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): December 22, 2023

ALLOVIR, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-39409**	**83-1971007**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

AlloVir, Inc.
1100 Winter Street
Waltham, Massachusetts 02451
(Address of principal executive offices, including zip code)

(617) 433-2605
(Registrant's telephone number, including area code)

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	Trade Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	ALVR	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 7.01 Regulation FD Disclosure

On December 22, 2023, AlloVir, Inc. ("AlloVir") issued a press release titled "AlloVir Provides Updates on Phase 3 Clinical Development Program for Posoleucel, an Allogeneic Virus-Specific T-Cell Therapy." The press release is attached hereto as Exhibit 99.1 and is incorporated into this Item 7.01 by reference.

The information in Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for 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 under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On December 22, 2023, AlloVir announced that it is discontinuing enrollment in its three ongoing Phase 3 Posoleucel studies for (i) prevention of clinically significant infections or diseases by multiple viruses, (ii) treatment of virus-associated hemorrhagic cystitis, and (iii) treatment of adenovirus, all following allogeneic hematopoietic cell transplant.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated December 22, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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.

AlloVir, Inc.

Date: December 22, 2023

By: /s/ William Wheeler
Name: William Wheeler
Title: *Senior Vice President, Corporate Law*

AlloVir Provides Updates on Phase 3 Clinical Development Program for Posoleucel, an Allogeneic Virus-Specific T Cell Therapy

Company to discontinue its three Phase 3 posoleucel studies following separate, pre-planned DSMB futility analyses concluding the studies were unlikely to meet their primary endpoints; no safety concerns identified

Company to prioritize capital preservation and review strategic options

AlloVir reported $213.3 million in cash, cash equivalents, and short-term investments as of September 30, 2023

Waltham, Mass – December 22, 2023 – AlloVir, Inc. (Nasdaq: ALVR), an allogeneic T cell immunotherapy company, today provided an update on its three Phase 3 clinical trials with posoleucel, an investigational off-the-shelf multi-virus-specific T cell therapy, which targets six viral pathogens in immunocompromised individuals: adenovirus (AdV), BK virus (BKV), cytomegalovirus (CMV), Epstein-Barr virus (EBV), human herpesvirus-6 (HHV-6) and JC virus (JCV). The company will discontinue its three global Phase 3 posoleucel studies – for prevention of clinically significant infections or diseases by multiple viruses, treatment of virus-associated hemorrhagic cystitis (vHC), and treatment of adenovirus (AdV) – following allogeneic hematopoietic cell transplant (allo-HCT). The company made the determination following three pre-planned analyses by three independent Data Safety Monitoring Boards (DSMBs) each of which recommended stopping its respective trial for futility after a review of the data suggested that each study was unlikely to meet its primary endpoint. There were no observed safety concerns raised by any of the DSMBs.

AlloVir is in the process of notifying regulatory agencies and clinical trial investigators involved in these trials of the findings.

“While we are disappointed by the unexpected outcome of these trials, we are encouraged by the apparent safety profile of posoleucel,” said Diana Brainard, MD, Chief Executive Officer of AlloVir. “In light of the DSMB recommendations, we will discontinue the prevention, vHC and AdV Phase 3 trials. We will continue to analyze the data from these studies to understand any variables that may have impacted outcomes or any apparent subpopulation benefits. We thank the patients, investigators and staff who participated in the trials.”

Dr. Brainard continued, “We established pre-planned futility analyses across these three Phase 3 trials, as each assessed a potentially highly innovative treatment for patients suffering with severe and complex medical conditions lacking significant prior clinical development, and we

also expected the trials would require substantial additional capital to bring them to completion. With these current results, we will immediately shift our focus to preserve our substantial remaining capital, review our pipeline, and assess strategic options."

AlloVir will review strategic alternatives for the Company and its portfolio of virus-specific T cell therapies. Such alternatives may include a merger, sale, divestiture of assets, licensing, or other strategic transaction. As of September 30, 2023, AlloVir had cash, cash equivalents and short-term investments of $213.3 million.

About AlloVir's Earlier Stage Virus-Specific T cell Pipeline

Adult Kidney Transplantation

AlloVir has earlier reported the results of its completed Phase 2 randomized, placebo-controlled trial evaluating posoleucel for the treatment of BKV infection in adult kidney transplant patients. After 24 weeks of treatment, 39% of patients receiving posoleucel experienced a ≥1-log viral load reduction, compared to 14% of patients receiving placebo.

Acute Respiratory Infection

The company has completed Part A of a randomized, placebo-controlled Phase 1b/2a trial with ALVR106 in 14 stem cell or solid organ transplant patients. ALVR106 is an investigational allogeneic, off-the-shelf, multi-virus-specific VST therapy candidate designed to target diseases caused by human metapneumovirus (hMPV), influenza, parainfluenza virus (PIV) and respiratory syncytial virus (RSV). Data has been accepted for presentation at a scientific conference in the first quarter of 2024.

Chronic Hepatitis B Infection

ALVR107 is an investigational allogeneic, off-the-shelf VST therapy designed to target hepatitis B virus (HBV)-infected cells and potentially cure patients with chronic HBV infection. Preclinical and IND-enabling studies support the advancement of ALVR107 into a clinical proof of concept study as a next step.

About AlloVir

AlloVir is an allogeneic T cell immunotherapy company with a focus on restoring natural immunity against life-threatening viral diseases in pediatric and adult patients with weakened immune systems. The company's innovative and proprietary technology platforms leverage off-the-shelf, allogeneic, single- and multi-virus-specific T cells for patients with T cell deficiencies who are at risk from the life-threatening consequences of viral diseases. AlloVir's technology and manufacturing process enable the potential for the treatment and prevention of a spectrum of devastating viruses with each single allogeneic cell therapy. For more information, visit www.allovir.com or follow us on X or LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding the potential of posoleucel for prevention of clinically significant infections or diseases by multiple viruses, the treatment of vHC, and treatment of AdV, AlloVir's development and regulatory status of our product candidates, the planned conduct of its preclinical studies, and clinical trials, and the Company's plans to review and consider strategic alternatives for the Company. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties, and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those related to the future of its business, future plans and strategies, its clinical results and other future conditions. Such forward-looking statements are subject to a number of material risks and uncertainties, including but not limited to, those set forth under the caption "Risk Factors" in the Company's most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC"), as supplemented by its most recent Quarterly Report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in the Company's subsequent filings with the SEC. AlloVir cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. AlloVir disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions, or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent AlloVir's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

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