single and multiple IV doses of AK006 were well tolerated with a favorable safety profile. Skin biopsies taken from AK006 treated healthy volunteers showed high levels of receptor occupancy confirming AK006 reaches skin tissue mast cells. AK006 showed dose linear exposure and with an estimated half-life of 21 days for the highest (720 mg) IV dose. Moreover, AK006 achieved serum concentrations consistent with levels demonstrating inhibitory activity in preclinical experiments.

We have also developed a formulation of AK006 for SC administration. As part of the Phase 1 study, we announced in October 2024 that in healthy volunteers single SC doses of AK006 were well tolerated with a favorable safety profile. Subcutaneous AK006 showed bioavailability of 77% and an estimated half-life of 12-22 days. Consistent with the IV formulation, skin biopsies taken from subcutaneous AK006 treated healthy volunteers showed high levels of receptor occupancy, confirming AK006 reaches skin tissue mast cells. We plan to use the SC formulation in subsequent AK006 clinical development.

We had also been developing lirentelimab (AK002) and, in conjunction with the Phase 2 lirentelimab results in atopic dermatitis and chronic spontaneous urticaria, we announced on January 16, 2024 that we no longer plan to pursue further development of lirentelimab. Lirentelimab has been administered in more than 1,000 patients, and with approximately 500 patients exposed for six months or more. Lirentelimab has generally been well tolerated with no long-term safety findings to date.

Since our inception in 2012, we have devoted substantially all of our resources and efforts towards the research and development of our product candidates. 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, achieve commercial approval 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 \$116.2 million and \$123.2 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of \$1,234.7 million.

In January 2024, we began implementing the 2024 Reorganization Plan to reduce operating costs and better align our workforce with the current clinical development plans of our business. Accordingly, we decided to halt lirentelimab-related activities across clinical, manufacturing, research and administrative functions. As a result, we reduced our workforce by approximately 50%. While this resulted in increased near-term costs, primarily in the first and second quarters of 2024, we believe that the 2024 Reorganization Plan will reduce our overall spending in subsequent quarters subject to periodic fluctuations caused by the timing of ongoing manufacturing development efforts and the timing of future clinical trials. Additionally, as described in Note 5 – *Impairment of Long-Lived Assets*, we recorded a \$27.3 million noncash charge related to the impairment of long-lived assets during the nine months ended September 30, 2024.

As of September 30, 2024, we had cash, cash equivalents and investments of \$92.7 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.

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 to conduct nonclinical research and development activities;
- costs incurred under service agreements with clinical contract research organizations (“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. However, consulting and personnel-related costs, laboratory supplies and non-capital equipment utilized in the conduct of in-house research, in-licensing fees, various pre-clinical research costs 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.

Expenses in the second half of 2024 are expected to decrease as compared to the first half of 2024, given the decreased expenses relating to lirentelimab and the implementation of the 2024 Reorganization Plan.

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.

Our general and administrative expenses decreased in the first half of 2024 following the employment severance related costs associated with the 2024 Reorganization Plan. We expect to continue to incur costs associated with operating as a public company, including expenses related to maintaining compliance with the rules and regulations of the SEC, and those of any national securities exchange on which our securities are traded, additional insurance premiums, information technology and facility activities, and other ancillary administrative and professional services.

Impairment of Long-Lived Assets

During the first quarter of 2024, as a result of the significant sustained decline observed in the Company's stock price and related market capitalization following our decision to halt the development of lirentelimab, the Company believed a triggering event occurred and the potential of impairment existed with respect to our long-lived assets. As a result of these factors, we performed an impairment analysis of the Company's long-lived assets. Based on this analysis, we recognized a long-lived asset impairment charge of \$27.3 million during the nine months ended September 30, 2024. For more information see Note 5 – *Impairment of Long-Lived Assets* in the accompanying notes to the Condensed Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

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.

