Humacyte Reports Fourth Quarter and Year End 2021 Financial Results and Provides Business Update

March 29, 2022

-- Advancing late-stage clinical and preclinical programs of the Human Acellular Vessel™ (HAV™) and other engineered tissues across several indications –

-- Multiple publications and scientific meeting presentations highlighting clinical and preclinical HAV results –

-- Conference call and live webcast at 8:00 am ET today –

DURHAM, N.C., March 29, 2022 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissue at commercial scale, today announced financial results for the fourth quarter and year ending December 31, 2021, and highlighted recent corporate accomplishments.

"We are proud of the significant progress Humacyte made in 2021, advancing our first-in-class regenerative medicine platform and universally implantable human tissues product candidates that we believe have the potential to transform the treatment of acute and chronic disease," said Laura Niklason, M.D., Ph.D., Founder, President and Chief Executive Officer of Humacyte. "We were pleased to expand the body of data supporting the potential of the HAV in our vascular clinical programs. In addition, we have pushed forward our preclinical small-diameter cardiovascular surgery product candidates and our biovascular pancreas tissue construct. We look forward to the expected completion of our late-stage clinical studies of the HAV for vascular trauma and arteriovenous (AV) access for hemodialysis as we work toward bringing these innovative engineered tissues to market."

Fourth Quarter 2021 and Recent Corporate Highlights

Advanced Program Updates

- Advancement of the Phase 2/3 trial of HAV in vascular trauma has continued and 50 patients have been enrolled in the study. To date, results observed in this non-blinded trial include a very low rate of infection (approximately 2%), no reports of amputation related to the HAV, and high patency rates. Humacyte also continues to build upon its strong relationship with the U.S. Department of Defense and, if FDA approval is received, expects to supply HAVs for use in treating military personnel as a result of this collaboration. The Company expects to file a Biologics License Application (BLA) for this indication in 2022 or 2023.

- The Company's Phase 3 trial of the HAV for AV access for hemodialysis is nearing completion of enrollment, with more than 210 patients currently enrolled out of a target of 240. The Company currently expects to file a BLA for this indication in 2023. The Company continues to work closely with its strategic partner and major shareholder Fresenius Medical Care (FMC), a leader in kidney care services, products and value-based care, providing what Humacyte believes are major market insight and commercial launch advantages.

- In advance of completion of the Phase 3 trial, five-year data from a Phase 2 clinical trial of patients receiving the HAV for access in hemodialysis were published in the journal *EJVES Vascular Forum*. Results showed long-term durability and usability of the HAV during the five-year follow-up period, with no reports of infection or immunogenicity.

- In preparation for the potential market launches of the HAV in trauma and AV access, during 2021 Humacyte successfully deployed its commercial-scale manufacturing system for the production of HAVs. Data from a Phase 2 clinical trial for AV access in hemodialysis using HAVs produced using the Humacyte's commercial-scale manufacturing systems demonstrated 12-month efficacy similar to HAVs produced in the development-scale systems previously used. In 2021, the FDA agreed to the use of HAVs produced in the commercial-scale system to supply the Company's ongoing clinical trials in the United States. The 12-month data were presented at the 6th World Congress of the Tissue Engineering and Regenerative Medicine International Society.

Broader Pipeline Updates

- The Company's HAVs are continuing to be used under an Expanded Access Program (EAP) authorized by the FDA, for patients with vascular conditions including critical limb ischemia and peripheral arterial disease (PAD). To date, more than 20 implants of the HAV have been completed in the US under this program.
    - Results from the first series of eight compassionate use cases where the HAV was used for treatment of critical

