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): January 16, 2024

Allakos Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38582**	**45-4798831**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(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

(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 January 16, 2024, Allakos Inc. (the "Company") issued a press release announcing its estimated, unaudited cash, cash equivalents and investments balance as of December 31, 2023, which it expects will fund operations into mid-2026. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 2.05 Costs Associated with Exit or Disposal Activities.

On January 16, 2024, the Company announced plans to halt development of lirentelimab, the Company's former lead product candidate, and focus on the clinical development of its AK006 program. As part of the corporate restructuring, the Company is halting lirentelimab-related activities across clinical, manufacturing, research and administrative functions. The Company also committed to reducing its workforce by approximately 50%.

The total costs related to halting lirentelimab-related activities and reducing the workforce are estimated to be approximately $30 million, with the majority of these amounts expected to be paid in the first half of 2024. Approximately $24 million will be incurred in connection with halting lirentelimab-related activities and the remaining approximately $6 million will be incurred in connection with the workforce reduction. These estimates are subject to a number of assumptions and actual results may differ. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the corporate restructuring.

A copy of the press release announcing the corporate restructuring is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 7.01 Regulation FD Disclosure.

On January 16, 2024, the Company issued a press release announcing its Phase 2 clinical trial of subcutaneous lirentelimab in patients with atopic dermatitis and its Phase 2b clinical trial of subcutaneous lirentelimab in patients with chronic spontaneous urticaria both did not achieve statistical significance on the primary endpoints. A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K.

All of the information in this Item 7.01 and Items 2.02 and 9.01 of this Form 8-K, including the attached Exhibit 99.1 and Exhibit 99.2, 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 (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such filing.

Forward Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. Forward-looking statements are identified by such words as "expect," "anticipate," "estimate" and words of similar import and are based on current expectations. All statements other than historical or current facts are forward-looking statements, including, without limitation, statements about the nature, timing and scope of the corporate restructuring, including the expected costs of such restructuring and expected timing of the payment of such costs, the Company's estimate of unaudited cash, cash equivalents and investments as of December 31, 2023, and the Company's cash runway. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements, including but not limited to, delays in the implementation of the Company's plans, unexpected restructuring or personnel-related termination or other costs, and the Company's ability to accurately forecast financial results. A further description of the risks and uncertainties relating to the business of the Company is contained in the section entitled "Risk Factors" in documents that the Company files from time to time with the SEC. The forward-looking statements in this report speak only as of the date hereof. Except as required by law, the Company does not undertake to publicly update or revise any forward-looking statements to reflect events or circumstances that may arise after the date hereof.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated January 16, 2024.
99.2	Press Release dated January 16, 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 hereunto duly authorized.

Allakos Inc.

Date: January 16, 2024

By: /s/ H. Baird Radford, III

H. Baird Radford, III
Chief Financial Officer

Allakos Announces a Restructuring to Focus on Development of AK006

- Existing cash to fund planned ongoing operations into mid-2026
- AK006 is being tested in a comprehensive Phase 1 clinical program, including:
  - ongoing single and multiple ascending dose trial in healthy volunteers
  - a randomized, double-blind, placebo-controlled trial in patients with CSU
  - a subcutaneous AK006 Phase 1 PK and bioavailability trial
- Management to host conference call and webcast today at 8:00 am E.T.

SAN CARLOS, Calif., Jan. 16, 2024 (GLOBE NEWSWIRE) -- Allakos Inc. (the Company) (Nasdaq: ALLK), a biotechnology company developing antibodies for the treatment of allergic, inflammatory and proliferative diseases, today announced a restructuring to reduce costs and to focus on AK006 clinical development and additional preclinical programs. As a result, the Company's cash runway is expected to extend into mid-2026.

Restructuring Activities

The Company will halt lirentelimab-related activities across clinical, manufacturing, research and administrative functions. As a result, the Company will reduce its workforce by approximately 50%.