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, 2024, as described in Note 5 – *Impairment of Long-Lived Assets*, we utilized estimates in relation to the valuation and impairment of long-lived assets, and as described in Note 10 – *Stock-Based Compensation*, we updated our method for estimating the expected term of our stock options effective January 1, 2024. There were no other changes to our critical accounting policies and estimates as disclosed in our 2023 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, 2024 and 2023

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

| | Three Months Ended September 30, | |
|---------------------------------------|----------------------------------|-------------|
| | 2024 | 2023 |
| Operating expenses | | |
| Research and development | \$ 10,874 | \$ 36,749 |
| General and administrative | 8,876 | 11,461 |
| Impairment of long-lived assets | — | — |
| Total operating expenses | 19,750 | 48,210 |
| Loss from operations | (19,750) | (48,210) |
| Interest income | 1,392 | 2,590 |
| Other expense, net | (14) | (6) |
| Net loss | (18,372) | (45,626) |
| Unrealized gain (loss) on investments | 325 | 87 |
| Comprehensive loss | \$ (18,047) | \$ (45,539) |

Research and Development Expenses

Research and development expenses were \$10.9 million for the three months ended September 30, 2024 compared to \$36.7 million for the three months ended September 30, 2023, a decrease of \$25.8 million. This quarter over quarter decrease is attributed to a \$16.4 million decrease in contract research and development costs following the halting of lircetelimumab development, which includes a \$4.6 million decrease relating to a change in estimated manufacturing costs upon resolution of the related work orders with the vendor, \$5.7 million decrease in compensation costs and \$3.7 million decrease in other research and development expenses.

General and Administrative Expenses

General and administrative expenses were \$8.9 million for the three months ended September 30, 2024 compared to \$11.5 million for the three months ended September 30, 2023, a decrease of \$2.6 million. The quarter over quarter change is attributed to a \$2.4 million decrease in compensation costs and \$0.2 million decrease in other general and administrative expenses.

Impairment of Long-Lived Assets

We recorded no expenses related to the impairment of long-lived assets during the three months ended September 30, 2024 and 2023.

Interest Income

Interest income was \$1.4 million and \$2.6 million for the three months ended September 30, 2024 and 2023, respectively, with the decrease attributed primarily to the lower balance of investments.

Other Expense, Net

Changes in other expense, net were minimal for the three months ended September 30, 2024 compared to the three months ended September 30, 2023, and primarily attributed to changes in foreign exchange gains and losses.

Net Loss

Net loss was \$18.4 million for the three months ended September 30, 2024 compared to net loss of \$45.6 million for the three months ended September 30, 2023. The net loss included noncash expenses for stock-based compensation, depreciation expense and noncash lease amortization costs for the three months ended September 30, 2024 and 2023 of \$8.0 million and \$12.4 million, respectively.

Comparison of the Nine Months Ended September 30, 2024 and 2023

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

| | Nine Months Ended September 30, | |
|---------------------------------------|---------------------------------|--------------|
| | 2024 | 2023 |
| Operating expenses | | |
| Research and development | \$ 65,120 | \$ 97,107 |
| General and administrative | 28,985 | 33,966 |
| Impairment of long-lived assets | 27,347 | — |
| Total operating expenses | 121,452 | 131,073 |
| Loss from operations | (121,452) | (131,073) |
| Interest income | 5,346 | 7,965 |
| Other expense, net | (88) | (42) |
| Net loss | (116,194) | (123,150) |
| Unrealized gain (loss) on investments | 284 | 212 |
| Comprehensive loss | \$ (115,910) | \$ (122,938) |

Research and Development Expenses

Research and development expenses were \$65.1 million for the nine months ended September 30, 2024 compared to \$97.1 million for the nine months ended September 30, 2023, a decrease of \$32.0 million. This period over period decrease is attributed to \$12.4 million of decrease in contract research and development costs, which includes a \$4.6 million decrease relating to a change in estimated manufacturing costs upon resolution of the related work orders with the vendor, \$10.3 million decreased compensation costs, \$4.0 million decreased equipment and overhead costs, and \$5.3 million decrease in other research and development expenses.

General and Administrative Expenses

General and administrative expenses were \$29.0 million for the nine months ended September 30, 2024 compared to \$34.0 million for the nine months ended September 30, 2023, a decrease of \$5.0 million. The period over period change included \$3.7 million of decreased compensation costs and \$1.3 million of decreased professional and other general and administrative expenses.

