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): February 10, 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 February 10, 2022, AlloVir, Inc. announced its financial results for the quarter and year ended December 31, 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 February 10, 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: February 10, 2022

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

For Immediate Release

AlloVir Reports Full-Year 2021 Financial Results and 2022 Outlook

Three ongoing Phase 3 registrational studies of posoleucel expected in 2022, targeting treatment and prevention indications with no approved therapies

Expanded enrollment in Phase 2 proof-of-concept study of posoleucel for the preemptive treatment of BK viremia in kidney transplant recipients; initial data submitted for presentation in 1H 2022

Advancing two additional virus-specific T cell therapies – ALVR106 to treat common respiratory viral infections and ALVR107 for hepatitis B cure

Strong cash position, with $248.1 million as of year-end 2021

Waltham, Mass., February 10, 2022 – AlloVir (Nasdaq: ALVR), a late clinical-stage allogeneic T cell immunotherapy company, today reported full-year 2021 financial results for the period ended December 31, 2021. The company also provided the outlook for 2022 across its pipeline of allogeneic, off-the-shelf, virus-specific T cell (VST) therapies for immunocompromised patients, including its lead product posoleucel, an investigational VST in development for the treatment and prevention of infections and diseases caused by six common devastating viruses – adenovirus (AdV), BK virus (BKV), cytomegalovirus (CMV), Epstein-Barr virus (EBV), human herpesvirus-6 (HHV-6) and JC virus (JCV).

“2022 is a year of execution and expansion for our clinical development program, as we implement three Phase 3 registrational studies across sites in North America, Europe and Asia, present new data that expand on posoleucel’s potential in both the treatment and prevention of six life-threatening viruses, and continue to advance two additional VST therapies,” said Diana Brainard, M.D., Chief Executive Officer of AlloVir. “Beyond our clinical development programs, we are also advancing the manufacturing of posoleucel in anticipation of commercial product requirements and global distribution. Our non-gene-edited VST manufacturing platform is commercially scalable and can achieve cost of goods similar to biologics. This positions us well for the next stage of our company’s growth as our pipeline continues to mature.”

Recent Highlights

Advancing Posoleucel Development

- At the American Society of Hematology (ASH) Annual Meeting in December 2021, AlloVir reported positive preliminary data from the open-label Phase 2 study assessing the safety and efficacy of posoleucel for the prevention of multiple viruses in high-risk allogeneic hematopoietic cell transplant (allo-HCT) patients. The preliminary data set demonstrated a substantial reduction in the expected rate of clinically significant viral infections or diseases and facilitates an accelerated path to Phase 3 development, which has been agreed to in principle by the U.S. Food and Drug Administration (FDA). The Phase 3 registrational study is expected to initiate in the first half of 2022.

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- In December 2021, AlloVir initiated a global Phase 3 registrational study of posoleucel for the treatment of AdV infections in adult and pediatric allo-HCT patients. The study is the second registrational trial of posoleucel to initiate. 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-HSCT patients.
- The FDA granted posoleucel Regenerative Medicine Advanced Therapy (RMAT) designation for the treatment of AdV infections, based on Phase 2 data and in recognition of the potential for posoleucel to address an unmet medical need. The FDA previously granted RMAT and orphan drug designations (ODD) to posoleucel for the treatment of hemorrhagic cystitis (HC) caused by BKV in adults and children following allo-HCT. The European Medicines Agency has granted posoleucel PRIority Medicines (PRIME) designation for the treatment of serious infections with AdV, BKV, CMV, EBV and HHV-6, and Orphan Medicinal Product (OMP) designation as a potential treatment of viral diseases and infections in patients undergoing HCT.
- Following a review at the end of last year of initial, blinded safety data from the ongoing posoleucel proof-of-concept (POC) study for BK viremia treatment in adult kidney transplant recipients, the study has been amended to begin enrolling patients with higher viral loads. BKV is detected in up to 20% of kidney transplant patients and can lead to graft loss and a return to end-stage renal disease and dialysis. There are no approved or effective BKV treatments.

