
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 14, 2024

Allakos Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38582
(Commission File Number)

45-4798831
(IRS Employer
Identification No.)

825 Industrial Road, Suite 500
San Carlos, California
(Address of Principal Executive Offices)

94070
(Zip Code)

Registrant's Telephone Number, Including Area Code: 650 597-5002

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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.

Item 2.02 Results of Operations and Financial Condition.

On March 14, 2024, Allakos Inc. (the “Company”) issued a press release reporting its financial results for the fourth quarter and full year ended December 31, 2023. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 2.02 of this Form 8-K, including the attached Exhibit 99.1, is intended to be furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

| Exhibit Number | Description |
|-------------------|--|
| 99.1 | Press Release dated March 14, 2024. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

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: March 14, 2024

By: /s/ H. Baird Radford, III

H. Baird Radford, III
Chief Financial Officer

Allakos Provides Business Update and Reports Fourth Quarter and Full Year 2023 Financial Results

SAN CARLOS, Calif., March 14, 2024 (GLOBE NEWSWIRE) – Allakos Inc. (the “Company”) (Nasdaq: ALLK), a biotechnology company developing antibodies for the treatment of allergic, inflammatory and proliferative diseases, today provided a business update and reported financial results for the fourth quarter and full year ended December 31, 2023.

Recent Allakos Events

- Completed dosing in the single ascending dose (SAD) cohorts and continued dosing in the multiple ascending dose (MAD) cohorts of the randomized, double-blind, placebo-controlled Phase 1 trial of Intravenous (IV) AK006 in healthy volunteers.
- Initiated the randomized, double-blind, placebo-controlled subcutaneous (SC) AK006 cohort in healthy volunteers.
- Published preclinical research in *Allergy* showing that AK006 controls mast cell function through interaction with multiple activating receptors and key signaling pathways.
- Presented preclinical data at the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting 2024 highlighting AK006’s mechanism of action and ability to reduce MRGPRX2-induced skin inflammation.
- Reported topline data from the Phase 2 study of SC lirentelimab in patients with atopic dermatitis and Phase 2b study of SC lirentelimab in patients with chronic spontaneous urticaria.
- Halted lirentelimab-related development activities and announced a restructuring plan to reduce costs and focus on AK006 clinical development. As a result of the restructuring, Allakos expects its cash runway to extend into mid-2026.

Upcoming Allakos Anticipated Milestones

- Report safety, pharmacokinetics (PK), and pharmacodynamic (PD) results from the Phase 1 trial of IV AK006 in healthy volunteers, including data to confirm Siglec-6 receptor occupancy in skin biopsy samples in Q2 2024.
- Initiate the randomized, double-blind, placebo-controlled Phase 1 trial of IV AK006 in patients with chronic spontaneous urticaria in Q2 2024.
- Report safety, PK, and PD results from the Phase 1 trial of SC AK006 in healthy volunteers, including data to confirm Siglec-6 receptor occupancy in skin biopsy samples in Q3 2024.
- Report topline data from the Phase 1 trial of IV AK006 in patients with CSU at year end 2024

Cash Guidance

The Company expects that the restructuring activities will extend the cash runway into mid-2026.

The Company ended the fourth quarter of 2023 with approximately \$170.8 million in cash, cash equivalents and investments. The Company's outlook for 2024 cash, cash equivalents and investments is as follows:

| | |
|---|------------------------|
| Cash, cash equivalents and investments at year end 2023 | \$171 million |
| Estimated 2024 net cash used in operating activities (GAAP) | (\$85 to \$90 million) |
| Estimated cash, cash equivalents and investments at year end 2024 | \$81 to \$86 million |

Components of estimated 2024 net cash used in operating activities for the year ended December 31, 2024 are as follows:

| | |
|--|----------------------|
| Estimated net cash used in operating activities (GAAP) | \$85 to \$90 million |
| Less: estimated lirentelimab closeout, severance and other costs ¹ | (\$30 million) |
| Estimated adjusted net cash used in operating activities (non-GAAP) ² | \$55 to \$60 million |

¹ The Company anticipates that the significant majority of the restructuring expenditures, including approximately \$4 million of severance, will be paid in the first half of 2024.