Impairment of Long-Lived Assets

We recorded \$27.3 million in expenses related to the impairment of long-lived assets during the nine months ended September 30, 2024.

Interest Income

Interest income was \$5.3 million and \$8.0 million for the nine months ended September 30, 2024 and 2023, respectively, with the decrease attributed primarily to the lower balance of investments.

Other Expense, Net

Changes in other expense, net were minimal for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023, and primarily attributed to changes in foreign exchange gains and losses.

Net Loss

Net loss was \$116.2 million for the nine months ended September 30, 2024 compared to net loss of \$123.2 million for the nine months ended September 30, 2023. The net loss included noncash expenses for the impairment of long-lived assets, stock-based compensation, depreciation expense and noncash lease costs for the nine months ended September 30, 2024 and 2023 of \$51.7 million and \$36.7 million, respectively.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2024, we had cash, cash equivalents and investments of \$92.7 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.

In May 2022, we filed a shelf registration statement on Form S-3 (File No. 3333-265085) with the SEC pursuant to which we may, from time to time, sell up to an aggregate of \$250.0 million of our common stock. On May 31, 2022, the registration statement was declared effective by the SEC, which allows us to access the capital markets for the three-year period following this effective date. Our September 2022 equity offering and our outstanding “at-the-market” offering program were offered under this Form S-3. Further details of these programs are included below.

Additionally, in November 2023, we filed a shelf registration statement on Form S-3 (File No. 333-275517) with the SEC pursuant to which we may, from time to time, sell up to an aggregate of \$250.0 million of our common stock. On November 24, 2023, the registration statement was declared effective by the SEC, which allows us to access the capital markets for the three-year period following this effective date.

“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 to date 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, 2024; however, we are not obligated to make any sales under this program.

Summary Cash Flows

Comparison of the nine months ended September 30, 2024 and 2023

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, | |
|---|---------------------------------|-------------|
| | 2024 | 2023 |
| Net cash used in operating activities | \$ (81,130) | \$ (92,212) |
| Net cash provided by investing activities | 24,962 | 72,986 |
| Net cash provided by financing activities | 177 | 2,528 |
| Net increase (decrease) in cash, cash equivalents and restricted cash | \$ (55,991) | \$ (16,698) |

Cash Used in Operating Activities

Net cash used in operating activities was \$81.1 million for the nine months ended September 30, 2024, which was primarily attributable to our net loss of \$116.2 million adjusted for net noncash charges of \$49.1 million and net changes in operating assets and liabilities of \$14.0 million. Noncash charges included approximately \$27.3 million of long-lived asset impairment, \$19.7 million in stock-based compensation expense, \$2.8 million in depreciation and amortization expense and \$1.8 million in noncash lease expense, partially offset by \$2.6 million in net accretion of premiums and discounts on investments.

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 and \$1.1 million in noncash lease expense, partially offset by \$4.3 million in net accretion of premiums and discounts on investments.

Cash Provided by Investing Activities

Net cash provided by investing activities was \$25.0 million for the nine months ended September 30, 2024, which consisted primarily of \$125.6 million in proceeds from maturities of investments, partially offset by \$100.5 million for the purchases of investments and \$0.1 million for the purchases of property and equipment.

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.

Cash Provided by Financing Activities

Net cash provided by financing activities was \$0.2 million for the nine months ended September 30, 2024, which consisted of 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 \$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.

Funding Requirements

As of September 30, 2024, we had cash, cash equivalents and investments, excluding restricted cash, of \$92.7 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 7 – *Leases*, and Note 8 – *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, 2024, 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, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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, 2023.

If we fail to maintain compliance with the minimum listing requirements, our common stock will be subject to delisting. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if our common stock is delisted.