Expanding into Respiratory Viruses

- A Phase 1/2 POC study 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 autologous and allo-HCT recipients initiated in December 2021.
- Data on ALVR109, a SARS-CoV-2 targeted VST available via compassionate use, further validated the potential of AlloVir's VSTs for the treatment of respiratory viruses. A case report detailing the use of ALVR109 in an immunocompromised heart transplant patient with severe refractory COVID-19 was published in the American Journal of Transplantation in December 2021; rapid clinical and virologic improvement occurred following the administration of ALVR109. Recent preclinical testing has demonstrated that ALVR109 retains potent antiviral activity against a broad range of variant strains including Omicron.

Manufacturing

- AlloVir established regional clinical distribution capabilities for its VSTs in Europe and Asia Pacific, thereby opening these geographies to participation in its clinical trials.
- AlloVir conducted a technology transfer of its VST manufacturing platform to ElevateBio's BaseCamp facility. In doing so, AlloVir added capacity and redundancy to its external manufacturing network of contract development and manufacturing organizations.

2022 Outlook

Three Phase 3 Studies of Posoleucel in Three Distinct Indications with No Approved Therapies

- Global enrollment is ongoing in registrational studies of posoleucel for the treatment of virus-associated HC and for the treatment of AdV infections, both in adult and pediatric allo-HCT patients. Enrollment of the HC trial is expected to be complete in the first half of 2023.
- A Phase 3 registrational trial for multi-virus prevention, using the dose, dosing interval and key endpoints from the Phase 2 study, is expected to initiate in the first half of this year, pending FDA review of the final study protocol. Multi-virus prevention has the potential to be clinically transformative, while also expanding the addressable patient population for posoleucel.

New Data Adding to the Understanding of the Potential for Posoleucel

- The company expects to report initial data from the ongoing posoleucel POC study for BKV treatment in KT recipients at a scientific meeting in the first half of 2022. The study is the first to evaluate the use of posoleucel in solid organ transplant (SOT) recipients; results from this study will also inform plans for a multi-virus prevention study in SOT patients. SOT represents a large opportunity to significantly expand the addressable patient population for posoleucel.
- Final results, including persistence data, from the posoleucel Phase 2 study for multi-virus prevention are expected to be presented at a scientific meeting in the second half of 2022.

Advancing Two Additional VST Therapies

- Enrollment in the Phase 1/2 POC study of ALVR106 for the treatment of multiple respiratory viral infections is ongoing.
- Preclinical and IND-enabling studies of ALVR107 to treat and cure hepatitis B will be completed in 2022 to support advancement into a POC study.

2021 Financial Highlights

- Research and development expenses were $120.7 million for the year ended December 31, 2021, compared with $49.7 million for the year ended December 31, 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.
- General and administrative expense was $49.1 million for the year ended December 31, 2021, compared with $21.6 million for the year ended December 31, 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.
- Stock-based compensation expense was $44.0 million and $9.4 million for the years ended December 31, 2021, and 2020, respectively.
- As of December 31, 2021, AlloVir had cash, cash equivalents and marketable securities of $248.1 million, compared with cash, cash equivalents and marketable securities of $356.3 million as of December 31, 2020.
- For the year ended December 31, 2021, net loss was $172.0 million or $2.74 per share, compared with a net loss of $69.8 million or $2.59 per share for the year ended December 31, 2020.

2022 Financial Guidance

- For fiscal year 2022, AlloVir expects 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.

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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.

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

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$248,120	$356,324
Other current assets	5,228	4,993
Total current assets	253,348	361,317
Other assets	33,246	9,504
Total assets	$286,594	$370,821
Liabilities and stockholders' equity		
Current liabilities	$ 37,853	$ 12,294
Long-term liabilities	23,475	5,463
Total liabilities	61,328	17,757
Total stockholders' equity	225,266	353,064
Total liabilities and stockholders' equity	$286,594	$370,821

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

	Years Ended December 31,	
	2021	2020
Operating expenses:		
Research and development	120,735	49,663
General and administrative	49,083	21,646
Total operating expenses	169,818	71,309
Loss from operations	(169,818)	(71,309)
Total other income (loss), net:		
Interest income	1,315	1,330
Other (loss) income, net	(2,452)	195
Loss before income taxes	(170,955)	(69,784)
Income tax expense	1,007	—
Net loss	$ (171,962)	$ (69,784)
Net loss per share — basic and diluted	$ (2.74)	$ (2.59)
Weighted-average common shares outstanding — basic and diluted	62,782,126	26,897,390

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