

**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): November 07, 2022

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 November 7, 2022, Allakos Inc. (the “Company”) issued a press release reporting its financial results for the third quarter ended September 30, 2022. 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 November 7, 2022. |
| 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: November 7, 2022

By: /s/ H. Baird Radford, III
H. Baird Radford, III
Chief Financial Officer

Allakos Provides Business Update and Reports Third Quarter 2022 Financial Results

SAN CARLOS, Calif., November 7, 2022 (GLOBE NEWSWIRE) – Allakos Inc. (the “Company”) (Nasdaq: ALLK), a biotechnology company developing lirentelimab (AK002) and AK006 for the treatment of allergic and inflammatory diseases, today provided a business update and reported financial results for the third quarter ended September 30, 2022.

Recent Allakos Events

- Allakos’s lirentelimab clinical development is focused on atopic dermatitis and chronic spontaneous urticaria.
 - o Initiated a Phase 2b randomized, double-blind, placebo-controlled study of subcutaneous lirentelimab in patients with chronic spontaneous urticaria (CSU) in the third quarter of 2022. The Phase 2b CSU clinical trial follows positive results from an open-label Phase 2a clinical trial with intravenous lirentelimab in patients with chronic urticaria, including cohorts of patients with omalizumab naïve CSU and omalizumab refractory CSU.
 - o Reported topline data from Phase 3 EoDyssey study of lirentelimab in patients with eosinophilic duodenitis (EoD) in the third quarter of 2022. Allakos is currently not planning to conduct additional studies in eosinophilic gastrointestinal diseases, but may do so in the future.
- Closed an underwritten common stock offering in September 2022. Aggregate proceeds received from the offering were approximately \$140.5 million, net of underwriting commissions and related expenses. Investors who purchased shares in the offering include Logos Capital, BVF Partners L.P., Deep Track Capital, New Enterprise Associates (NEA), Vivo Capital, Frazier Life Sciences, Braidwell LP, Commodore Capital, RTW Investments, L.P., TCGX, Surveyor Capital (a Citadel Company), and Alta Partners.

Upcoming Allakos Milestones

- Complete IND-enabling studies of AK006 during 2022 and initiate the first-in-human study in the first half of 2023.
- Report topline data from the Phase 2 study of subcutaneous lirentelimab in patients with atopic dermatitis in the second half of 2023.
- Report topline data from the Phase 2b study of subcutaneous lirentelimab in patients with chronic spontaneous urticaria in the second half of 2023.

Third Quarter 2022 Financial Results

Research and development expenses were \$18.4 million in the third quarter of 2022 compared to \$43.6 million in the third quarter of 2021. Third quarter of 2022 research and development expenses included a \$12.2 million benefit from selling or receiving refunds from the disposal of previously expensed raw materials. Excluding the \$12.2 million benefit, research and development expenses decreased from the prior year third quarter due to a decrease in contract research and development and clinical costs primarily relating to lirentelimab, partially offset by an increase in equipment and overhead costs.

General and administrative expenses were \$13.0 million in the third quarter of 2022 compared to \$19.1 million in the third quarter of 2021. Third quarter of 2022 general and administrative expenses decreased by \$6.1 million compared to the same period in 2021 due to decreases in personnel-related costs, equipment and overhead related costs and other general and administrative expenses.

Including the \$12.2 million benefit received from raw material disposals, Allakos reported a net loss of \$30.8 million in the third quarter of 2022 compared to \$62.7 million in the third quarter of 2021. Additionally, the third quarter of 2022 included non-cash expenses for stock-based compensation of \$10.7 million, compared to \$12.5 million in the same period in 2021, and depreciation of \$1.5 million, compared to \$0.4 million in the same period in 2021. Net loss per basic and diluted share was \$0.53 for the third quarter of 2022 compared to \$1.16 in the third quarter of 2021. Weighted-average shares outstanding used to calculate basic and diluted loss per share was 58.2 million and 54.1 million for the third quarter of 2022 and 2021 respectively. As part of the September 21, 2022 common stock offering, 29.9 million shares were sold resulting in 85.2 million shares outstanding as of September 30, 2022.

Allakos ended the third quarter of 2022 with \$325.3 million in cash, cash equivalents and investments.