The continued listing standards of The Nasdaq Stock Market LLC (“Nasdaq”) applicable to the Nasdaq Global Select Market require, among other things, that the minimum price of a listed company’s stock be at or above \$1.00. If the minimum bid price is below \$1.00 for a period of more than 30 consecutive trading days, the listed company will fail to be in compliance with Nasdaq’s listing rules and, if the listed company does not regain compliance within a 180-day grace period, it may be subject to delisting. In order to regain compliance, the bid price of the listed company’s common stock must close at a price of at least \$1.00 per share for a minimum of 10 consecutive trading days within a 180-day grace period. In the event a listed company does not regain compliance by the end of the Compliance Period, that company may be eligible for additional time to regain compliance (the “Second Compliance Period”) pursuant to Nasdaq Listing Rule 5810(c)(3)(A)(i) by transferring to the Nasdaq Capital Market. To qualify for the Second Compliance Period, the listed company would need to submit a transfer application and pay an application fee and, in addition, would be required to meet the continued listing requirement for the market value of its publicly held shares and all other initial listing standards for Nasdaq, with the exception of the bid price requirement, and will need to provide written notice of its intention to cure the deficiency during the Second Compliance Period, by effecting a reverse stock split, if necessary. There can be no assurance that a listed company will be eligible for the Second Compliance Period, if applicable, or that the Nasdaq Listing Qualifications Staff (the “Staff”) would grant that company’s request for continued listing subsequent to any delisting notification. If the listed company fails to regain compliance, its common stock would be subject to delisting.

On August 13, 2024, we received a letter from the Staff indicating that, based upon the closing bid price of shares of our common stock for the 30 consecutive business day period from July 1, 2024 through August 12, 2024, we did not meet the minimum bid price of \$1.00 per share required for continued listing on the Nasdaq Global Select Market pursuant to Nasdaq Listing Rule 5450(a)(1). The letter also indicated that, pursuant to Nasdaq Listing Rule 5810(c)(3)(A), we would be afforded 180 calendar days to regain compliance with the bid price requirement. On November 5, 2024, we received a letter from the Staff stating that for the last 10 consecutive business days, from October 10, 2024, to November 4, 2024, the closing bid price of our common stock has been \$1.00 per share or greater, that the Staff has determined that we have regained compliance with Nasdaq Listing Rule 5450(a)(1), and that the matter is now closed. However, there can be no assurance that we will maintain compliance with the minimum bid price requirement or any other Nasdaq listing standards. If we fail to maintain compliance with one or more Nasdaq listing standards, our common stock will be subject to delisting. Delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

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 \$185.7 million for the year ended December 31, 2023 and \$116.2 million for the nine months ended September 30, 2024. As of September 30, 2024, we had an accumulated deficit of \$1,234.7 million. We have devoted substantially all of our resources and efforts to research and development. Our lead product candidate, AK006, is in early 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, AK006 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, 2024, we had \$92.7 million in cash, cash equivalents and investments. We filed: (i) on August 4, 2022, a prospectus supplement to our shelf registration statement on Form S-3 (File No. 333-265085) 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 such shelf registration statement 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, 2024 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 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 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 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.

Rule 10b5-1 Trading Plans

During our last fiscal quarter, no director or officer, as defined in Rule 16a-1(f), adopted or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement,” each as defined in Regulation S-K Item 408.

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 | |
| 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, 2024, has been formatted in Inline XBRL and is contained in Exhibit 101. | | | | | X |

* 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 6, 2024

By: /s/ Robert Alexander
Robert Alexander, Ph.D.
Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 6, 2024

By: /s/ H. Baird Radford, III
H. Baird Radford, III
Chief Financial Officer
(Principal Financial and Accounting Officer)

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

I, 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 6, 2024

By: _____ /s/ Robert Alexander
Robert Alexander, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

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

I, 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 6, 2024

By: _____ /s/ H. Baird Radford, III
H. Baird Radford, III
Chief Financial Officer
(Principal Financial and Accounting Officer)

**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, 2024 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 6, 2024

By: _____
/s/ Robert Alexander
Robert Alexander, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

**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, 2024 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 6, 2024

By: _____
/s/ H. Baird Radford, III
H. Baird Radford, III
Chief Financial Officer
(Principal Financial and Accounting Officer)