limb ischemia and acute trauma were presented at the 46th Annual Winter Meeting of the Vascular and Endovascular Surgery Society. In this high-risk group of patients having no alternatives for vascular reconstruction, five of the bypasses performed with the HAV currently remain patent (with follow-up times ranging from four to 20 months after surgery). No instances of HAV infection were noted, highlighting the potential of the HAV to expand limb salvage options for patients who have exhausted current revascularization options.
    - Results from a case study of a patient who received the HAV as a replacement for an infected synthetic iliofemoral bypass graft were published in the *Journal of Vascular Surgery: Cases, Innovations and Techniques*. This was the first use of the HAV in the treatment of a patient with an infected prosthetic vascular graft, performed in April 2019 under the EAP. Twenty-two months post-implantation, the patient has resumed regular physical activity and no signs of infection of the HAV implant have been observed. Now approaching three years post-implantation, the patient discusses her experience and resuming normal life after receiving the HAV. The full story aired on NBC15 WMTV Madison on March 27, 2022, and can be viewed here: Arterial transplant recipient celebrates three years of survivorship.

- The first preclinical study of the use of the Company's small-diameter (3.5mm) HAV in coronary artery bypass grafting (CABG) was presented at Advanced Therapies Week in January 2022. The HAV maintained patency and researchers observed host-cell remodeling and regeneration in a non-human primate (baboon) model, which is considered to be highly predictive of human outcomes.

- Positive results from a preclinical study of the small-diameter HAV for use as a pediatric Blalock-Thomas-Taussig (BTT) shunt in a primate model simulating pediatric heart disease were presented at the American Heart Association's Scientific Sessions 2021. Each of the HAVs remained patent during the study and researchers observed repopulation with vascular cells.

- Preclinical results of the Company's biovascular pancreas (BVP), an HAV coated with islets, were presented at the 18th World Congress of the International Pancreas and Islet Transplantation Association in October 2021. In the preclinical study, researchers observed that animals implanted with the BVP normalized glucose over time, supporting the BVP as a potential approach for transplanting pancreatic islets that produce insulin for the treatment of type 1 diabetes.

- Throughout the fourth quarter, the Company and outside investigators presented results at ten additional scientific and medical meetings, highlighting progress in the development of the Company's broad pipeline and proprietary bioengineering platform. Included among the presentations were results related to use of the HAV in vascular trauma, AV access and peripheral arterial disease, preclinical research related to the biovascular pancreas for Type-1 diabetes, lung regeneration, and the Company's biomanufacturing platform.

Corporate Updates

- As part of the Company's preparation for potential commercial launch of the HAV in vascular trauma and AV access for hemodialysis, market research was conducted with 60 vascular surgeons in the U.S. Receptivity towards adoption of the HAV was high, with conclusions including:
    - Approximately 80% of trauma bypass patients would be eligible for HAV if approved by the FDA. Reduced operative time without additional infection risk was perceived to be the biggest benefits of the HAV.
    - Surgeons surveyed were highly receptive to the HAV for use in AV access if approved by the FDA due to the potential infection resistance and potential for reduced catheter exposure due to rapid useability for dialysis access.

- In December, the Company appointed three Surgical Key Opinion Leaders (KOLs), Alan P. Kypson, M.D., FACS; Luigi Pascarella, M.D., FACS; and Todd E. Rasmussen, M.D., FACS, (Col, ret. USAF MC), to advisory positions. In these roles, the KOLs lend their expertise and support to guide the education and clinical advancement efforts of the HAV and help identify opportunities to advance the Company's early-stage complex tissue constructs pipeline and platform.

Fourth Quarter and Year Ended 2021 Financial Highlights

- The Company reported cash, cash equivalents and short-term investments of $225.5 million as of December 31, 2021, compared to $39.9 million as of December 31, 2020. The increase in cash, cash equivalents and short-term investments resulted from the $242.4 million in proceeds from the August 26, 2021 merger with Alpha Healthcare Acquisition Corp. (the "Merger") and related PIPE financing, partially offset by $56.8 million in net cash used in operating, investing and other financing activities during the year. The Company believes that the cash, cash equivalents and short-term investments are adequate to fund operations through the end of 2024, past the Company's current expected timelines for potential approvals of the HAV in vascular trauma and AV access for hemodialysis.

