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 5, 2021

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.
139 Main Street, Suite 500
Cambridge, Massachusetts 02142
(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 5, 2021, AlloVir, Inc. announced its financial results for the quarter ended September 30, 2021. 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 5, 2021
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 5, 2021

By: /s/ Edward Miller
Name: Edward Miller
Title: *General Counsel*

Exhibit 99.1

For Immediate Release

AlloVir Reports Third Quarter 2021 Financial Results

Company is prioritizing prevention and treatment programs with the potential to transform transplant patient care and outcomes

Positive interim data from posoleucel multi-virus prevention Phase 2 study will be presented at ASH

Posoleucel Phase 3 study for the treatment of adenovirus and ALVR106 proof-of-concept clinical trial for the treatment of multiple respiratory viruses are on track to initiate this year

Cambridge, Mass., November 5, 2021 – AlloVir (Nasdaq: ALVR), a late clinical-stage cell therapy company, today reported financial results for the third quarter ended September 30, 2021. The company also shared progress on the advancement of its prioritized virus-specific T cell (VST) programs to prevent or treat life-threatening viral diseases.

"AlloVir's allogeneic, off-the-shelf, virus-specific T cell platform has the potential to transform the care of and outcomes for patients – from stem cell and solid organ transplant recipients to broader patient groups with immunodeficiency. The interim data we will be presenting at ASH provide the first look at the potential for posoleucel, a multi-virus specific T cell therapy, to change the treatment paradigm for stem cell transplant recipients, moving upstream to prevent the most common life-threatening viral diseases for these patients before they occur," said Diana Brainard, M.D., Chief Executive Officer, AlloVir. "Across our portfolio, we are prioritizing programs with the largest potential benefit for patients, including the prevention of life-threatening viral diseases caused by six devastating viruses with a single therapy. We are focusing on key areas where there are limited or no treatment options, such as hemorrhagic cystitis, BK viremia and adenovirus."

Upcoming Q4 2021 Highlights/Activities:

- Initial data from the open-label cohort of a Phase 2 clinical trial to assess the safety and efficacy of posoleucel for the prevention of multiple viruses following allogeneic hematopoietic stem cell transplantation (allo-HSCT) will be presented at the 63rd American Society of Hematology Annual Meeting in December (Abstract #1760). The study is evaluating the potential for posoleucel to prevent clinically significant viral infections (adenovirus, BK virus, cytomegalovirus, Epstein-Barr virus, human herpesvirus-6, JC virus) in high-risk, adult and pediatric allo-HSCT patients. The study is ongoing and continues to enroll patients.
- In December, AlloVir plans to submit initial data from its Phase 2 proof-of-concept (POC) clinical trial with posoleucel for the preemptive treatment of BK viremia in adult kidney transplant recipients, for presentation at a scientific congress in the first half of 2022. BK viremia is detected in up to 20% of kidney transplant patients and can lead to nephropathy causing decreased kidney survival and a return to end-stage renal disease and dialysis.

-more-

- AlloVir remains on track to initiate a Phase 3 study this year evaluating posoleucel for the treatment of adenovirus (AdV) in adult and pediatric allo-HSCT recipients. AdV-associated viral disease is among the leading causes of life-threatening complications following allo-HSCT, occurring in 32% of pediatric and 6% of adult allo-HSCT patients. AdV-associated viral disease often results in multi-organ involvement with the virus invading the brain, lungs, liver and other vital organs. There is no approved treatment for adenovirus infection.
- A POC clinical trial of ALVR106, an investigational multi-respiratory VST therapy designed to target infections and diseases caused by human metapneumovirus, influenza, parainfluenza virus and respiratory syncytial virus in allogeneic and autologous HSCT recipients, is on track to initiate before year-end, coinciding with the respiratory virus season.
- Preclinical and Investigational New Drug (IND)-enabling studies for ALVR107 to treat hepatitis B virus (HBV) are on track for completion by the end of this year. Chronic HBV infection is associated with significant morbidity and mortality. Current treatment options for chronic HBV consist of life-long antiviral therapy to suppress virus replication, which can slow the progression of liver cirrhosis and reduce the incidence of liver cancer. However, there are no curative therapies available.

Recent Clinical and Scientific Highlights:

- Positive preclinical and early clinical data presented in an oral presentation at IDWeek™ 2021 demonstrated that ALVR109, an investigational VST therapy targeting SARS-CoV-2, provides antiviral activity and coverage against multiple variant strains, including Delta. Beyond SARS-CoV-2, these data reinforce the potential for AlloVir's VST therapies to address the major public health issue posed by ubiquitous respiratory viruses.
- In October, the U.S. Food and Drug Administration granted Orphan Drug Designation to posoleucel for the treatment of virus-associated hemorrhagic cystitis. Posoleucel previously received Regenerative Medicine Advanced Therapy (RMAT) designation from the FDA, and Orphan Medicinal Product and PRIority MEdicines (PRIME) designations from the European Medicines Agency.

Third Quarter Financial Highlights:

- Research and development expenses were $33.1 million for the quarter ended September 30, 2021, compared with $17.2 million for the quarter ended September 30, 2020. 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 and external consultants in support of research activities.
- The general and administrative expense was $12.4 million for the quarter ended September 30, 2021, compared with $6.7 million for the quarter ended September 30, 2020. The increase year-over-year was primarily attributable to increased headcount and professional fees for legal and accounting associated with operating as a public company.

-more-

- Stock-based compensation expense was $10.3 million and $3.9 million for the quarter ended September 30, 2021, and 2020, respectively.
- As of September 30, 2021, AlloVir had cash, cash equivalents, and marketable securities of $275.8 million, compared with $356.3 million as of December 31, 2020.
- For the quarter ended September 30, 2021, net loss was $45.5 million or $0.72 per share, compared with a net loss of $23.6 million or $0.58 per share for the quarter ended September 30, 2020.

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. 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.

-more-

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

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$ 275,841	$ 356,324
Other current assets	6,031	4,993
Total current assets	281,872	361,317
Other assets	34,658	9,504
Total assets	$ 316,530	$ 370,821
Liabilities and stockholders' equity		
Current liabilities	$ 24,173	$ 12,294
Long-term liabilities	25,053	5,463
Total liabilities	49,226	17,757
Total stockholders' equity	267,304	353,064
Total liabilities and stockholders' equity	$ 316,530	$ 370,821

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,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	33,062	17,182	79,132	32,906
General and administrative	12,442	6,718	34,890	12,987
Total operating expenses	45,504	23,900	114,022	45,893
Loss from operations	(45,504)	(23,900)	(114,022)	(45,893)
Total other income (loss), net:				
Interest income	253	112	1,233	735
Other (loss) income, net	(259)	174	(1,232)	573
Net loss	$ (45,510)	$ (23,614)	$ (114,021)	$ (44,585)
Net loss per share — basic and diluted	$ (0.72)	$ (0.58)	$ (1.82)	$ (2.93)
Weighted-average common shares outstanding — basic and diluted	62,962,434	40,465,705	62,588,898	15,195,000

###

Contact:

Sonia Choi
AlloVir
schoi@allovir.com