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 2, 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 2.02 Results of Operations and Financial Condition

On November 2, 2023, AlloVir, Inc. announced its financial results for the quarter ended September 30, 2023. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K, including 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 (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 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 No.	Description
99.1	Press release dated November 2, 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: November 2, 2023

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

Exhibit 99.1

AlloVir Reports Third Quarter 2023 Financial Results

—Posoleucel, a highly innovative off-the-shelf, multi-virus-specific investigational T cell therapy, continues to advance in three distinct, Phase 3, first-to-market indications in immunocompromised patients

—Enrollment in posoleucel pivotal Phase 3 multi-virus prevention, virus-associated hemorrhagic cystitis and adenovirus studies all progressing with topline data for all three studies anticipated in the second half of 2024

—Progressing global commercial launch planning for posoleucel across all indications

—As of September 30, 2023, AlloVir had cash, cash equivalents, and short-term investments of $213.3 million providing runway through all pivotal trial data readouts

Waltham, Mass – November 2, 2023 – AlloVir, Inc. (Nasdaq: ALVR), a late-clinical stage allogeneic T cell immunotherapy company, today reported financial results from the third quarter ended September 30, 2023. AlloVir continues to progress its highly innovative lead therapeutic candidate, posoleucel, by enrolling globally in three Phase 3 trials for first-to-market indications. AlloVir is in a position of strength with significant financial resources to support operations through topline data readouts for all three trials anticipated in the second half of 2024.

“At AlloVir, we are dedicated to serving immunocompromised patients suffering from devastating and life-threatening viral diseases,” said Diana Brainard, M.D., Chief Executive Officer, AlloVir. “We are working with urgency to complete enrollment in our three global Phase 3 pivotal trials of posoleucel to deliver this potentially transformative therapy to patients that can benefit from the prevention and treatment of viral diseases with limited to no approved or effective therapies today. We expect a catalyst rich next 12 months with clinical and regulatory milestones and continued commercial preparations in advance of a potential 2025 launch.”

Recent and Upcoming Highlights/Activities

- The company’s Phase 3 registrational trials of posoleucel in allo-HCT patients continue to enroll with data anticipated from all three trials in the second half of 2024.
- The company presented results from a Phase 2 randomized, placebo-controlled trial evaluating posoleucel for the treatment of BKV in adult kidney transplant recipients at the European Society for Organ Transplantation (ESOT) Congress 2023 in September.
- The company continues to work with regulatory agencies to gain alignment on a Phase 3 clinical study design to evaluate posoleucel’s treatment of BKV infection in kidney transplant patients.

- The company completed enrollment in Part A of the Phase 1b/2a clinical trial of ALVR106, a multi-respiratory virus-specific T cell therapy targeting human metapneumovirus, influenza, parainfluenza, and respiratory syncytial virus (RSV) in allo-HCT and solid organ transplant patients. Data will be shared at a future scientific congress.

Third Quarter Financial Results

- Research and development expenses were $34.2 million for the quarter ended September 30, 2023, compared with $30.0 million for the quarter ended September 30, 2022. The increase year-over-year was primarily attributable to an increase in costs related to the development of the company's lead product candidate, posoleucel.
- General and administrative expenses were consistent at $12.8 million for the quarter ended September 30, 2023, compared with $12.9 million for the quarter ended September 30, 2022.
- Stock-based compensation expenses were $10.5 million and $10.9 million for the quarter ended September 30, 2023, and 2022, respectively.
- As of September 30, 2023, AlloVir had cash, cash equivalents, and short-term investments of $213.3 million, compared with cash, cash equivalents, and short-term investments of $233.8 million as of December 31, 2022.
- For the quarter ended September 30, 2023, net loss was $44.3 million or $0.39 per share compared with a net loss of $42.1 million or $0.50 per share for the quarter ended September 30, 2022.

2023 Financial Guidance

- For fiscal year 2023, AlloVir expects operating expenses to be in the range of $150 million to $170 million, excluding non-cash expenses.

About Posoleucel

AlloVir's lead product, posoleucel, is in late-stage clinical development as an allogeneic, off-the-shelf, multi-virus-specific T cell therapy targeting 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). In a Phase 2 open-label study of posoleucel for the prevention of clinically significant infections due to the six viruses posoleucel targets, 88% of allo-HCT patients who received posoleucel remained free of clinically significant infections through week 14, the primary endpoint. Moreover, the non-relapse mortality rate in patients who received posoleucel was 0% through the 52-week follow-up visit. Additionally, in the positive Phase 2 proof-of-concept CHARMS treatment study, which enrolled allo-HCT recipients infected by one or more of the six viruses posoleucel targets, more than 90% of patients who failed conventional treatment and received posoleucel demonstrated a complete or partial clinical response based on predefined criteria.

About AlloVir

AlloVir is a leading late-clinical stage cell therapy company focused 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 platform leverages 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. The company is advancing multiple mid- and late-stage clinical trials across its product portfolio. 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 as a treatment for three distinct indications in allo-HCT patients, the potential of posoleucel to prevent infection or disease, the potential of posoleucel to treat vHC or AdV, the timing of data readouts for our three Phase 3 studies and regulatory milestones, the projection that our cash will fund operations through data readouts for our three Phase 3 pivotal trials, that the next 12 months will be catalyst rich with clinical and regulatory milestones, that preventing viral infections in allo-HCT patients could be transformational, our anticipated commercial launch in 2025, AlloVir's development and regulatory status of its product candidates, the planned conduct of its preclinical studies, and clinical trials and its prospects for success in those studies and trials, and its strategy, business plans and focus. 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 safety and efficacy of posoleucel, AlloVir's financial results, the timing for the initiation and successful completion of AlloVir's clinical trials of its product candidates, whether and when, if at all, AlloVir's product candidates will receive approval from the U.S. Food and Drug Administration (FDA), or other foreign regulatory authorities, competition from other biopharmaceutical companies, supply chain, and business operations and other risks identified in AlloVir's SEC filings, including AlloVir's form 10-Q for the period ended June 30, 2023. 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.

Media and Investor:
ir@allovir.com

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$ 213,318	$ 233,795
Other current assets	6,701	9,257
Total current assets	220,019	243,052
Other assets	28,293	34,027
Total assets	$ 248,312	$ 277,079
Liabilities and stockholders' equity		
Current liabilities	$ 33,066	$ 24,338
Long-term liabilities	19,912	28,222
Total liabilities	52,978	52,560
Total stockholders' equity	195,334	224,519
Total liabilities and stockholders' equity	$ 248,312	$ 277,079

ALLOVIR, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited, in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 34,156	$ 30,004	$ 99,698	$ 90,450
General and administrative	12,805	12,946	37,797	40,318
Total operating expenses	46,961	42,950	137,495	130,768
Loss from operations	(46,961)	(42,950)	(137,495)	(130,768)
Total other income (loss), net:				
Interest income	1,522	668	4,362	978
Other income (loss), net	1,167	210	2,411	(634)
Loss before income taxes	(44,272)	(42,072)	(130,722)	(130,424)
Income tax expense	—	—	—	150
Net loss	$ (44,272)	$ (42,072)	$ (130,722)	$ (130,574)
Net loss per share — basic and diluted	$ (0.39)	$ (0.50)	$ (1.30)	$ (1.83)
Weighted-average common shares outstanding — basic and diluted	113,894,188	84,948,837	100,683,322	71,213,219