- Revenue was $177.0 thousand for the fourth quarter of 2021 compared to $124.0 thousand for the fourth quarter of 2020,

and was $1.3 million for the year ended December 31, 2021, compared to $1.5 million for the year ended December 31, 2020. Revenue in all periods related to grants supporting the development of the HAV.

- Research and development expenses were $16.3 million for the fourth quarter of 2021 compared to $13.2 million for the fourth quarter of 2020, and were $61.3 million for the year ended December 31, 2021, compared to $54.1 million for the year ended December 31, 2020. The current-year increases resulted primarily from increased personnel, external services and materials expenses designed to support expanded research and development initiatives, the development of the commercial-scale manufacturing process, and support of clinical studies.

- General and administrative expenses were $5.6 million for the fourth quarter of 2021 compared to $2.6 million for the fourth quarter of 2020, and were $21.1 million for the year ended December 31, 2021, compared to $12.0 million for the year ended December 31, 2020. The current-year increase resulted primarily from non-cash stock compensation expense related to hiring leadership personnel, increases in professional fees and insurance costs related to the completion of the Merger and transition to being a public company, and additional personnel and recruiting costs associated with company growth.

- Other net income (expenses) was $64.2 million for the fourth quarter of 2021 compared to ($0.5) million for the fourth quarter of 2020, and was $54.7 million for the year ended December 31, 2021, compared to ($1.9) million for the year ended December 31, 2020. The current-year increase in other net income resulted primarily from non-cash gains related to the remeasurement of the contingent earnout liability associated with the Merger.

- Net income was $42.6 million for the fourth quarter of 2021 compared to a net loss of $16.2 million for the fourth quarter of 2020, and the net loss was $26.5 million for the year ended December 31, 2021, compared to $66.5 million for the year ended December 31, 2020. The current-year increase in net income for the fourth quarter and decrease in the net loss for the year, resulted from the increase in other net income described above.

Shortly after the filing of its Annual Report on Form 10-K with the SEC, the Company expects to file a Post-Effective Amendment to its Form S-1 registration statement that was declared effective on October 25, 2021 (as amended by Post-Effective Amendment No. 1, which was declared effective on November 24, 2021). The filing of the Post-Effective Amendment is not a new registration of securities but is filed solely to update the Form S-1, including with respect to the Company's audited financial statements for the year ended December 31, 2021. Certain stockholders whose shares are registered on the Form S-1 are subject to the terms of an Investor Rights and Lock-up Agreements, which includes restrictions on transfer until the termination of applicable lock-up periods.

Conference Call and Webcast Details

Date:	Tuesday, March 29, 2022
Time:	8:00 a.m. ET
Conference Call Details:	Toll-Free: 1-877-704-4453 International: 1-201-389-0920 Conference ID: 13728056
Webcast:	Webcast Link - Click Here

A replay of the webcast will be available following the conclusion of the live broadcast and will be accessible on the investors section of the Company's website for at least 30 days.

About Humacyte

Humacyte, Inc. (Nasdaq: HUMA) is developing a disruptive biotechnology platform to deliver universally implantable bioengineered human tissues and organs designed to improve the lives of patients and transform the practice of medicine. The Company develops and manufactures acellular tissues to treat a wide range of diseases, injuries and chronic conditions. Humacyte's initial opportunity, a portfolio of human acellular vessels (HAVs), is currently in late-stage clinical trials targeting multiple vascular applications, including vascular trauma repair, arteriovenous access for hemodialysis, and peripheral arterial disease. Preclinical development is also underway in coronary artery bypass grafts, pediatric heart surgery, treatment of type 1 diabetes, and multiple novel cell and tissue applications. Humacyte's 6mm HAV for arteriovenous (AV) access for performing hemodialysis was the first product candidate to receive the FDA's Regenerative Medicine Advanced Therapy (RMAT) designation, and the HAV technology received priority designation for the treatment of vascular trauma by the U.S. Secretary of Defense. For more information, visit www.Humacyte.com.