² For additional information on the Company's use of non-GAAP financial information, please see the section titled "Non-GAAP Financial Measure" below.

Fourth Quarter 2023 Financial Results

Research and development expenses were \$53.8 million in the fourth quarter of 2023 compared to \$35.4 million in the fourth quarter of 2022, an increase of \$18.4 million. This quarter over quarter increase is attributed to \$15.0 million of increased manufacturing costs and \$3.4 million of increased other research and development expenses related primarily to our clinical studies.

General and administrative expenses were \$11.2 million for the fourth quarter of 2023 compared to \$10.8 million for the fourth quarter of 2022, an increase of \$0.4 million. The quarter over quarter change included \$0.3 million of increase stock-based compensation expenses and \$0.1 million increase in other general and administrative expenses.

Allakos reported a net loss of \$62.6 million in the fourth quarter of 2023 compared to \$43.0 million in the fourth quarter of 2022. The fourth quarter of 2023 included noncash expenses for stock-based compensation of \$10.2 million, compared to \$9.3 million in the same period in 2023, and depreciation expense of \$1.5 million in each of the fourth quarters of 2023 and 2022. Net loss per basic and diluted share was \$0.71 for the fourth quarter of 2023 compared to \$0.50 in the fourth quarter of 2022.

Allakos ended the fourth quarter of 2023 with \$170.8 million in cash, cash equivalents and investments resulting in a net decrease in cash, cash equivalents and investments of \$23.1 million during the fourth quarter of 2023.

About Allakos

Allakos is a clinical stage biotechnology company developing therapeutics that target immunomodulatory receptors present on immune effector cells involved in allergy, inflammatory and proliferative diseases.

Activating these immunomodulatory receptors allows for the direct targeting of cells involved in disease pathogenesis and, in the setting of allergy and inflammation, has the potential to result in broad inhibition of inflammatory cells. The Company's most advanced product candidate is AK006. AK006 targets Siglec-6, an inhibitory receptor expressed on mast cells. Mast cells are widely distributed in the body and play a central role in the inflammatory response. 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. In preclinical studies, AK006 appears to provide deep mast cell inhibition and, in addition to its inhibitory activity, reduce mast cell numbers. For more information, please visit the Company's website at www.allakos.com.

Non-GAAP Financial Measure

In this press release, Allakos' estimated net cash used in operating activities is provided in accordance with generally accepted accounting principles (GAAP) in the United States and also on a non-GAAP basis. Non-GAAP estimated adjusted net cash used in operating activities excludes estimated lirntelimab closeout, severance and other costs. Non-GAAP estimated adjusted net cash used in operating activities is provided as a complement to estimated net cash used in operating activities provided in accordance with GAAP because management believes the non-GAAP financial measure is useful to investors in assessing the Company's operating performance. Management also uses the non-GAAP financial measure to establish operational goals that are communicated internally and externally, to manage the Company's business and to evaluate its performance.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 as contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements include, but are not limited to, Allakos' progress, business plans and areas of focus; the expected timing of reporting data from its clinical trial of AK006; the clinical potential of AK006; and Allakos' anticipated clinical milestones. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from current expectations and beliefs, including but not limited to: Allakos' stages of clinical drug development; Allakos' ability to timely initiate and complete clinical trials for AK006; Allakos' ability to obtain required regulatory approvals for its clinical trials; uncertainties related to the enrollment of patients in its clinical trials; Allakos' ability to demonstrate sufficient safety and efficacy of its product candidates in its clinical trials; uncertainties related to the success of clinical trials, regardless of the outcomes of preclinical testing or early-stage trials; Allakos' ability to obtain regulatory approvals to market its product candidates; market acceptance of Allakos' product candidates; uncertainties related to the projections of the size of patient populations suffering from the diseases Allakos is targeting; Allakos' ability to advance additional product candidates beyond AK006; uncertainties related to Allakos' ability to realize the contemplated benefits of its restructuring and related reduction in force; Allakos' ability to accurately forecast financial results; Allakos' ability to obtain additional capital to finance its operations, research and drug development; general economic and market conditions, both domestic and international; domestic and international regulatory obligations; and other risks. Information regarding the foregoing and additional risks may be found in the section entitled "Risk Factors" in documents that Allakos files from time to time with the SEC. These documents contain and identify important factors that could cause the actual results for Allakos to differ materially from those contained in Allakos' forward-looking statements. Any forward-looking statements contained in this press release speak only as of the date hereof, and Allakos specifically disclaims any obligation to update any forward-looking

