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): December 17, 2020

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 8.01 Other Events

On December 17, 2020, AlloVir, Inc. issued a press release titled “AlloVir Announces FDA Clearance of Investigational New Drug Application for ALVR106, an Allogeneic, Off-the-Shelf, Multi-Virus Specific T Cell Therapy Targeting Four Devastating Respiratory Viruses”. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated into this Item 8.01 by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated December 17, 2020

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: December 17, 2020

By: /s/ Edward Miller
Edward Miller
General Counsel

Exhibit 99.1

AlloVir Announces FDA Clearance of Investigational New Drug Application for ALVR106, an Allogeneic, Off-the-Shelf, Multi-Virus Specific T Cell Therapy Targeting Four Devastating Respiratory Viruses

Proof-of-concept phase 1/2 trial to initiate in 2021 to treat severe respiratory viral infections in patients following hematopoietic stem cell transplantation

ALVR106 designed to target devastating diseases caused by four respiratory viruses: respiratory syncytial virus, influenza, parainfluenza virus, and human metapneumovirus

Cambridge, Mass, December 17, 2020 – AlloVir (Nasdaq: ALVR), a late clinical-stage cell therapy company, announced that the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application for ALVR106, an allogeneic, off-the-shelf virus-specific T cell therapy (VST) designed to target infections and diseases caused by respiratory syncytial virus (RSV), influenza, parainfluenza virus (PIV), and human metapneumovirus (hMPV). The IND enables AlloVir to initiate a Phase 1/2 proof-of-concept clinical study in allogeneic and autologous hematopoietic stem cell transplant (HSCT) patients with respiratory infections caused by RSV, influenza, PIV or hMPV.

“Respiratory viruses are a leading cause of morbidity and mortality in HSCT patients, and based on evidence from our preclinical studies, we believe ALVR106 could transform the treatment and prevention of respiratory infections and substantially reduce the associated morbidity and mortality of these infections in the future,” said Ercem Atillasoy, M.D., Chief Regulatory and Safety Officer of AlloVir. “The clearance of the IND for ALVR106 advances our third program into clinical trials further exploring the power of our proprietary virus-specific T cell therapy platform.”

Respiratory tract infections due to RSV, influenza, PIV, and hMPV are a major public health concern and are detected in up to 40 percent of allogeneic HSCT patients. These viral infections can progress from upper respiratory tract infections to more serious lower respiratory tract infections, which are associated with mortality rates of 20-45 percent in HSCT patients.

As previously disclosed, this proof-of-concept clinical trial will initiate in 2021 as the company is assessing the impact of the COVID-19 pandemic on the incidence, diagnosis, and treatment of the respiratory viral infections which ALVR106 targets.

About ALVR106

ALVR106 is an allogeneic, off-the-shelf, multi-virus specific VST investigational therapy designed to target infections and diseases caused by the respiratory syncytial virus (RSV), influenza, parainfluenza virus (PIV), and human metapneumovirus (hMPV). In vitro data demonstrate that ALVR106 has antiviral activity against each of the targeted viruses with minimal or no activity against non-virus-infected cells. This preclinical data supports the potential for antiviral benefit and safety of ALVR106 when administered to patients.

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 patients with weakened immune systems. The company’s innovative and proprietary technology platforms leverage off-the-shelf, allogeneic, 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 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 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, 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.

Media contact:
Courtney Heath
ScientPR
AlloVirPR@scientpr.com
617-872-2462

Investor contact:
Medha Chadha
AlloVir
ir@allovir.com