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 5, 2022

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 5, 2022, AlloVir, Inc. announced its financial results for the quarter ended March 31, 2022. 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 5, 2022
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 5, 2022

By: /s/ Vikas Sinha
Name: Vikas Sinha
Title: *President and Chief Financial Officer*

Exhibit 99.1

For Immediate Release

AlloVir Reports First Quarter 2022 Financial Results

Initiated posoleucel registrational study to prevent six devastating viral infections and now enrolling high-risk allo-HCT patients in the U.S., Western Europe and Asia

FDA granted RMAT designation to posoleucel for Phase 3 multi-virus prevention indication with an estimated annual addressable patient population of 40,000 allo-HCT patients

Progressed enrollment in three Phase 3 studies for posoleucel and a Phase 2 trial for ALVR106

Completed enrollment in Phase 2 study of posoleucel for the treatment of BK viremia in kidney transplant patients; initial blinded data will be presented at the American Transplant Congress in June

Waltham, Mass., May 5, 2022 – AlloVir, Inc. (Nasdaq: ALVR), a multiple Phase 3 clinical trial stage allogeneic T cell immunotherapy company, today reported financial results for the first quarter ended March 31, 2022. The company also shared progress across its virus-specific T cell (VST) programs, with its lead product, posoleucel, advancing into Phase 3 development for the prevention of infections and disease from six devastating viruses that commonly impact patients following allogeneic hematopoietic cell transplant (allo-HCT) – adenovirus (AdV), BK virus (BKV), cytomegalovirus (CMV), Epstein-Barr virus (EBV), human herpes virus-6 (HHV-6) and JC virus (JCV). Multi-virus prevention has the potential to transform the management of transplant patients, who currently have limited to no approved treatment options for these infections that threaten patient survival. The U.S. Food and Drug Administration (FDA) granted posoleucel Regenerative Medicine Advanced Therapy (RMAT) designation for this multi-virus prevention approach in high-risk adult and pediatric allo-HCT patients.

“We are focused on rapidly advancing our lead product candidate, posoleucel, with the aim of delivering this potentially transformative therapy to patients in need as quickly as possible. Based on the strength of our Phase 2 data in both treatment and prevention, we now have three Phase 3 studies underway that aim to address a spectrum of needs in the post-allo-HCT setting – as a treatment for patients already suffering the devastating impact of viral infections and disease, as a preemptive therapy for patients who have reactivated one or more viruses, and as a prophylactic therapy in high-risk patients without viremia,” said Diana Brainard, M.D., Chief Executive Officer, AlloVir. “The multi-virus prevention approach is the most transformative use of posoleucel and, accordingly, we are seeing strong enthusiasm from hematologists and infectious disease specialists as we expand our Phase 3 study sites and enrollment.”

Recent Highlights

- At the Annual Meeting of the European Society for Blood and Bone Marrow Transplantation (EBMT) in March 2022, AlloVir reported updated preliminary data from the open-label Phase 2 study assessing the safety and efficacy of posoleucel for multi-virus prevention in high-risk allo-HCT patients. The updated data set, which includes more patients and longer follow-up, continues to demonstrate a substantial reduction in the expected rate of clinically significant infections with posoleucel therapy.