Forward-Looking Statements

This press release contains forward-looking statements that are based on beliefs and assumptions and on information currently available. In some cases, you can identify forward-looking statements by the following words: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this press release, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Forward-looking statements in this press release include, but are not limited to, statements regarding the Company's cash runway, *the initiation, timing, progress, and results of our preclinical and clinical trials; the anticipated characteristics and performance of our HAVs; our ability to successfully complete, preclinical and clinical trials for our HAVs; the anticipated benefits of our HAVs relative to existing alternatives; the anticipated commercialization of our HAVs and our ability to manufacture at commercial scale; the implementation of our business model and strategic plans for our business; our rights and obligations under our partnership with Fresenius Medical Care; the scope of protection we are able to establish and*

maintain for intellectual property rights covering our HAVs and related technology; the timing or likelihood of regulatory filings and approvals; timing, scope, and rate of reimbursement for our HAVs; and our estimated available market opportunity. We cannot assure you that the forward-looking statements in this press release will prove to be accurate. These forward-looking statements are subject to a number of significant risks and uncertainties that could cause actual results to differ materially from expected results, including, among others, the impact of COVID-19 on Humacyte's business, changes in applicable laws or regulations, the possibility that Humacyte may be adversely affected by other economic, business, and/or competitive factors, and other risks and uncertainties, including those included under the header "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021, filed by Humacyte with the SEC. Most of these factors are outside of Humacyte's control and are difficult to predict. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements in this press release represent our views as of the date of this press release. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this press release.

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Humacyte, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(unaudited)

(in thousands except for share and per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	**2020**	**2021**	**2020**
Grant Revenue	$ 177	$ 124	$ 1,263	$ 1,491
Operating expenses:				
Research and development	16,250	13,199	61,341	54,078
General and administrative	5,554	2,597	21,130	12,013
Total operating expenses	21,804	15,796	82,471	66,091
Loss from operations	**(21,627)**	**(15,672)**	**(81,208)**	**(64,600)**
Other income (expenses), net				
Change in fair value of contingent earnout liability	65,540	—	55,772	—
Other expenses (net)	(1,328)	(540)	(1,041)	(1,924)
Total other income (expenses), net	64,212	(540)	54,731	(1,924)
Net income (loss) and comprehensive income (loss)	**$ 42,585**	**$ (16,212)**	**$ (26,477)**	**$ (66,524)**
Net income (loss) per share, basic	$ 0.41	$ (2.81)	$ (0.66)	$ (11.54)
Weighted-average shares outstanding, basic	103,003,506	5,765,688	39,970,398	5,765,688
Net income (loss) per share, diluted	$ 0.41	$ (2.81)	$ (0.66)	$ (11.54)
Weighted-average shares outstanding, diluted	104,743,854	5,765,688	39,970,398	5,765,688

Humacyte, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	As of December 31,	
	2021	**2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 217,502	$ 39,929
Short-term investments	8,000	—
Prepaid expenses and other current assets	3,838	1,520
Total current assets	229,340	41,449
Property, plant and equipment, net	35,034	40,978
Lease right-of-use assets, net	22,159	24,261
Total assets	**$ 286,533**	**$ 106,688**
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,094	$ 2,274
Accrued expenses	6,757	4,592
Other current liabilities	2,199	4,367
Total current liabilities	11,050	11,233
Contingent earnout liability	103,660	—
Finance lease obligation, net of current portion	21,109	23,090
SVB loan payable	27,361	—
Other long-term liabilities	1,179	1,693
Total liabilities	**164,359**	**36,016**
Redeemable convertible preferred stock	—	420,989
Stockholders' equity (deficit)		
Common stock and additional paid-in capital	536,747	37,779
Accumulated deficit	(414,573)	(388,096)
Total stockholders' equity (deficit)	122,174	(350,317)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	**$ 286,533**	**$ 106,688**