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): May 6, 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 May 6, 2021, AlloVir, Inc. announced its financial results for the quarter ended March 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 May 6, 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: May 6, 2021

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

Exhibit 99.1

AlloVir Reports First Quarter 2021 Financial Results

- Viralym-M pivotal trial in virus-associated hemorrhagic cystitis continues to progress enrollment

- Viralym-M proof-of-concept studies in multi-virus prevention in stem cell transplant and BK viremia in kidney transplant continue to progress with initial data expected 4Q21

- Additional Viralym-M pivotal and proof-of-concept clinical trials expected to initiate in 2H21

- ALVR109 proof-of-concept study in high-risk COVID-19 patients progressing, initial data expected in 4Q21

- ALVR106 IND cleared with proof-of-concept study in RSV, influenza, human metapneumovirus, and parainfluenza expected to initiate in 2H21

- Dr. Diana Brainard's transition from independent director to CEO has commenced with an official start date of May 17; David Hallal to continue to serve as Executive Chairman of the Board

CAMBRIDGE, Mass.—(BUSINESS WIRE)—May 6, 2021 – AlloVir (Nasdaq: ALVR), a late clinical-stage cell therapy company, today reported financial results for the first quarter ended March 31, 2021.

"The first quarter of 2021 was one of significant progress for AlloVir and moved us closer towards our ambition to transform the lives of patients suffering from devastating and life-threatening viral diseases," said David Hallal, Chief Executive Officer and Chairman of the Board, AlloVir. "The appointment of Dr. Diana Brainard as our new CEO brings an unparalleled track record of success in building strong, durable global virology franchises, that have impacted the world, and I look forward to working with Diana and the team in my new role as Executive Chairman of the Board."

Dr. Diana Brainard, AlloVir's newly named Chief Executive Officer, continued by saying, "With a world-renowned team of scientists, clinical and regulatory experts, and company operators, AlloVir has quickly advanced to become a leader in the development of innovative cell therapies. The remainder of 2021 will be an exciting time of growth for the company, which is on track to have initial data readouts from three clinical trials and initiate up to four more this year. Together with the Board, the executive team and all of AlloVir's high-performing employees, I look forward to advancing our impressive pipeline of mid- and late-stage clinical trials with a commitment to bringing innovative therapies to patients in need around the globe."

Business Updates and Upcoming Milestones

First Quarter Business and Scientific Updates

- Announced appointment of Dr. Diana Brainard as Chief Executive Officer, effective May 17, 2021. Dr. Brainard is a physician-scientist specializing in infectious diseases, with more than 20 years of experience in the biopharmaceutical industry and academic medicine, most recently serving as Senior Vice President and Head of the Virology Therapeutic Area at Gilead Sciences.
- The World Health Organization (WHO) approved posoleucel as the recommended international nonproprietary name for Viralym-M (ALVR105).
- Data were presented in an oral presentation at the 2021 Transplantation & Cellular Therapy Meeting Digital Experience from the Phase 2 proof-of-concept (POC) CHARMS study. The subgroup analysis found that treatment with Viralym-M for virus-associated hemorrhagic cystitis (HC) in the post allogeneic hematopoietic stem cell transplant (allo-HSCT) setting was generally safe and well-tolerated and associated with rapid resolution of macroscopic hematuria.
- Real-world data demonstrating the economic and clinical burden associated with viral infections and diseases following allo-HSCT in pediatric and adult patients were presented at the 2021 Transplantation & Cellular Therapy Meeting Digital Experience, and a publication summarizing the burden of virus-associated HC following allo-HSCT was published online in the journal *Transplantation and Cellular Therapy*.

Viralym-M for HSCT Recipients

- The Phase 3 multicenter, double-blind, placebo-controlled clinical trial to assess the efficacy and safety of Viralym-M for the treatment of virus-associated HC in pediatric and adult patients following allo-HSCT, is ongoing. Virus-associated HC, a common manifestation after HSCT, is a devastating disease with no approved or effective treatment options.
- 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 is ongoing, and initial data from the open-label phase of the trial are expected in the fourth quarter of 2021. The trial is targeting the prevention of clinically significant BK virus (BKV), cytomegalovirus (CMV), adenovirus (AdV), Epstein-Barr virus (EBV), human herpesvirus 6 (HHV-6), or JC virus (JCV) infections.
- Two additional pivotal clinical trials are expected to initiate in the second half of 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.

Viralym-M for Solid Organ Transplant (SOT) Recipients

- The Phase 2 POC trial for the preemptive treatment of BK viremia in adult kidney transplant recipients is ongoing, with initial data anticipated in the fourth quarter of 2021. BK viremia can be a devastating complication for kidney transplant patients leading to decreased kidney survival and return to End-Stage Renal Disease and dialysis.
- A Phase 2 POC trial in CMV for SOT recipients is expected to initiate in the second half of 2021.

ALVR109 for COVID-19

- The POC clinical trial of ALVR109 – a virus-specific T-cell targeting SARS-CoV-2, the virus that causes the severe and life-threatening viral disease, COVID-19 – is ongoing with initial data expected in the fourth quarter of 2021.

ALVR106 for Multi-Respiratory Viruses

- In Q4 2020, the FDA cleared the IND application for ALVR106, an allogeneic, off-the-shelf, multi-respiratory virus-specific T cell therapy designed to target infections and diseases caused by respiratory syncytial virus (RSV), influenza, parainfluenza virus (PIV), and human metapneumovirus (hMPV).
- A POC clinical trial of ALVR106 in allogeneic and autologous HSCT recipients is expected to be initiated in the second half of 2021.
- 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 Programs

- The company is on track to complete preclinical and IND-enabling studies for both ALVR107 to treat hepatitis B virus and ALVR108 for the treatment of human herpesvirus-8 in the second half of 2021.

First Quarter 2021 Financial Highlights

- Research and development expenses were $20.4 million for the quarter ended March 31, 2021, compared to $6.8 million for the quarter ended March 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.

- The general and administrative expense was $10.5 million for the quarter ended March 31, 2021, compared to $3.0 million for the quarter ended March 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 $8.1 million and $0.6 million for the quarter ended March 31, 2021, and 2020, respectively.
- As of March 31, 2021, AlloVir had cash, cash equivalents, and marketable securities of $337.0 million, which compares to cash, cash equivalents, and marketable securities of $356.3 million as of December 31, 2020.
- For the quarter ended March 31, 2021, net loss was $30.9 million or $0.50 per share compared to a net loss of $9.3 million or $4.21 per share for the quarter ended March 31, 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 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 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.

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)

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$336,992	$ 356,324
Other current assets	2,672	4,993
Total current assets	339,664	361,317
Other assets	11,617	9,504
Total assets	$351,281	$ 370,821
Liabilities and stockholders' equity		
Current liabilities	$ 15,500	$ 12,294
Long-term liabilities	5,412	5,463
Total liabilities	20,912	17,757
Total stockholders' equity	330,369	353,064
Total liabilities and stockholders' equity	$351,281	$ 370,821

ALLOVIR, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited, in thousands, except share and per share data)

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	20,393	6,839
General and administrative	10,470	3,001
Total operating expenses	30,863	9,840
Loss from operations	(30,863)	(9,840)
Total other income (loss), net:		
Interest income	505	457
Other income (loss), net	(565)	44
Net loss	$ (30,923)	$ (9,339)
Net loss per share - basic and diluted	$ (0.50)	$ (4.21)
Weighted-average common shares outstanding - basic and diluted	62,193,734	2,215,958

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