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): August 3, 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 August 3, 2023, AlloVir, Inc. announced its financial results for the quarter ended June 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 August 3, 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: August 3, 2023

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

Exhibit 99.1

AlloVir Reports Second Quarter 2023 Financial Results

Company's three Phase 3 global registrational trials for its allogeneic, off-the-shelf, virus-specific T cell therapy, posoleucel, in three distinct, first-to-market indications in allo-HCT patients continue to enroll, with data anticipated in second half of 2024

Positive data from the Phase 2 trial of posoleucel for treatment of BK viremia in kidney transplant recipients presented orally at late-breaking session at the American Transplant Congress (ATC 2023)

ALVR106, a multi-respiratory virus-specific T cell therapy targeting human metapneumovirus, influenza, parainfluenza, and respiratory syncytial virus, completed enrollment in the dose-escalation (Part A) portion of the Phase 1b/2a clinical trial in HCT and solid organ transplant patients

Recent stock offering extends cash runway through Phase 3 data readouts and into 2025

Waltham, Mass – August 3, 2023 – AlloVir, Inc. (Nasdaq: ALVR), a late-clinical stage allogeneic T cell immunotherapy company, today reported financial results from the second quarter ended June 30, 2023. The company shared progress across its allogeneic, off-the-shelf virus-specific T cell (VST) programs, including its lead investigational therapy, posoleucel, for prevention and treatment of life-threatening infections and diseases from up to six viruses that commonly impact patients following allogeneic hematopoietic cell transplant (allo-HCT), and for the treatment of BK viremia (BKV) in adult kidney transplant recipients.

"We are excited to be advancing our company's three Phase 3 global registrational trials of posoleucel for three indications that threaten allo-HCT recipients. Treating and preventing life-threatening viral infections using T cells that focus on restoring natural immunity addresses a significant unmet need for allo-HCT patients, which could have a significant impact on patient outcomes, morbidity, and survival," said Diana Brainard, M.D., Chief Executive Officer, AlloVir. "We are very pleased with our progress to date and are on track to report data from all three studies in the second half of 2024."

Recent Highlights

- In May 2023, the company announced the appointment of Cintia Piccina, PharmD, MBA, as Chief Commercial Officer. Ms. Piccina is an industry veteran with cell therapy expertise and more than 25 years of global commercial leadership experience. She is driving AlloVir's global commercialization strategy, with a focus on its lead product, posoleucel. She is also responsible for building a commercial team in anticipation of a potential 2025 launch.
- AlloVir delivered an oral presentation at the 49th annual meeting of the European Society for Blood and Marrow Transplantation (EBMT 2023) detailing positive results from the Phase 2 study of posoleucel for the prevention of clinically significant infections from six common and devastating viruses in allo-HCT recipients, including 0% non-relapse mortality at the 52-week follow-up visit.

- The company presented final results from a Phase 2 randomized, placebo-controlled trial evaluating posoleucel for the treatment of BKV in adult kidney transplant recipients at the American Transplant Congress (ATC 2023) in June 2023. Findings demonstrated that treatment with posoleucel was safe, well tolerated and produced clinically meaningful reductions in BK viral load as compared to placebo with the greatest antiviral activity seen among patients with higher viral loads and those who received more frequent posoleucel dosing. The company is preparing to meet with the FDA to gain alignment on a Phase 3 clinical study design to evaluate posoleucel's treatment of BKV infection in kidney transplant patients.
- In June 2023, the company closed a public offering of common stock with gross proceeds of approximately $75.0 million before deducting underwriting discounts and commissions and other estimated offering expenses. The company anticipates that its cash position will fund operations into 2025, through anticipated data readouts from the posoleucel Phase 3 trials.
- 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 from this dose-escalation portion of the clinical trial will be submitted for presentation at a future scientific congress.

Upcoming Highlights/Activities

- Data from three Phase 3 registrational trials of posoleucel in three indications for allo-HCT patients is anticipated in the second half of 2024:
  - The prevention of clinically significant infection or disease from adenovirus (AdV), BKV, cytomegalovirus (CMV), Epstein-Barr virus (EBV), human herpesvirus-6 (HHV-6) and JC virus (JCV)
  - The treatment of virus-associated hemorrhagic cystitis (vHC)
  - The treatment of AdV infection

Second Quarter Financial Results

- Research and development expenses were $34.8 million for the quarter ended June 30, 2023, compared with $31.4 million for the quarter ended June 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 $12.5 million for the quarter ended June 30, 2023, compared with $13.2 million for the quarter ended June 30, 2022. The decrease year-over-year was primarily attributable to a decrease in consulting and personnel related costs.
- Stock-based compensation expense was $10.3 million and $11.0 million for the quarter ended June 30, 2023, and 2022, respectively.
- As of June 30, 2023, AlloVir had cash, cash equivalents, and short-term investments of $246.5 million, compared with cash, cash equivalents, and short-term investments of $233.8 million as of December 31, 2022.

- For the quarter ended June 30, 2023, net loss was $45.3 million or $0.48 per share compared with a net loss of $44.6 million or $0.69 per share for the quarter ended June 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 viremia (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 Twitter 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, 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, the projection that our cash will fund operations through data readouts for our three Phase 3 trials and into 2025, 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 March 31, 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

ALLOVIR, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$246,536	$ 233,795
Other current assets	6,376	9,257
Tolal current assets	252,912	243,052
Other assets	29,780	34,027
Total assets	$282,692	$ 277,079
Liabilities and stockholders’ equity		
Current liabilities	$ 30,563	$ 24,338
Long-term liabilities	23,016	28,222
Total liabilities	53,579	52,560
Tolal stockholders’ equity	229,113	224,519
Total liabilities and stockholders’ equity	$282,692	$ 277,079

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 34,824	$ 31,379	$ 65,543	$ 60,446
General and administrative	12,480	13,245	24,992	27,371
Total operating expenses	47,304	44,624	90,535	87,817
Loss from operations	(47,304)	(44,624)	(90,535)	(87,817)
Total other income (loss), net:				
Interest income	1,516	162	2,841	310
Other (loss) income, net	521	(27)	1,244	(845)
Loss before income taxes	(45,267)	(44,489)	(86,450)	(88,352)
Income tax expense	—	150		150
Net loss	$ (45,267)	$ (44,639)	$ (86,450)	$ (88,502)
Net loss per share — basic and diluted	$ (0.48)	$ (0.69)	$ (0.92)	$ (1.38)
Weighted-averge common share outstanding — basic and diluted	94,625,837	64,467,483	93,968,407	64,231,579