Cash Guidance

The Company ended the fourth quarter of 2023 with approximately $171 million in cash, cash equivalents and investments (unaudited). The Company's outlook for 2024 cash, cash equivalents and investments is as follows:

Cash, cash equivalents and investments at year end 2023 (unaudited)	$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)	$55 to $60 million

[1] The Company anticipates that the significant majority of the restructuring expenditures will be paid in the first half of 2024.

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

Anticipated Allakos Milestones

- Q1 2024: Complete dosing in the single ascending dose (SAD) and multiple ascending dose (MAD) cohorts of the randomized, double-blind, placebo-controlled Phase 1 trial of Intravenous (IV) AK006 in healthy volunteers.
- Q1 2024: Initiate the randomized, double-blind, placebo-controlled subcutaneous (SC) AK006 cohort in healthy volunteers.

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

About Siglec-6 and AK006

Siglec-6 is a member of the family of cell surface receptors called Sialic acid-binding immunoglobulin-type lectins (Siglecs). Siglec-6 is found on the surface of mature mast cells, and therefore offers a way to target mast cells. Siglec-6 exerts inhibition through its intracellular immunoreceptor tyrosine-based motif (ITIM).

ITIM bearing receptors antagonize activating receptors and consequently have important roles in regulating the immune system. The inhibitory function is derived from the ability of the ITIMs to recruit SH2 domain-containing phosphatases which work to oppose activating signals driven by kinase signaling cascades. Disrupting kinase signaling cascades has been a successful strategy for treating inflammatory diseases as evidenced by approved drugs which target JAK, KIT, BTK, SYK, and others. However, often these kinase signaling pathways are active in multiple cell types, which can result in unintended side effects when disrupted.

AK006 is a humanized IgG1 monoclonal antibody which activates the inhibitory receptor Siglec-6. AK006 is directed to an extracellular epitope of the Siglec-6 receptor that was identified for its ability to generate strong inhibitory signals to mast cells. Furthermore, AK006 was engineered to have higher cell surface residence time which may increase mast cell inhibition. In addition to inhibition, in preclinical studies AK006 reduces mast cell numbers via antibody-dependent cellular phagocytosis (ADCP) in the presence of activated macrophages.

Conference Call and Webcast Information
The webcast and conference call will take place at 8:00 am ET / 5:00 am PT on January 16th, 2024. Please click **here** to pre-register to participate in the conference call and obtain your dial in number and PIN.

A webcast of the live call will be available online in the investor relations section of the Allakos **website**. Access to the webcast replay will be available approximately two hours after completion of the call and will be archived on the Company's website for approximately 30 days.

About Allakos
Allakos is a clinical stage biotechnology company developing therapeutics which 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 antibody in ongoing clinical development 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 lirentelimab 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; Allakos' expectations regarding its financial position and guidance, including estimated lirentelimab closeout, severance and other costs and the timing of payment of restructuring expenditures, ending 2023 and 2024 cash, cash equivalents and investments, and cash runway; the potential of AK006; and Allakos' anticipated 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 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; 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 to 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.

Source: Allakos Inc.

Investor Contact:
Adam Tomasi, President
Alex Schwartz, VP Strategic Finance and Investor Relations
ir@allakos.com

Media Contact:
Denise Powell
denise@redhousecomms.com

Exhibit 99.2

Allakos Announces Phase 2 Lirentelimab Trials in Atopic Dermatitis and Chronic Spontaneous Urticaria Did Not Meet Their Primary Endpoints

– Allakos plans not to pursue further development of lirentelimab; will focus on AK006 clinical development and additional preclinical programs –

– Management to host conference call and webcast today at 8:00 am E.T. –

SAN CARLOS, Calif., Jan. 16, 2024 (GLOBE NEWSWIRE) – Allakos Inc. (the "Company") (Nasdaq: ALLK), a biotechnology company developing antibodies for the treatment of allergic, inflammatory and proliferative diseases, today announced topline data from its phase 2 clinical trial in patients with atopic dermatitis (ATLAS) and from its Phase 2b clinical trial in patients with chronic spontaneous urticaria (MAVERICK).

