# 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): May 4, 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 May 4, 2023, AlloVir, Inc. announced its financial results for the quarter ended March 31, 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 May 4, 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: May 4, 2023

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

**Exhibit 99.1**

**AlloVir Reports First Quarter 2023 Financial Results**

*Company's three posoleucel Phase 3 global registrational trials for three distinct, first-to-market indications continue to enroll with data readouts on track for 2024*

*Positive results from a randomized, double-blind, placebo-controlled Phase 2 study of posoleucel in kidney transplant recipients with BK viremia will be presented at the American Transplant Congress 2023 later this quarter*

**WALTHAM, MA – May 4, 2023 –** AlloVir (Nasdaq: ALVR), a late-clinical stage allogeneic T cell immunotherapy company, today reported financial results from the first quarter ended March 31, 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 continue to focus our efforts on rapidly advancing the three global Phase 3 ongoing registrational trials evaluating our lead investigational product, posoleucel, for the prevention and treatment of common, yet devastating, and potentially life-threatening viral infections and diseases in allo-HCT patients where significant unmet need persists," said Diana Brainard, MD, Chief Executive Officer, AlloVir. "In tandem, we reported final positive results from the Phase 2 study of posoleucel for the treatment of BKV, the first demonstration of its safety and antiviral effect in solid organ transplant recipients. We continue to be encouraged by the potential of posoleucel as a transformative therapeutic for transplant patients."

*Recent Highlights*

- In January 2023, the company announced plans to report data from its three Phase 3 registrational studies for posoleucel in 2024 across three distinct indications – the prevention of clinically significant infection or disease from adenovirus (AdV), BK virus, cytomegalovirus (CMV), Epstein-Barr virus (EBV), human herpesvirus-6 (HHV-6) and JC virus (JCV), the treatment of virus-associated hemorrhagic cystitis (vHC), and the treatment of AdV infection, all in allo-HCT patients. These viral infections have limited to no approved preventive therapies or treatment options, threatening patient survival.
- In February 2023, the company announced positive final results from a Phase 2 study of posoleucel being evaluated for the treatment of BKV in adult kidney transplant recipients, the first demonstration of posoleucel in solid organ transplant patients. Data demonstrate the safety profile of posoleucel and its antiviral activity, which is amplified in high viral load patients who have the greatest unmet need, suggesting it could potentially offer a transformative treatment option for kidney transplant patients with BKV.

- Positive long-term follow-up data from the Phase 2 trial exploring the potential of posoleucel for the prevention of clinically significant infections were presented at the 49th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT 2023) in April 2023. These new findings demonstrate that the high-risk allo-HCT patients who received posoleucel experienced continued low rates of clinically significant infections or end-organ disease and 0% non-relapse mortality. Data continue to substantiate the potential clinical benefit posoleucel could provide to high-risk allo-HCT patients.
- In February 2023, a case report of the treatment of refractory AdV infection in a CAR-T recipient with posoleucel was presented at the 2023 Tandem Meetings | Transplantation & Cellular Therapy Meetings of ASTCT and CIBMR (Poster 453). Findings demonstrate that posoleucel appeared to be safe and effective against devastating viral infections in patients receiving lymphodepletion chemotherapy and CAR-T therapy.
- The company announced the appointment of Derek Adams, PhD, a leading authority in biologic and gene therapies manufacturing, to its Board of Directors.

*Upcoming Highlights/Activities*

- The company plans to present comprehensive results from the BKV Phase 2 study as a late-breaking oral presentation at the American Transplant Congress (ATC) 2023 and will work with regulatory authorities and transplant specialists to inform next steps for this program as well as AlloVir's broader solid organ transplant strategy.

**First Quarter Financial Highlights**

- Research and development expenses were $30.7 million for the quarter ended March 31, 2023, compared with $29.1 million for the quarter ended March 31, 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 March 31, 2023, compared with $14.1 million for the quarter ended March 31, 2022. The decrease year-over-year was primarily attributable to a decrease in consulting and personnel related costs.
- Stock-based compensation expense was $10.0 million and $10.5 million for the quarter ended March 31, 2023, and 2022, respectively.
- As of March 31, 2023, AlloVir had cash, cash equivalents, and short-term investments of $202.6 million, compared with cash, cash equivalents, and short-term investments of $233.8 million as of December 31, 2022.
- For the quarter ended March 31, 2023, net loss was $41.2 million or $0.44 per share compared with a net loss of $43.9 million or $0.69 per share for the quarter ended March 31, 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 AlloVir**

AlloVir is a leading late clinical-stage cell therapy 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. 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 future enrollment status and timing for data readouts for AlloVir's three Phase 3 clinical trials, the potential safety and efficacy of AlloVir's product candidates, the development and regulatory status of AlloVir's 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 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, the impact of the COVID-19 pandemic on AlloVir's product development plans, supply chain, and business operations and other risks identified in AlloVir's annual report on Form 10-K for year ended December 31, 2023 and in its other SEC filings. 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.

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2023 | 2022 |
| Operating expenses: | | |
| Research and development | 30,718 | 29,067 |
| General and administrative | 12,513 | 14,126 |
| Total operating expenses | 43,231 | 43,193 |
| Loss from operations | (43,231) | (43,193) |
| Total other income (loss), net: | | |
| Interest income | 1,325 | 148 |
| Other income (loss), net | 723 | (818) |
| Net loss | $ (41,183) | $ (43,863) |
| Net loss per share — basic and diluted | $ (0.44) | $ (0.69) |
| Weighted-average common shares outstanding — basic and diluted | 93,303,672 | 63,993,053 |

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

| | March 31, 2023 | December 31, 2022 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash, cash equivalents and short-term investments | $ 202,570 | $ 233,795 |
| Other current assets | 9,705 | 9,257 |
| Total current assets | 212,275 | 243,052 |
| Other assets | 31,769 | 34,027 |
| Total assets | $ 244,044 | $ 277,079 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities | $ 24,959 | $ 24,338 |
| Long-term liabilities | 25,553 | 28,222 |
| Total liabilities | 50,512 | 52,560 |
| Total stockholders' equity | 193,532 | 224,519 |
| **Total liabilities and stockholders' equity** | $ 244,044 | $ 277,079 |

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