Humacyte First Quarter 2022 Financial Results and Business Update

May 13, 2022

-- Human Acellular Vessels™ (HAVs™) shipped to six hospitals in Ukraine for treatment of civilian and military vascular trauma injuries --

-- Strengthened leadership team with appointment of Shamik Parikh M.D., as Chief Medical Officer --

-- Multiple scientific meeting presentations and publications highlighting clinical and preclinical HAV data --

-- Conference call and live webcast at 8:00 a.m. ET today --

DURHAM, N.C., May 13, 2022 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissues, complex tissue systems, and organs at commercial scale, today announced financial results for the first quarter ended March 31, 2022, and highlighted recent corporate accomplishments.

"We are pleased by the progress Humacyte has made in the first quarter of 2022 as we continue to advance our universally implantable, bioengineered human tissue platform. We believe our lead candidate, the HAV, is uniquely suited for scenarios in which the current standard of care is unavailable or inadequate. During the humanitarian crisis in Ukraine, we are proud to be able to provide HAVs to front-line hospitals for the treatment of military and civilian vascular trauma injuries." said Laura Niklason, M.D., Ph.D., Founder, President and Chief Executive Officer of Humacyte. "In addition, we were pleased to welcome Dr. Shamik Parikh as our Chief Medical Officer. Dr. Parikh joins us at a pivotal time, as we look forward to the planned completion of our late-stage clinical trials in vascular trauma and arteriovenous access for hemodialysis and, if approved, work to bring the HAV to market in its initial indications."

First Quarter 2022 and Recent Corporate Highlights

Clinical Updates

- This week, Humacyte launched an initiative to provide its HAVs to multiple hospitals in Ukraine for the treatment of wounded civilians and soldiers suffering from vascular trauma injuries. The Company worked with the Office of International Programs within the U.S. Food and Drug Administration (FDA), as well as the Ukraine Ministry of Health, to coordinate export and import of the investigational HAV for humanitarian use. Six hospitals in Ukraine, including those located in Kyiv, Kharkiv, and in other cities, will be the recipients of the initial shipment, with additional site requests from Ukraine currently being processed. The Company has also collaborated with surgeons who have extensive experience with the HAV to provide training on the use of the HAV to surgeons in Ukraine. While outside of the scope of the ongoing Phase 2/3 trial in vascular trauma, the Company expects that this humanitarian program will provide additional real-world evidence of the potential impact of the HAV in the treatment of vascular injury.

- Humacyte plans to share new HAV clinical immunogenicity data, reporting on bloodwork from patients who have received the HAV, during a presentation at the American Transplant Congress 2022 meeting taking place in Boston June 4-8, 2022. The presentation will be delivered during the '*Bioengineering in Transplantation: Where We are and Where are We Going?* session on June 8 at 7:00 a.m. ET.

- Humacyte continues to partner with Frenova, a subsidiary of Fresenius Medical Care, a major shareholder and collaborator of the Company, on quantifying the costs of dialysis access in hemodialysis patients in the United States and in Europe. The Company believes that evaluation of rates of infectious and other access complications will enable it to quantify the potential health economic benefits of the HAV in patients with kidney failure.

- Throughout the first quarter, the HAV was the subject of multiple presentations at scientific conferences and publications in scientific journals, including:

    - 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*. At 22 months post-implantation, the patient had resumed regular physical activity and no signs of infection of the HAV implant have been observed.
    - Surgeons from the Uniformed Services University and Walter Reed National Medical Center of the Health Sciences reported on the first eight FDA-approved expanded access cases using the HAV for arterial repair and reconstruction. In this case series of patients with either critical limb ischemia or vascular trauma, the HAV was

observed to resist infection, provided reliable patency, and offered surgeons an immediately available biologic conduit option. The report on this case series was published in the *Annals of Vascular Surgery* in April 2022.
  - Five-year data from a Phase 2 clinical trial of patients receiving the HAV for arteriovenous 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.
  - The first preclinical study of the use of the Company's small-diameter (3.5 mm) HAV in coronary artery bypass grafting was presented at Advanced Therapies Week. The HAV was observed to maintain patency and exhibited host-cell remodeling and regeneration in a non-human primate (baboon) model, which is considered to be highly predictive of human outcomes.

