AlloVir Reports Third Quarter 2020 Financial Results

November 10, 2020

- Completed initial public offering raising $317.7M in gross proceeds

- Viralym-M (multi-virus-specific T cell therapy) registrational study in lead indication in virus-associated hemorrhagic cystitis and proof-of-concept study in prevention of multiple viral infections on track to initiate before year end

- ALVR109 (virus-specific T cell therapy designed to combat SARS-CoV-2) Phase 1/2 clinical trial initiated for the treatment of high risk COVID-19 patients

- Commenced tech transfer for AlloVir proprietary virus-specific T-cell manufacturing process to ElevateBio BaseCamp, as part of planned manufacturing capacity expansion and redundancy within supply chain

CAMBRIDGE, Mass., Nov. 10, 2020 (GLOBE NEWSWIRE) -- AlloVir (Nasdaq: ALVR), a late clinical-stage cell therapy company, today reported financial results for the third quarter ended September 30, 2020.

“In the third quarter, we completed our $317.7 million initial public offering creating a solid financial foundation for the next stage of AlloVir’s growth,” said David Hallal, Chairman and Chief Executive Officer of AlloVir. “We are now focused on leveraging our robust capabilities to execute our objectives across our pipeline, including commencing up to nine pivotal and proof-of-concept studies across three cell therapies this year and throughout 2021.”

David Hallal continued, “the Phase 1/2 clinical trial with ALVR109, our virus-specific T cell therapy designed to combat SARS-CoV-2 – the virus that causes COVID-19 – has been initiated in high-risk patients and we are on track to initiate two additional studies with our lead product, Viralym-M, including a registrational, Phase 3 clinical trial for the treatment of virus-associated hemorrhagic cystitis and a proof-of-concept study for the prevention of multiple viral infections, both in allogeneic stem cell transplant patients before year end.”

Third Quarter Business Highlights

- In August, the company closed its initial public offering (IPO) raising $317.7 million in gross proceeds prior to deducting underwriting discounts, commissions and offering expenses. The company expects its current cash and cash equivalents, inclusive of IPO net proceeds, will be sufficient to fund its current operating plan into 2023.
- AlloVir expanded its regulatory expertise and management team by hiring Ercem Atillasoy, M.D., to the newly created position of Chief Regulatory and Safety Officer. Dr. Atillasoy has over 25 years of experience in clinical development, regulatory affairs, and safety. Most recently, he was the regulatory head at Merck and Co., responsible for all regulatory activities globally for the Infectious Disease and Vaccines franchises.
- In September, Dana Alexander, M.B.A., joined the team as Senior Vice President, Technical Operations. Mr. Alexander brings more than 20 years of experience in biopharmaceutical operations, most recently as Head of Viral Vector Business Operations and Site General Manager at Brammer Bio, now part of Thermo Fisher Scientific. Prior to Brammer Bio, he held senior operational and manufacturing leadership positions at Anika Therapeutics and Genzyme, a Sanofi Company.
- AlloVir has commenced tech transfer of its proprietary T cell manufacturing platform to ElevateBio BaseCamp, creating redundancy and ensuring manufacturing supply for full clinical pipeline with dedicated good manufacturing practice (GMP) capacity.

Viralym-M (ALVR105) Program Highlights

- The planned 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 (HC) following allogeneic hematopoietic stem cell transplantation (allo-HSCT) is on track to initiate in before year end.
- Additionally, a proof-of-concept (POC) clinical trial targeting the prevention of BK virus (BKV), cytomegalovirus (CMV), adenovirus (AdV), Epstein Barr virus (EBV), human herpesvirus 6 (HHV-6), and JC virus (JCV) in patients following allo-HSCT is also expected to initiate before year end
- Real-world data demonstrating the burden of multi-virus infections following allo-HSCT, was presented in a poster session at IDWeek 2020.
- Results from the Phase 2, POC, CHARMS study with Viralym-M as well as data demonstrating the economic and clinical burden of virus-associated HC in patients following allo-HSCT will be showcased in two oral presentations at the 62nd American Society of Hematology Annual Meeting & Exposition (ASH) in December 2020.

