Humacyte Third Quarter 2024 Financial Results and Business Update

- FDA review of acellular tissue engineered vessel (ATEV™) BLA for theTreatment of Vascular Trauma is ongoing -

- Results from the V007 Phase 3 clinical trial of the ATEV in arteriovenous (AV) access for hemodialysis patients presented at American Society of Nephrology's Kidney Week 2024 -

- Long-term results from the humanitarian program where the ATEV was used to treat vascular injuries suffered during the Ukraine conflict were presented at the U.S. Department of Defense's foremost scientific meeting -

- Conference call and live webcast at 8:30 a.m. ET today -

DURHAM, N.C., Nov. 08, 2024 (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 third quarter ended September 30, 2024 and highlighted recent accomplishments.

"Our biologics license application (BLA) for our ATEV in vascular trauma remains under review by the U.S. Food and Drug Administration (FDA)," said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. "FDA leadership has not provided us a timeline for the completion of their review. As noted in our previous announcements, during the course of the BLA review the FDA conducted inspections of our manufacturing facilities and clinical sites and has actively engaged with us in multiple discussions regarding our BLA filing, including post-marketing and labeling discussions. Based on these interactions, we remain confident in the approvability of the ATEV in treating vascular trauma."

"We continue to make progress with the ATEV in its other investigational indications, including hemodialysis access, and with the advancement of our broader pipeline," continued Dr. Niklason. "Recently, expanded results from our V007 Phase 3 clinical trial in patients with end-stage renal disease were presented at *Kidney Week 2024,* the premier nephrology meeting. The ATEV was observed to have superior functional patency over the autologous fistula control group not only in the overall study population but in important subgroups that are historically underserved by the current standard of care. In October we submitted our New Technology Add-on Payment, or NTAP application, to the Centers for Medicare & Medicaid Services (CMS). In addition, the ATEV received its third Regenerative Medicine Advanced Therapy (RMAT) designation from the FDA, specifically in advanced peripheral artery disease. This serves as a recognition from the FDA that Humacyte's ATEV may provide an important therapeutic option for patients with advanced arterial disease in their legs, who are facing potential amputation. We also expanded the patent protection covering our BioVascular Pancreas (BVP™) product candidate for the treatment of type 1 diabetes."

Third Quarter 2024 and Recent Corporate Highlights

ATEV (acellular tissue engineered vessel)

- **FDA requires additional time to complete review of BLA for ATEV in the Treatment of Vascular Trauma** – On August 9, 2024, in a phone call, Center for Biologics Evaluation and Research (CBER) leadership from the FDA notified Humacyte that the FDA will require additional time to complete its review of the Company's BLA for the ATEV in the vascular trauma indication. The ATEV trauma BLA was submitted to FDA in December 2023. FDA granted a Priority Review in February 2024, and assigned an original PDUFA date of August 10, 2024. The FDA has not provided a timeline for the completion of their review.

- ***NTAP Application*** – To support reimbursement for the ATEV if approved by the FDA in the vascular trauma indication, in October 2024 Humacyte submitted an application for an NTAP reimbursement to CMS. The window for filing NTAP applications occurs once annually, with decisions being made the following year. Humacyte's application is for the fiscal year 2026 NTAP cycle, which if approved would make the NTAP effective starting October 1, 2025. Receiving the NTAP reimbursement can allow hospitals to receive up to approximately 65% of the sales price of a biologic product. Requirements for receiving NTAP reimbursement are several, including technological novelty as well as clear evidence of clinical improvement for patients.

- **Presentation at *Kidney Week 2024*** – Positive results from the V007 Phase 3 clinical trial of the ATEV in AV access for patients with end-stage renal disease were presented on October 26, 2024 at the American Society of Nephrology's (ASN) *Kidney Week 2024*, the premier nephrology meeting. In the Phase 3 trial, the ATEV was observed to have superior function and patency at six and 12 months (co-primary endpoints) compared to autogenous fistula, which is the current standard of care for hemodialysis patients. The ATEV was also observed to have superior function and patency in female, obese, and diabetic patients, each of which is a high-need subgroup with historically poor outcomes with AV fistula procedures. The late-breaking podium presentation, titled "Prospective Randomized Trial of Humacyte's Acellular Tissue Engineered Vessel Versus Autologous Arteriovenous Fistula for Hemodialysis Access," was presented by Mohamad A. Hussain, MD, PhD, RPVI, FAHA, FRCSC, FACS, Vascular and Endovascular Surgeon-Scientist at Brigham and Women's Hospital, Core Faculty at the Center for Surgery and Public Health, and Assistant Professor of Surgery at Harvard Medical School.

- **Presentation of Long-Term Results from Treatment of Ukraine War Injuries** – Positive long-term results from the humanitarian program conducted in Ukraine under which the ATEV was used to treat vascular injuries suffered during the conflict were presented on August 26, 2024 at the Military Health System Research Symposium (MHSRS), the U.S. Department of Defense's foremost scientific meeting. Patients treated with the ATEV included those injured due to mine blasts, shrapnel, and high velocity ballistics. In long-term follow-up, the ATEV was observed to have high rates of patency (blood flow) and the avoidance of amputation and infection despite the severe nature of the wartime injuries treated.