- Based on the initial Phase 2 prevention study data, AlloVir initiated a global Phase 3 registrational study of posoleucel for the prevention of clinically significant infections and end-organ disease from posoleucel's six target viruses in high-risk allo-HCT patients, either as prophylactic therapy in patients without viremia or preemptive therapy for patients who have reactivated one or more viruses. As 90% of allo-HCT patients reactivate at least one of these viruses, there is a large global market opportunity for the prevention of devastating viral diseases, with an estimated addressable patient population of 40,000 allo-HCT patients annually.
- In April 2022, FDA granted posoleucel a third RMAT designation for multi-virus prevention, based on the initial Phase 2 prevention study data. This adds to existing RMAT designations for the treatment of AdV infection and for the treatment of hemorrhagic cystitis caused by BK viremia in adults and children, both following allo-HCT. Posoleucel is the only cell or gene therapy with three RMAT indications.
- AlloVir initiated a Phase 3 registrational study of posoleucel for the treatment of AdV infections in adult and pediatric allo-HCT patients. AdV-associated viral disease is among the leading causes of life-threatening complications following allo-HCT, often involving multiple vital organs, including the brain, lungs and liver, and occurs in 32% of pediatric and 6% of adult allo-HCT patients.
- Two compassionate use case reports of posoleucel therapy for refractory disseminated AdV infection post allo-HCT were presented at the 2022 Tandem Meetings |Transplantation & Cellular Therapy Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood & Marrow Transplant Research (CIBMTR). Following posoleucel therapy, both patients experienced reductions in viral load below the level of quantitation.
- Shawn Tomasello joined AlloVir's Board of Directors in March 2022. Ms. Tomasello brings more than 35 years of broad experience building and leading commercial organizations in the life sciences industry, with specific expertise in cell and gene therapy.

Upcoming Q2 2022 Highlights/Activities

- The ongoing Phase 2 study of posoleucel for the treatment of BK viremia in kidney transplant patients has fully enrolled ahead of schedule and the study is now expected to complete by year-end. Initial blinded data from the study will be presented at the American Transplant Congress in June (Abstract 387). Topline study results are expected to be released early next year, once the trial has completed.
- Compassionate use case reports of ALVR109 administered to four immunocompromised patients with protracted COVID-19 infection will be presented at the American Transplant Conference (Abstract 9011). Viral suppression and clinical improvement were observed in all four patients following administration of ALVR109 therapy.
- Preclinical data on ALVR107, an investigational VST to cure chronic hepatitis B, will be presented at the International Liver Congress in June.

First Quarter Financial Highlights

- Research and development expenses were $29.1 million for the quarter ended March 31, 2022, compared with $20.4 million for the quarter ended March 31, 2021. The increase year-over-year is attributable to costs related to the development of the company's product candidates, increased activity in outsourcing of manufacturing and an increase in headcount in support of research activities.

- The general and administrative expense was $14.1 million for the quarter ended March 31, 2022, compared with $10.5 million for the quarter ended March 31, 2021. The increase year-over-year was primarily attributable to increased headcount to support operations.
- Stock-based compensation expense was $10.5 million and $8.1 million for the quarter ended March 31, 2022, and 2021, respectively.
- As of March 31, 2022, AlloVir had cash, cash equivalents, and marketable securities of $201.4 million, compared with $248.1 million as of December 31, 2021.
- For the quarter ended March 31, 2022, the net loss was $43.9 million or $0.69 per share, compared with a net loss of $30.9 million or $0.50 per share for the quarter ended March 31, 2021.

2022 Financial Guidance

- For fiscal year 2022, AlloVir continues to expect operating expenses to be in the range of $130 million to $145 million, excluding non-cash stock compensation 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 AlloVir's development and regulatory status of our 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, or 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 SEC filings, including but not limited to the risks discussed in AlloVir's Annual Report on Form 10-K for the year ended December 31, 2021 and in our other 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.

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

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$201,375	$ 248,120
Other current assets	5,066	5,228
Total current assets	206,441	253,348
Other assets	24,649	33,246
Total assets	$231,090	$ 286,594
Liabilities and stockholders' equity		
Current liabilities	$ 18,639	$ 37,853
Long-term liabilities	20,776	23,475
Total liabilities	39,415	61,328
Total stockholders' equity	191,675	225,266
Total liabilities and stockholders' equity	$231,090	$ 286,594

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

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	$ 29,067	$ 20,393
General and administrative	14,126	10,470
Total operating expenses	43,193	30,863
Loss from operations	(43,193)	(30,863)
Total other income (loss), net:		
Interest income	148	505
Other (loss) income, net	(818)	(565)
Loss before income taxes	(43,863)	(30,923)
Income tax expense	—	—
Net loss	$ (43,863)	$ (30,923)
Net loss per share — basic and diluted	$ (0.69)	$ (0.50)
Weighted-average common shares outstanding — basic and diluted	63,993,053	62,193,734

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