

**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 9, 2020**

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.)

**975 Island Drive, Suite 201
Redwood City, California 94065**
(Address of principal executive offices, including zip code)

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

Not Applicable
(Former name or former address, if changed since last report)

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 |

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 (see General Instruction A.2. below):

- 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))

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 9, 2020, Allakos Inc. (the “Company”) issued a press release reporting its financial results for the third quarter ended September 30, 2020. 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

| <u>Exhibit Number</u> | <u>Description</u> |
|---------------------------|-----------------------------------------------------------------------------|
| 99.1 | Press Release dated November 9, 2020. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Allakos Inc.

Date: November 9, 2020

By: _____
/s/ Robert Alexander
Robert Alexander
Chief Executive Officer

Allakos Reports Third Quarter 2020 Financial Results and Provides Business Update

REDWOOD CITY, Calif., November 9, 2020 – Allakos Inc. (the “Company”) (Nasdaq: ALLK), a biotechnology company developing lirentelimab (AK002) for the treatment of eosinophil and mast cell-related diseases, today reported financial results for the third quarter ended September 30, 2020 and provided an update of its ongoing development activities.

Business Updates

- Announced positive results from our prospective prevalence study showing that 45% (181/405) of symptomatic patients biopsied with chronic unexplained gastrointestinal (GI) symptoms or functional gastrointestinal disorders (FGIDs) such as irritable bowel syndrome (IBS) and functional dyspepsia (FD) met the histologic criteria for eosinophilic gastritis (EG) and/or eosinophilic duodenitis (EoD). The results suggest that EG and/or EoD are significantly underdiagnosed among these patients. Since many people in the United States and worldwide suffer from chronic unexplained gastrointestinal symptoms or FGIDs, the results from this study suggest that EG and/or EoD may be more common than previously documented in the literature.
- Announced positive safety, pharmacokinetic, and pharmacodynamic results from a randomized, double-blind, placebo-controlled Phase 1 study of subcutaneous lirentelimab in healthy volunteers. The results showed that subcutaneously administered lirentelimab had bioavailability of 63% and suppressed eosinophils for up to 85 days. Subcutaneously administered lirentelimab was well tolerated with no serious adverse events, no injection site reactions, and no injection reactions/infusion-related reactions.
- Announced the publication of the positive results from the Phase 2 study of lirentelimab in patients with EG and/or EoD (ENIGMA) in the *New England Journal of Medicine*.
- Closed an underwritten public offering in November 2020, issuing 3,506,098 shares of common stock at an offering price of \$82.00 per share. Aggregate net proceeds received from the offering were approximately \$271.7 million, after deducting underwriting discounts and commissions.
- The randomized, double-blind, placebo-controlled Phase 3 study of lirentelimab in patients with EG and/or EoD is ongoing with topline data expected in the second half of 2021.
- The randomized, double-blind, placebo-controlled Phase 2/3 study of lirentelimab in patients with eosinophilic esophagitis (EoE) is ongoing with topline data expected in the second half of 2021.

Third Quarter 2020 Financial Results

Research and development expenses were \$30.4 million in the third quarter of 2020 as compared to \$16.1 million in the same period in 2019, an increase of \$14.3 million.

General and administrative expenses were \$12.1 million in the third quarter of 2020 as compared to \$7.5 million in the same period in 2019, an increase of \$4.6 million.

Allakos reported a net loss of \$42.1 million in the third quarter of 2020 as compared to \$21.7 million in the same period in 2019, an increase of \$20.4 million. Net loss per basic and diluted share was \$0.86 for the third quarter of 2020 compared to \$0.47 in the same period in 2019.

Allakos ended the third quarter of 2020 with \$419.8 million in cash, cash equivalents and marketable securities, which does not include the \$271.7 million of net proceeds received from the Company's follow-on public offering in November 2020.