"We are disappointed that these trials did not meet their primary endpoint, particularly given the need for new treatment options for patients with these severe diseases. Given that neither trial met its primary endpoint, we have decided to not pursue further clinical development of lirentelimab," said Craig Paterson, M.D., Chief Medical Officer of Allakos. "We express our gratitude to all of the clinical trial investigators, site coordinators and patients in these trials."

ATLAS: Phase 2 Trial of Lirentelimab in Patients with Atopic Dermatitis

	Lirentelimab (n=61)	Placebo (n=61)	p-value
Baseline Eczema Area and Severity Index (EASI)	26.8	26.9	
Primary Endpoint			
Proportion of patients who achieved EASI-75[1]	23%	18%	NS
Prespecified Endpoints			
Percent change in EASI	-36%	-26%	NS
Percent Change in EASI: in patients with baseline IGA-3	-30% (n=29)	-34% (n=30)	NS
Percent Change in EASI: in patients with baseline IGA-4	-45% (n=32)	-19% (n=31)	p=0.0476
≥4-Point Improvement in PP-NRS (Itch)	20%	8%	p=0.0696

1 = proportion of participants achieving a 75% reduction in the Eczema Area and Severity Index
NS = Not Significant

MAVERICK: Phase 2b Trial of Lirentelimab in Patients with Chronic Spontaneous Urticaria

	Lirentelimab (n=64)	Placebo (n=59)	p-value
Baseline Urticaria Activity Score (UAS7)	31.4	32.4	
Primary Endpoint			
Change in UAS7	-7.9 (-27%)	-8.4 (-26%)	NS
Prespecified Endpoints			
UAS7=0: Complete Response	6%	0%	NS
HSS7=0: Weekly Hives Severity Score of 0	6%	3%	NS
ISS7=0: Weekly Itch Severity Score of 0	9%	2%	NS

Eosinophils Levels
Consistent with previously reported antibody-dependent cellular cytotoxicity (ADCC) activity of lirentelimab on eosinophils, patients treated with lirentelimab showed sustained depletion of blood eosinophil counts. In the ATLAS trial, lirentelimab-treated patients' blood eosinophils decreased by 96% versus placebo-treated patients' blood eosinophils which decreased by 15%. In the MAVERICK trial, lirentelimab-treated patients' blood eosinophils decreased by 95% versus placebo-treated patients' blood eosinophils which increased by 9%.

Safety Results
Across both trials safety was similar to previous clinical trials of lirentelimab. The most common adverse events were injection-related reactions (IRRs). In the ATLAS trial, 18.5% of lirentelimab treated patients experienced IRRs versus 6.2% of placebo treated patients. In the MAVERICK trial, 18.2% of lirentelimab treated patients experienced IRRs versus 8.2% of placebo treated patients.

Phase 2 ATLAS Trial Design
The 14-week, randomized, double-blind, placebo controlled, multicentered trial evaluated the efficacy, safety and tolerability of lirentelimab versus placebo in adult patients with moderate-to-severe atopic dermatitis inadequately controlled by topical medications. 122 patients were randomized 1:1 to receive 300 mg of subcutaneous lirentelimab (n=61) or placebo (n=61) once every two weeks (Q2W). The primary endpoint was the proportion of patients who achieve at least a 75% reduction from baseline in eczema area and severity index (EASI-75) at 14 weeks.

Phase 2b MAVERICK Trial Design
The 12-week, randomized, double-blind, placebo controlled, multicentered trial evaluated the efficacy, safety and tolerability of lirentelimab versus placebo in adult patients with moderate-to-severe chronic spontaneous urticaria refractory to antihistamines. 123 patients were randomized 1:1 to receive 300 mg of subcutaneous lirentelimab (n=64) or placebo (n=59) once every two weeks (Q2W). The primary endpoint was the absolute change from baseline in Urticaria Activity Control (UAS)-7 at 12 weeks.

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