Corporate Updates

- In April, Humacyte announced the appointment of Shamik J. Parikh, M.D., as Chief Medical Officer. In this role, Dr. Parikh leads the Company's global clinical development strategy, including oversight of the preclinical and clinical development, clinical operations, and medical affairs functions. Dr. Parikh brings more than two decades of leadership experience in academia and at global pharmaceutical companies, where he oversaw clinical and drug strategy, clinical research and development, product launches, medical affairs and drug safety, across multiple therapeutic areas including a 16-year tenure at AstraZeneca.

First Quarter 2022 Financial Highlights

- The Company reported cash, cash equivalents and short-term investments of $206.2 million as of March 31, 2022, compared to $225.5 million as of December 31, 2021. The $19.3 million net use of cash, cash equivalents and short-term investments for the first quarter 2022 resulted from spending related to net operating activities for the quarter, including clinical and earlier-stage programs and preparation for the Company's anticipated commercial launch. The Company believes that its 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 $233 thousand for the first quarter of 2022, compared to $155 thousand for the first quarter of 2021. Revenue in both periods related to grants supporting the development of the HAV.

- Research and development expenses were $16.3 million for the first quarter of 2022, compared to $15.1 million for the first quarter of 2021. The current-period increase resulted primarily from increased personnel and materials expenses designed to support expanded research and development initiatives and the support of clinical trials.

- General and administrative expenses were $5.7 million for the first quarter of 2022, compared to $4.8 million for the first quarter of 2021. The current-period increase resulted primarily from the transition to being a public company and preparation for the planned U.S. commercial launch of the HAV, if approved, including increased personnel costs, professional fees and insurance costs.

- Other net income (expenses) was $1.9 million for the first quarter of 2022, compared to $(0.5) million for the first quarter of 2021. The current-period increase in other net income resulted primarily from non-cash gains related to the remeasurement of the contingent earnout liability associated with the August 2021 merger with Alpha Healthcare Acquisition Corp., partially offset by an increase in interest expense related to the Company's loan facility with Silicon Valley Bank.

- Net loss was $19.8 million for the first quarter of 2022, compared to $20.3 million for the first quarter of 2021. The current-period decrease in net loss resulted from the increase in other net income described above, partially offset by expense increases also described above.

Conference Call and Webcast Details

Date:	Friday, May 13, 2022
Time:	8:00 a.m. ET
Conference Call Details:	Toll-Free: 1-877-704-4453 International: 1-201-389-0920 Conference ID: 13729522
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 complex tissue and organ systems 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 has also received FDA Fast Track designation. The HAV received priority designation for the treatment of vascular trauma by the U.S. Secretary of Defense. The HAV is an investigational product and has not been approved for sale by the FDA or any international regulatory agency. 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; our expectations regarding our initiative to provide HAVs to Ukraine; 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 and in subsequent SEC filings. 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 Loss

(unaudited)

(in thousands except for share and per share amounts)

	Three Months Ended March 31,	
	2022	**2021**
Grant Revenue	$ 233	$ 155
Operating expenses:		
Research and development	16,314	15,137
General and administrative	5,682	4,787
Total operating expenses	21,996	19,924

Loss from operations	**(21,763)**	**(19,769)**
Other income (expenses), net		
Change in fair value of contingent earnout liability	3,258	—
Other expenses (net)	(1,327)	(532)
Total other income (expenses), net	1,931	(532)
Net loss and comprehensive loss	**$ (19,832)**	**$ (20,301)**
Net loss per share, basic and diluted	$ (0.19)	$ (3.46)
Weighted-average shares outstanding, basic and diluted	103,004,088	5,874,700

Humacyte, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 198,222	$ 217,502
Short-term investments	8,000	8,000
Prepaid expenses and other current assets	3,073	3,838
Total current assets	209,295	229,340
Property, plant and equipment, net	33,540	35,034
Lease right-of-use assets, net	21,633	22,159
Total assets	**$ 264,468**	**$ 286,533**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,037	$ 2,094
Accrued expenses	5,460	6,757
Other current liabilities	2,266	2,199
Total current liabilities	10,763	11,050
Contingent earnout liability	100,402	103,660
Finance lease obligation, net of current portion	20,581	21,109
SVB loan payable	27,739	27,361
Other long-term liabilities	1,093	1,179
Total liabilities	**160,578**	**164,359**
Stockholders' equity		
Common stock and additional paid-in capital	538,295	536,747
Accumulated deficit	(434,405)	(414,573)
Total stockholders' equity	103,890	122,174
Total liabilities and stockholders' equity	**$ 264,468**	**$ 286,533**