



AlloVir Reports First Quarter 2023 Financial Results

May 4, 2023

Company's three posoleucel Phase 3 global registrational trials for three distinct, first-to-market indications continue to enroll with data readouts on track for 2024

Positive results from a randomized, double-blind, placebo-controlled Phase 2 study of posoleucel in kidney transplant recipients with BK viremia will be presented at the American Transplant Congress 2023 later this quarter

WALTHAM, Mass.--(BUSINESS WIRE)--May 4, 2023-- AlloVir (Nasdaq: ALVR), a late-clinical stage allogeneic T cell immunotherapy company, today reported financial results from the first quarter ended March 31, 2023. The company shared progress across its allogeneic, off-the-shelf-virus specific T cell (VST) programs, including its lead investigational therapy, posoleucel, for prevention and treatment of life-threatening infections and diseases from up to six viruses that commonly impact patients following allogeneic hematopoietic cell transplant (allo-HCT), and for the treatment of BK viremia (BKV) in adult kidney transplant recipients.

"We continue to focus our efforts on rapidly advancing the three global Phase 3 ongoing registrational trials evaluating our lead investigational product, posoleucel, for the prevention and treatment of common, yet devastating, and potentially life-threatening viral infections and diseases in allo-HCT patients where significant unmet need persists," said Diana Brainard, MD, Chief Executive Officer, AlloVir. "In tandem, we reported final positive results from the Phase 2 study of posoleucel for the treatment of BKV, the first demonstration of its safety and antiviral effect in solid organ transplant recipients. We continue to be encouraged by the potential of posoleucel as a transformative therapeutic for transplant patients."

Recent Highlights

- In January 2023, the company announced plans to report data from its three Phase 3 registrational studies for posoleucel in 2024 across three distinct indications – the prevention of clinically significant infection or disease from adenovirus (AdV), BK virus, cytomegalovirus (CMV), Epstein-Barr virus (EBV), human herpesvirus-6 (HHV-6) and JC virus (JCV), the treatment of virus-associated hemorrhagic cystitis (vHC), and the treatment of AdV infection, all in allo-HCT patients. These viral infections have limited to no approved preventive therapies or treatment options, threatening patient survival.
- In February 2023, the company [announced](#) positive final results from a Phase 2 study of posoleucel being evaluated for the treatment of BKV in adult kidney transplant recipients, the first demonstration of posoleucel in solid organ transplant patients. Data demonstrate the safety profile of posoleucel and its antiviral activity, which is amplified in high viral load patients who have the greatest unmet need, suggesting it could potentially offer a transformative treatment option for kidney transplant patients with BKV.
- Positive long-term follow-up data from the Phase 2 trial exploring the potential of posoleucel for the prevention of clinically significant infections were presented at the 49th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT 2023) in April 2023. These new findings demonstrate that the high-risk allo-HCT patients who received posoleucel experienced continued low rates of clinically significant infections or end-organ disease and 0% non-relapse mortality. Data continue to substantiate the potential clinical benefit posoleucel could provide to high-risk allo-HCT patients.
- In February 2023, a case report of the treatment of refractory AdV infection in a CAR-T recipient with posoleucel was presented at the 2023 Tandem Meetings | Transplantation & Cellular Therapy Meetings of ASTCT and CIBMR (Poster 453). Findings demonstrate that posoleucel appeared to be safe and effective against devastating viral infections in patients receiving lymphodepletion chemotherapy and CAR-T therapy.
- The company announced the appointment of Derek Adams, PhD, a leading authority in biologic and gene therapies manufacturing, to its Board of Directors.

Upcoming Highlights/Activities

- The company plans to present comprehensive results from the BKV Phase 2 study as a late-breaking oral presentation at the American Transplant Congress (ATC) 2023 and will work with regulatory authorities and transplant specialists to inform next steps for this program as well as AlloVir's broader solid organ transplant strategy.

First Quarter Financial Highlights

- Research and development expenses were \$30.7 million for the quarter ended March 31, 2023, compared with \$29.1 million for the quarter ended March 31, 2022. The increase year-over-year was primarily attributable to an increase in costs related to the development of the company's lead product candidate, posoleucel.
- General and administrative expenses were \$12.5 million for the quarter ended March 31, 2023, compared with \$14.1 million for the quarter ended March 31, 2022. The decrease year-over-year was primarily attributable to a decrease in consulting and personnel related costs.
- Stock-based compensation expense was \$10.0 million and \$10.5 million for the quarter ended March 31, 2023, and 2022, respectively.
- As of March 31, 2023, AlloVir had cash, cash equivalents, and short-term investments of \$202.6 million, compared with cash, cash equivalents, and short-term investments of \$233.8 million as of December 31, 2022.
- For the quarter ended March 31, 2023, net loss was \$41.2 million or \$0.44 per share compared with a net loss of \$43.9 million or \$0.69 per share for the quarter ended March 31, 2022.

2023 Financial Guidance

- For fiscal year 2023, AlloVir expects operating expenses to be in the range of \$150 million to \$170 million, excluding non-cash 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](#).

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 the future enrollment status and timing for data readouts for AlloVir's three Phase 3 clinical trials, the potential safety and efficacy of AlloVir's product candidates, the development and regulatory status of AlloVir's 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 (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 annual report on Form 10-K for year ended December 31, 2023 and in its other 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 STATEMENTS OF OPERATIONS
(unaudited, in thousands, except share and per share data)

	Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development	30,718	29,067
General and administrative	12,513	14,126
Total operating expenses	<u>43,231</u>	<u>43,193</u>
Loss from operations	(43,231)	(43,193)
Total other income (loss), net:		
Interest income	1,325	148
Other income (loss), net	723	(818)
Net loss	<u>\$ (41,183)</u>	<u>\$ (43,863)</u>
Net loss per share --- basic and diluted	<u>\$ (0.44)</u>	<u>\$ (0.69)</u>
Weighted-average common shares outstanding---basic and diluted	<u>93,303,672</u>	<u>63,993,053</u>

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

	March 31,	December 31,
	2023	2022
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	\$ 202,570	\$ 233,795
Other current assets	9,705	9,257
Total current assets	212,275	243,052
Other assets	31,769	34,027
Total assets	\$ 244,044	\$ 277,079
Liabilities and stockholders' equity		
Current liabilities	\$ 24,959	\$ 24,338
Long-term liabilities	25,553	28,222
Total liabilities	50,512	52,560
Total stockholders' equity	193,532	224,519
Total liabilities and stockholders' equity	\$ 244,044	\$ 277,079

View source version on [businesswire.com](https://www.businesswire.com/news/home/20230504005266/en/): <https://www.businesswire.com/news/home/20230504005266/en/>

Media and Investor Contact:

IR@allovir.com

Source: AlloVir