statement, except as required by law. These forward-looking statements should not be relied upon as representing Allakos' views as of any date subsequent to the date of this press release.

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Source: Allakos Inc.

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

| | Three Months Ended | | Twelve Months Ended | |
|--|--------------------|--------------------|---------------------|---------------------|
| | December 31, | | December 31, | |
| | 2023 | 2022 | 2023 | 2022 |
| Operating expenses | | | | |
| Research and development | \$ 53,801 | \$ 35,388 | \$ 150,908 | \$ 265,081 |
| General and administrative | 11,182 | 10,828 | 45,148 | 57,348 |
| Total operating expenses | <u>64,983</u> | <u>46,216</u> | <u>196,056</u> | <u>322,429</u> |
| Loss from operations | <u>(64,983)</u> | <u>(46,216)</u> | <u>(196,056)</u> | <u>(322,429)</u> |
| Interest income | 2,382 | 2,775 | 10,347 | 3,673 |
| Other income (expense), net | 50 | 452 | 8 | (1,196) |
| Net loss | <u>(62,551)</u> | <u>(42,989)</u> | <u>(185,701)</u> | <u>(319,952)</u> |
| Unrealized gain (loss) on investments | 122 | (220) | 334 | (131) |
| Comprehensive loss | <u>\$ (62,429)</u> | <u>\$ (43,209)</u> | <u>\$ (185,367)</u> | <u>\$ (320,083)</u> |
| Net loss per common share: | | | | |
| Basic and diluted | <u>\$ (0.71)</u> | <u>\$ (0.50)</u> | <u>\$ (2.14)</u> | <u>\$ (5.06)</u> |
| Weighted-average number of common shares outstanding: | | | | |
| Basic and diluted | <u>87,567</u> | <u>85,262</u> | <u>86,798</u> | <u>63,284</u> |

ALLAKOS INC.
UNAUDITED CONDENSED BALANCE SHEETS
(in thousands)

| | December 31, | |
|---|---------------------|-------------------|
| | 2023 | 2022 |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 66,440 | \$ 87,217 |
| Investments | 104,354 | 192,569 |
| Prepaid expenses and other current assets | 9,095 | 29,057 |
| Total current assets | <u>179,889</u> | <u>308,843</u> |
| Property and equipment, net | 33,369 | 39,144 |
| Operating lease right-of-use assets | 24,136 | 30,225 |
| Other long-term assets | 6,216 | 8,208 |
| Total assets | <u>\$ 243,610</u> | <u>\$ 386,420</u> |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 1,764 | \$ 4,832 |
| Accrued expenses and other current liabilities | 34,814 | 25,206 |
| Total current liabilities | <u>36,578</u> | <u>30,038</u> |
| Operating lease liabilities, net of current portion | 38,215 | 45,949 |
| Total liabilities | <u>74,793</u> | <u>75,987</u> |
| Stockholders' equity: | | |
| Common stock | 88 | 85 |
| Additional paid-in capital | 1,287,156 | 1,243,408 |
| Accumulated other comprehensive loss | 50 | (284) |
| Accumulated deficit | <u>(1,118,477)</u> | <u>(932,776)</u> |
| Total stockholders' equity | <u>168,817</u> | <u>310,433</u> |
| Total liabilities and stockholders' equity | <u>\$ 243,610</u> | <u>\$ 386,420</u> |