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 antibodies are lirentelimab (AK002) and AK006. Lirentelimab selectively targets both mast cells and eosinophils, two types of white blood cells that are widely distributed in the body and play a central role in the inflammatory response. Inappropriately activated mast cells and eosinophils have been identified as key drivers in a number of severe diseases affecting the gastrointestinal tract, eyes, skin, lungs and other organs. Allakos is developing lirentelimab for the treatment of atopic dermatitis, chronic spontaneous urticaria and potentially additional indications. Allakos is currently not planning to conduct additional studies in eosinophilic gastrointestinal diseases, but may do so in the future. Lirentelimab has received orphan drug designations for eosinophilic gastritis (EG), eosinophilic duodenitis (EoD), and eosinophilic esophagitis (EoE) from the U.S. Food and Drug Administration. AK006 targets Siglec-6, an inhibitory receptor expressed selectively on mast cells. In pre-clinical research, AK006 appears to provide deeper mast cell inhibition than lirentelimab and, in addition to its inhibitory activity, reduce mast cell numbers. Allakos plans to begin human clinical trials with AK006 in the first half of 2023. For more information, please visit the Company's website at www.allakos.com.

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 topline data from its Phase 2 and 2b clinical trials of lirentelimab, the completion of IND-enabling studies for AK006 and initiation of a first-in-human study with AK006. 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 lirentelimab and 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 lirentelimab; Allakos' ability to obtain additional capital to finance its operations; general economic and market conditions; and other risks. Information regarding the foregoing and additional risks may be found in the section entitled "Risk Factors" set forth in Allakos' most recent Annual Report on Form 10-K filed with the SEC on March 1, 2022, Allakos' Quarterly Report on Form 10-Q filed with the SEC on November 7, 2022, and future reports to be filed 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 | | Nine Months Ended | |
|---|--------------------|-------------|-------------------|--------------|
| | September 30, | | September 30, | |
| | 2022 | 2021 | 2022 | 2021 |
| Operating expenses | | | | |
| Research and development | \$ 18,438 | \$ 43,560 | \$ 229,693 | \$ 123,460 |
| General and administrative | 13,007 | 19,056 | 46,520 | 51,936 |
| Total operating expenses | 31,445 | 62,616 | 276,213 | 175,396 |
| Loss from operations | (31,445) | (62,616) | (276,213) | (175,396) |
| Interest income | 711 | 74 | 898 | 307 |
| Other expense, net | (103) | (187) | (1,648) | (407) |
| Net loss | (30,837) | (62,729) | (276,963) | (175,496) |
| Unrealized gain (loss) on investments | 196 | (13) | 89 | 11 |
| Comprehensive loss | \$ (30,641) | \$ (62,742) | \$ (276,874) | \$ (175,485) |
| Net loss per common share: | | | | |
| Basic and diluted | \$ (0.53) | \$ (1.16) | \$ (4.95) | \$ (3.27) |
| Weighted-average number of common shares outstanding: | | | | |
| Basic and diluted | 58,169 | 54,069 | 55,905 | 53,644 |

ALLAKOS INC.
UNAUDITED CONDENSED BALANCE SHEETS
(in thousands)

| | September 30, 2022 | December 31, 2021 |
|---|-----------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 205,290 | \$ 152,822 |
| Investments | 120,030 | 271,416 |
| Prepaid expenses and other current assets | 13,882 | 27,343 |
| Total current assets | 339,202 | 451,581 |
| Property and equipment, net | 40,215 | 43,100 |
| Operating lease right-of-use assets | 30,464 | 31,707 |
| Other long-term assets | 8,685 | 8,436 |
| Total assets | <u>\$ 418,566</u> | <u>\$ 534,824</u> |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 4,616 | \$ 13,692 |
| Accrued expenses and other current liabilities | 22,972 | 26,557 |
| Total current liabilities | 27,588 | 40,249 |
| Operating lease liabilities, net of current portion | 46,799 | 49,099 |
| Total liabilities | 74,387 | 89,348 |
| Stockholders' equity: | | |
| Common stock | 85 | 54 |
| Additional paid-in capital | 1,233,945 | 1,058,399 |
| Accumulated other comprehensive loss | (64) | (153) |
| Accumulated deficit | (889,787) | (612,824) |
| Total stockholders' equity | 344,179 | 445,476 |
| Total liabilities and stockholders' equity | <u>\$ 418,566</u> | <u>\$ 534,824</u> |