About Allakos

Allakos is a clinical stage biotechnology company developing antibodies that target immunomodulatory receptors present on immune effector cells involved in allergic, inflammatory, and proliferative diseases. The Company's lead antibody, lirentelimab (AK002), is being evaluated in a Phase 3 study in eosinophilic gastritis (EG) and/or eosinophilic duodenitis (EoD) and a Phase 2/3 study in eosinophilic esophagitis (EoE). Lirentelimab targets Siglec-8, an inhibitory receptor selectively expressed on human mast cells and eosinophils. Inappropriately activated eosinophils and mast cells have been identified as key drivers in a number of severe diseases affecting the gastrointestinal tract, eyes, skin, lungs and other organs. Lirentelimab has been tested in multiple clinical studies. In these studies, lirentelimab eliminated blood and tissue eosinophils, inhibited mast cells and improved disease symptoms in patients with EG and/or EoD, EoE, mast cell gastrointestinal disease, severe allergic conjunctivitis, chronic urticaria and indolent systemic mastocytosis. 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 and business plans, the expected timing of anticipated study results and plans relating to its future clinical trials. 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 complete clinical trials for, and if approved, commercialize lirentelimab (AK002), its lead compound; Allakos' ability to obtain required regulatory approvals for its product candidates; 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 later-stage clinical trials, regardless of the outcomes of preclinical testing and early-stage trials; 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; and other important risk factors set forth in Allakos' most recent Annual Report on Form 10-K filed with the SEC on February 25, 2020, Quarterly Report on Form 10-Q filed with the SEC on November 9, 2020 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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ALLAKOS INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share data)
(unaudited)

| | Three Months Ended | | Nine Months Ended | |
|-------------------------------------------------------|--------------------|-------------|-------------------|-------------|
| | September 30, | | September 30, | |
| | 2020 | 2019 | 2020 | 2019 |
| Operating expenses | | | | |
| Research and development | \$ 30,380 | \$ 16,067 | \$ 77,011 | \$ 45,276 |
| General and administrative | 12,055 | 7,517 | 35,701 | 19,292 |
| Total operating expenses | 42,435 | 23,584 | 112,712 | 64,568 |
| Loss from operations | (42,435) | (23,584) | (112,712) | (64,568) |
| Interest income, net | 766 | 1,887 | 4,039 | 3,888 |
| Other expense, net | (417) | (35) | (529) | (77) |
| Net loss | (42,086) | (21,732) | (109,202) | (60,757) |
| Unrealized gain (loss) on marketable securities | (620) | (12) | 30 | 117 |
| Comprehensive loss | \$ (42,706) | \$ (21,744) | \$ (109,172) | \$ (60,640) |
| Net loss per common share: | | | | |
| Basic and diluted | \$ (0.86) | \$ (0.47) | \$ (2.24) | \$ (1.38) |
| Weighted-average number of common shares outstanding: | | | | |
| Basic and diluted | 48,950 | 46,280 | 48,819 | 44,025 |

ALLAKOS INC.
CONDENSED BALANCE SHEETS
(in thousands)

| | September 30, 2020 <u>(unaudited)</u> | December 31, 2019 |
|------------------------------------------------|---------------------------------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 104,303 | \$ 38,367 |
| Investments in marketable securities | 315,452 | 457,534 |
| Prepaid expenses and other current assets | <u>5,012</u> | <u>3,969</u> |
| Total current assets | 424,767 | 499,870 |
| Property and equipment, net | 7,340 | 8,410 |
| Operating lease right-of-use assets | 5,558 | 5,775 |
| Other long-term assets | <u>2,839</u> | <u>2,839</u> |
| Total assets | <u>\$ 440,504</u> | <u>\$ 516,894</u> |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 7,581 | \$ 5,963 |
| Accrued expenses and other current liabilities | <u>11,359</u> | <u>7,098</u> |
| Total current liabilities | 18,940 | 13,061 |
| Other long-term liabilities | <u>7,752</u> | <u>8,112</u> |
| Total liabilities | 26,692 | 21,173 |
| Stockholders' equity: | | |
| Common stock | 49 | 48 |
| Additional paid-in capital | 712,282 | 685,020 |
| Accumulated other comprehensive gain | 167 | 137 |
| Accumulated deficit | <u>(298,686)</u> | <u>(189,484)</u> |
| Total stockholders' equity | 413,812 | 495,721 |
| Total liabilities and stockholders' equity | <u>\$ 440,504</u> | <u>\$ 516,894</u> |