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 11, 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 February 11, 2021, AlloVir, Inc. announced its financial results for the quarter and year ended December 31, 2020. 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 11, 2021

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 11, 2021

By: /s/ David Hallal
David Hallal
Chief Executive Officer

Exhibit 99.1

AlloVir Reports Full Year 2020 Financial Results

- *Initiated Phase 3 pivotal clinical trial with Viralym-M, an off-the-shelf multi-virus-specific investigational T-cell therapy, for the treatment of virus-associated hemorrhagic cystitis*
- *Initiated two additional Phase 2 proof-of-concept clinical trials with Viralym-M, including a first-of-its-kind, multi-virus prevention study in HSCT recipients and a study for the treatment BK viremia in kidney transplant recipients*
- *Initiated a proof-of-concept clinical trial with ALVR109, an off-the-shelf virus-specific investigational T-cell therapy designed to combat SARS-COV-2, to evaluate its safety and efficacy as a treatment for high-risk patients with COVID-19*
- *FDA cleared IND for ALVR106, an allogeneic, off-the-shelf, multi-respiratory virus-specific investigational T-cell therapy*

Cambridge, MA, February 11, 2021 – AlloVir (Nasdaq: ALVR), a late clinical-stage cell therapy company, today provided a corporate update and reported full-year 2020 financial results for the period ended December 31, 2020.

"Since completing our initial public offering in 2020, our team achieved our ambitious milestones, as planned. These milestones included obtaining clearance from the U.S. Food and Drug Administration (FDA) for two Investigational New Drug (IND) applications, initiating three clinical trials with our lead therapy, Viralym-M, as well as initiating our proof-of-concept (POC) clinical trial with our SARS-COV-2 virus-specific T-cell (VST) therapy, ALVR109," said David Hallal, Chairman and Chief Executive Officer of AlloVir. "We're pleased that dosing has commenced with our initial two investigational VST therapies, Viralym-M and ALVR109. We look forward to enrolling an increasing number of patients in our clinical trials throughout 2021, while also initiating up to four additional clinical trials with our three clinical-stage cell therapies Viralym-M, ALVR109 and ALVR106."

Recent Highlights

Viralym-M for Allogeneic HSCT Recipients

- The Phase 3, multicenter, double-blind placebo-controlled clinical trial to assess the safety and efficacy of Viralym-M for the treatment of virus-associated hemorrhagic cystitis (HC) in pediatric and adult patients following allogeneic hematopoietic stem cell transplantation (allo-HSCT) was initiated. Sites are actively recruiting patients and the trial is ongoing.

- A first-of-its-kind, multi-virus prevention, Phase 2, POC clinical trial to assess the safety and efficacy of Viralym-M in pediatric and adult patients following allo-HSCT was initiated. The trial is targeting the prevention of BK virus (BKV), cytomegalovirus (CMV), adenovirus (AdV), Epstein Barr virus (EBV), human herpesvirus 6 (HHV-6), and JC virus (JCV). Sites are actively recruiting patients and the trial is ongoing.
- Results from the Phase 2, POC CHARMS clinical trial with Viralym-M, and data that highlight the economic and clinical burden of virus-associated HC in pediatric and adult patients following allo-HSCT, were presented in two oral presentations at the 62nd American Society of Hematology Annual Meeting & Exposition (ASH) in December. The CHARMS data demonstrated that patients treated with Viralym-M saw a 93% response rate overall and a 100% response rate for at least one virus in patients with more than one viral infection. Viralym-M was generally well-tolerated in allo-HSCT patients with at least one drug refractory infection. Based on these data and the critical medical need, Viralym-M was granted PRIority MEdicines (PRIME) designation by the European Medicines Agency and Regenerative Medicine Advanced Therapy (RMAT) designation by the FDA.

Viralym-M for SOT Recipients

- A Phase 2 POC trial of Viralym-M for the preemptive treatment of BK viremia in adult kidney transplant recipients has been initiated. BK viremia is one of the most feared complications for kidney transplant patients leading to decreased graft survival. Sites are actively recruiting patients and the trial is ongoing.

ALVR109 for COVID-19

- The Phase 1 POC clinical trial for ALVR109, an allogeneic, off-the-shelf VST therapy candidate designed to target SARS-CoV-2, the virus that causes the severe and life-threatening viral disease, COVID-19, has been initiated. The trial is actively recruiting patients and ongoing.
- Preclinical ALVR109 data were presented during an oral presentation at ASH in December, demonstrating specific antiviral activity. In the study, the VST therapy produced effector molecules and selectively killed viral antigen-expressing targets while leaving non-infected targets intact.