ALVR109 Program Highlights

- Initial clinical trial manufacturing runs of ALVR109 have been released and the proof-of-concept clinical trial with ALVR109 has been initiated.
- In September, the U.S. Food and Drug Administration (FDA) cleared the Investigational New Drug application (IND) for ALVR109, AlloVir's allogeneic, off-the-shelf, virus-specific T cell therapy candidate designed to target SARS-CoV-2, the virus that causes the severe and life-threatening viral disease, COVID-19.
- Pre-clinical data on this program will be presented in an oral session at ASH and will be featured in the conference press program.

ALVR106 Program Highlights

- AlloVir anticipates filing the IND before year end for ALVR106, an allogeneic, off-the-shelf, multi-respiratory, virus-specific T cell therapy designed to target respiratory syncytial virus (RSV), influenza, parainfluenza virus (PIV), and human metapneumovirus (hMPV).
- The POC clinical trial will now 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.
- Real-world data demonstrating the burden of respiratory tract infections following allo-HSCT was presented in an oral session at IDWeek 2020.

Third Quarter 2020 Financial Highlights

- Research and development expenses were $17.2 million for the quarter ended September 30, 2020 compared to $5.7 million for the quarter ended September 30, 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 $6.7 million for the quarter ended September 30, 2020 compared to $2.8 million for the quarter ended September 30, 2019. The increase year-over-year was primarily attributable to legal, accounting and professional fees related to costs associated with operating activities and the preparations for becoming a public company.
- Stock-based compensation expense was $3.9 million and $0.6 million for the three months ended September 30, 2020 and 2019, respectively.
- As of September 30, 2020, AlloVir had cash, cash equivalents, and marketable securities of $378.5 million, which compares to cash, cash equivalents, and marketable securities of $104.5 million as of June 30, 2020.
- For the quarter ended September 30, 2020, net loss was $23.6 million or $0.58 per share compared to a net loss of $7.3 million or $4.97 per share for the quarter ended September 30, 2019. The total number of common shares outstanding as of September 30, 2020 was 65,106,873.

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.

ALLOVIR, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
UNAUDITED

	Three Months Ended	Nine Months Ended

(in thousands, except share and per share data)	September 30,		September 30,	
	2020	2019	2020	2019
Revenue	$ –	$ –	$ –	$ 165
Operating expenses:				
Research and development	17,182	5,655	32,906	9,561
General and administrative	6,718	2,823	12,987	7,800
Total operating expenses	23,900	8,478	45,893	17,361
Loss from operations	(23,900)	(8,478)	(45,893)	(17,196)
Total other income, net:				
Interest income	112	781	735	1,400
Other income, net	174	427	573	700
Net loss	$ (23,614)	$ (7,270)	$ (44,585)	$ (15,096)
Net loss per share --- basic and diluted	$ (0.58)	$ (4.97)	$ (2.93)	$ (13.67)
Weighted-average common shares outstanding---basic and diluted	40,465,705	1,463,421	15,195,000	1,104,454

ALLOVIR, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
UNAUDITED

(in thousands)	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	$ 378,488	$ 126,077
Other current assets	5,453	1,236
Total current assets	383,941	127,313
Other assets	9,769	12,109
Total assets	$ 393,710	$ 139,422
Liabilities and stockholders' deficit		
Current liabilities	$ 13,521	$ 9,106
Long-term liabilities	6,286	8,692
Total liabilities	19,807	17,798
Preferred stock	–	173,127
Total stockholders' equity (deficit)	373,903	(51,503)
Total liabilities, preferred stock, and stockholders' deficit	$ 393,710	$ 139,422

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

Investor contact:
Medha Chadha
AlloVir
ir@allovir.com