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 7, 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 7, 2020, AlloVir, Inc. issued a press release titled “Positive Phase 2 Proof-of-Concept Data for Viralym-M and Burden of Disease Data Presented in Oral Presentations at the 62nd American Society of Hematology Annual Meeting”. 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 7, 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 7, 2020

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

Exhibit 99.1

Positive Phase 2 Proof-of-Concept Data for Viralym-M and Burden of Disease Data Presented in Oral Presentations at the 62nd American Society of Hematology Annual Meeting

- Viralym-M, an allogeneic, off-the-shelf, multi-virus specific T-cell therapy demonstrates 93% of patients achieved a clinical response after treatment of viral infections and disease in patients following allogeneic HSCT

- Real-world findings demonstrate significantly higher healthcare costs, health resource utilization and worse clinical outcomes in allogeneic HSCT patients with virus-associated hemorrhagic cystitis

Cambridge, Mass., December 7, 2020 – AlloVir (Nasdaq: ALVR), a late clinical-stage cell therapy company, today announced that results from the Phase 2, proof-of-concept CHARMS study demonstrated that an allogeneic, off-the-shelf, multi-virus specific T cell therapy, Viralym-M (ALVR105), achieved a 93% clinical response and was generally well-tolerated in allogeneic hematopoietic stem cell transplantation (allo-HSCT) patients with at least one drug refractory infection. The findings were highlighted during an oral presentation at the 62nd American Society of Hematology Annual Meeting (ASH). In a second oral presentation, a health outcomes analysis showed the high economic and clinical burden of virus-associated hemorrhagic cystitis (V-HC) in patients following allo-HSCT.

“There is an urgent need for new therapies that improve the treatment and prevention of viral infections which have significantly impacted immunocompromised patients as well as burdened the healthcare system,” said Agustin Melian, MD, Chief Medical Officer and Head of Global Medical Sciences of AlloVir. “The data presented at ASH highlight the potential of Viralym-M in treating immunocompromised patients who are at a greater risk of viral infection.”

Oral Presentation: **Treatment of Severe, Drug-Refractory Viral Infections with Allogeneic, Off-the-Shelf, Multi-virus Specific T Cell Therapy in Patients Following HSCT: Results from a Phase 2 Study**

Presenter: Bilal Omer, MD, Center for Cell and Gene Therapy, Baylor College of Medicine, Texas Children’s Hospital, Houston Methodist Hospital, Houston, TX

Efficacy and safety data of Viralym-M in allo-HSCT recipients with at least one treatment-refractory infection (BKV, CMV, AdV, EBV, HHV-6, and/or JCV) were evaluated in the CHARMS study, a Phase 2 proof-of-concept clinical trial. Allo-HSCT patients who had either failed antiviral therapy or were unable to tolerate standard antivirals were enrolled and received a single infusion of Viralym-M. If a partial response was achieved, patients could receive up to four additional doses after four weeks, at two-week intervals.

Ninety-three percent (93%) of the patients achieved a complete (viral load returning to normal range and resolution of clinical signs/symptoms) or partial (a ³50% decrease in viral load and/or 50% improvement of clinical signs/symptoms) response by six weeks post-infusion. One hundred percent (100%) of patients who had two or more viral infections (11 of 11) responded to Viralym-M with 19 of the 23 viral infections across these 11 patients responding to treatment. Treatment with Viralym-M was generally well tolerated.

“Patients receiving an allogeneic hematopoietic stem cell transplant are at increased risk for multiple viral infections and diseases, which ultimately put them at risk for serious and life-threatening outcomes,” said Bilal Omer, MD, Center for Cell and Gene Therapy, Baylor College of Medicine, Texas Children’s Hospital, Houston Methodist Hospital and presenting author. “Currently there is a lack of effective treatments and those that are available have significant toxicities. Data from the CHARMS study suggest that Viralym-M has the potential to safely and effectively treat the most common viral infections in patients following allogeneic HSCT and may address a critical unmet need in this patient population.”

Oral Presentation: Economic and Clinical Burden of Virus-Associated Hemorrhagic Cystitis in Patients Following Allogeneic Hematopoietic Stem Cell Transplantation

Presenter: Joseph P. McGuirk, DO, the University of Kansas Cancer Center, Westwood, KS

U.S. claims data were analyzed to compare health care reimbursement, health resource utilization, and clinical outcomes between allo-HSCT patients with virus-associated hemorrhagic cystitis (V-HC) to those without V-HC. The unadjusted mean reimbursement per patient group was $292,401 higher for patients with V-HC compared to patients without V-HC. Adjusted reimbursements were also significantly higher for V-HC patients with and without GVHD compared to patients without V-HC ($p<.0001$).

V-HC was associated with increased hospital length of stay and additional days in the intensive care unit. Readmission rates also increased for patients with V-HC compared to those without V-HC ($p<.0001$). The mean overall hospital LOS was prolonged by 27.1 days ($p<0.0001$), or 55% longer, for allo-HSCT patients with V-HC versus patients without V-HC.

In an adjusted analysis examining time to all-cause mortality, patients with V-HC had a 70% higher risk of mortality, even after adjusting for presence of GVHD as well as other baseline factors. V-HC was also associated with increased incidence for renal impairment in the follow-up period in patients with or without GVHD.

“Viral infections or disease including the viruses associated with hemorrhagic cystitis are a major complication in patients who have undergone allogeneic hematopoietic stem cell transplantation,” said Joseph P. McGuirk, DO, the University of Kansas Cancer Center and presenting author. “These data show that virus associated hemorrhagic cystitis has a significant impact on patient outcomes including a greater risk of death and new renal impairment, while also placing a substantial burden on our healthcare system, highlighting the unmet clinical need for effective strategies to prevent and/or treat virus-associated hemorrhagic cystitis in allo-HSCT recipients.”

Viral Infections in Immunocompromised Patients

In healthy individuals, virus-specific T-cells (VSTs) from the body's natural defense system provide protection against numerous disease-causing viruses. However, in patients with a weakened immune system these viruses may be uncontrolled. Viral diseases are common and can cause potentially devastating and life-threatening consequences in immunocompromised patients. For example, up to 90% of patients will reactivate at least one virus following an allogeneic stem cell transplant and two-thirds of these patients reactivate more than one virus, resulting in significant and prolonged morbidity, hospitalization, and premature death. Typically, when viruses infect immunocompromised patients, standard antiviral treatment does not address the underlying problem of a weakened immune system and therefore many patients suffer with life-threatening outcomes such as multi-organ damage and failure, and even death.

Viralym-M (ALVR105)

AlloVir's lead product Viralym-M (ALVR105) is in late-stage clinical development as an allogeneic, off-the-shelf, multi-virus specific T-cell therapy targeting six common viral pathogens in immunocompromised individuals: BK virus, cytomegalovirus, adenovirus, Epstein-Barr virus, human herpesvirus 6, and JC virus. The company plans to initiate a Phase 3, multicenter, double-blind, placebo-controlled study to assess the efficacy and safety of Viralym-M for the treatment of patients with virus-associated hemorrhagic cystitis (V-HC) following allo-HSCT before year end. A proof-of-concept clinical trial targeting the prevention of BKV, CMV, AdV, EBV, HHV-6, and JCV in patients following allo-HSCT is also expected to initiate by the end of 2020. Viralym-M has received Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration (FDA), as well as PRIority MEdicines (PRIME) and Orphan Drug Designations (ODD) from the European Medicines Agency.

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

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