ALVR106 for Multi-Respiratory Viruses

- AlloVir announced that the FDA cleared the IND application for ALVR106, an allogeneic, off-the-shelf, multi-respiratory VST therapy designed to target infections and diseases caused by respiratory syncytial virus (RSV), influenza, parainfluenza virus (PIV), and human metapneumovirus (hMPV).

2021 Outlook

Viralym-M for HSCT Recipients

- Two additional pivotal clinical trials are expected to be initiated in 2021, including for the treatment of CMV and the treatment of AdV in adult and pediatric allo-HSCT recipients. CMV and AdV-associated diseases are among the leading causes of life-threatening complications following allo-HSCT, often resulting in multi-organ involvement with the viruses invading the brain, the lungs, the liver, and other vital organs.
- Initial data from the open-label phase of the POC multi-virus prevention trial in allo-HSCT recipients is expected in the second half of 2021.

Viralym-M for SOT Recipients

- A Phase 1 POC clinical trial will be initiated in CMV for solid organ transplant recipients.
- Interim data is also anticipated in the second half of 2021 from the POC trial in BK viremia in kidney transplant recipients.

ALVR109 for COVID-19

- Topline data from the ALVR109 POC clinical trial in COVID-19 is expected in the second half of 2021.

ALVR106 for Multi-Respiratory Viruses

- A POC clinical trial for ALVR106, targeting multiple respiratory viruses, including RSV, influenza, PIV, and hMPV, in allogeneic and autologous HSCT recipients, is expected to be initiated in the upcoming 2021 respiratory virus season.
- The company will continue to assess the impact of the COVID-19 pandemic on the incidence, diagnosis, and treatment of the respiratory viral infections that ALVR106 targets.

Pipeline Program and Corporate Milestones

- The company plans to complete preclinical, IND-enabling studies for both ALVR107 for the treatment of hepatitis B virus and ALVR108 for the treatment of human herpesvirus-8 in the second half of 2021.
- The company remains on track to expand the capacity of its manufacturing network in 2021 with the addition of ElevateBio Basecamp.

2020 Financial Highlights

- Research and development expenses were $49.7 million for the year ended December 31, 2020 compared to $16.2 million for the year ended December 31, 2019. 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 $21.6 million for the year ended December 31, 2020 compared to $10.6 million for the year ended December 31, 2019. The increase year-over-year was primarily attributable to legal, accounting and professional fees related to costs associated with operating activities and preparing for and executing the company's initial public offering.
- Stock-based compensation expense was $9.4 million and $2.9 million for the years ended December 31, 2020 and 2019, respectively.
- As of December 31, 2020, AlloVir had cash, cash equivalents, and marketable securities of $356.3 million, which compares to cash, cash equivalents, and marketable securities of $126.1 million as of December 31, 2019.
- For the year ended December 31, 2020, net loss was $69.8 million or $2.59 per share compared to a net loss of $23.8 million or $18.54 per share for the year ended December 31, 2019. The total number of common shares outstanding as of December 31, 2020 was 61,931,255.

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 targeting devastating viruses for patients with T-cell deficiencies who are at risk from the life-threatening consequences of viral diseases. AlloVir's technology and manufacturing process enables 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.

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.
CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$356,324	$126,077
Other current assets	4,993	1,236
Total current assets	361,317	127,313
Other assets	9,504	12,109
Total assets	$370,821	$139,422
Liabilities and stockholders' equity (deficit)		
Current liabilities	$ 12,294	$ 9,106
Long-term liabilities	5,463	8,692
Total liabilities	17,757	17,798
Preferred stock	—	173,127
Total stockholders' equity (deficit)	353,064	(51,503)
Total liabilities, preferred stock, and stockholders' equity (deficit)	$370,821	$139,422

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

	Years Ended December 31,	
	2020	2019
Revenue	$ —	$ 165
Operating expenses:		
Research and development	49,663	16,248
General and administrative	21,646	10,618
Total operating expenses	71,309	26,866
Loss from operations	(71,309)	(26,701)
Total other income, net:		
Interest income	1,330	2,065
Other income, net	195	797
Net loss	$ (69,784)	$ (23,839)
Net loss per share — basic and diluted	$ (2.59)	$ (18.54)
Weighted-average common shares outstanding—basic and diluted	26,897,390	1,285,933

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