- **ATEV Received Third Regenerative Medicine Advanced Therapy (RMAT) Designation from FDA** – In July 2024, the FDA granted RMAT designation of the ATEV for patients with advanced peripheral artery disease (PAD). This RMAT designation was granted at the same time as the FDA cleared a new Investigational New Drug (IND) application for the PAD indication. This is the third RMAT designation granted by the FDA for Humacyte's ATEV, in addition to previous RMAT designations for vascular trauma repair and AV access in hemodialysis.

- **Vascular Trauma Key Opinion Leader Webinar** – On September 30, 2024, Humacyte held an event featuring Charles Fox, MD (University of Maryland School of Medicine), Rishi Kundi MD, RPVI, FACS, FSVS (University of Maryland School of Medicine), and YingWei Lum, MD, MPH (Johns Hopkins School of Medicine), who discussed unmet clinical needs in treating urgent arterial repair after extremity vascular trauma. The event highlighted the potential civilian applications and military usage of the ATEV as a treatment for vascular trauma through patient case studies.

The ATEV is an investigational product and has not been approved for sale by the FDA or any other regulatory agency.

Earlier-Stage Pipeline and Corporate Updates

- **Patent Allowance for BioVascular Pancreas** – In September 2024, the U.S. Patent Office allowed a patent covering Humacyte's BVP product candidate for the treatment of type 1 diabetes. The BVP is designed to enable the delivery and survival of insulin-producing islets inside the body using the ATEV as a carrier for the islets. The new U.S. Patent, titled "Bioartificial Vascular Pancreas," covers the design and composition of the BVP.

- **Completion of Registered Direct Offering** – In October 2024, Humacyte completed a transaction with an institutional investor to purchase approximately $30.0 million worth of its common stock and warrants in a registered direct offering.

Third Quarter 2024 Financial Highlights

- There was no revenue for either the third quarter of 2024 or the third quarter of 2023, and there was no revenue for the nine months ended September 30, 2024 and 2023.

- Research and development expenses were $22.9 million for the third quarter of 2024, compared to $23.8 million for the second quarter of 2024. The decrease in expenses compared to the prior quarter was due to a reduction in clinical trial costs. Research and development expenses for the third quarter of 2024 were $22.9 million compared to $18.6 million for the third quarter of 2023, and were $67.9 million for the nine months ended September 30, 2024, compared to $56.4 million for the nine months ended September 30, 2023. The year-over-year increases resulted primarily from increased materials and personnel expenses to support expanded research and development initiatives and our clinical trials, including the expansion of manufacturing activities and support of the FDA review of the BLA in vascular trauma.

- General and administrative expenses were $7.3 million for the third quarter of 2024, compared to $5.7 million for the second quarter of 2024. The increase in expenses compared to the prior quarter was due to increased sales and marketing expenses in anticipation of the planned commercial launch of the ATEV in vascular trauma. General and administrative expenses for the third quarter of 2024 were $7.3 million compared to $6.1 million for the third quarter of 2023, and were $18.4 million for the nine months ended September 30, 2024, compared to $17.5 million for the nine months ended September 30, 2023. The increases during 2024 resulted primarily from preparation for the planned commercial launch of the ATEV. Major changes in expenses included increases in personnel expenses, external services and professional fees, partially offset by decreases in non-cash stock compensation expense and insurance expense.

- Other net expense was $9.0 million for the third quarter of 2024, compared to $27.2 million for the second quarter of 2024. The decrease in other net expense compared to the prior quarter was due to a reduction in the non-cash remeasurement of the contingent earnout liability associated with the Company's August 2021 merger with Alpha Healthcare Acquisition Corp. Other net expense for the third quarter of 2024 was $9.0 million compared to $1.4 million for the third quarter of 2023, and other net expense of $41.5 million for the nine months ended September 30, 2024, compared to $11.8 million for the nine months ended September 30, 2023. The year-over-year increases in other net expense resulted primarily from the non-cash remeasurement of the contingent earnout liability.

- Net loss was $39.2 million for the third quarter of 2024, compared to $56.7 million for the second quarter of 2024. The decrease in net loss compared to the prior quarter was due to the reduction in the non-cash remeasurement of the contingent earnout liability and the net effect of operating expense changes described above. Net loss was $39.2 million for the third quarter of 2024 compared to $26.0 million for the third quarter of 2023, and net loss was $127.8 million for the nine months ended September 30, 2024, compared to $85.7 million for the nine months ended September 30, 2023. The year-over-year increases in net loss resulted primarily from the non-cash remeasurement of the contingent earnout liability, and operating expense increases, described above.

- The Company reported cash, cash equivalents and restricted cash of $71 million as of September 30, 2024. Subsequent to September 30, 2024, the Company received an additional $29.6 million in net proceeds from sales of common stock and warrants. Total net cash used was $9.9 million for the first nine months of 2024, compared to net cash used of $49.4 million for the first nine months of 2023. The decrease in net cash used resulted primarily from the receipt of approximately $43.0 million in net proceeds from an underwritten public offering of Humacyte's common stock in March 2024, and $20 million in proceeds from an additional draw under its funding arrangement with Oberland Capital Management.

Conference Call and Webcast Details

Title:	Humacyte Third Quarter 2024 Financial Results and Corporate Update
Date:	Friday, November 8, 2024
Time:	8:30 a.m. ET
Conference Call Details:	Toll-Free: 1-877-704-4453 International: 1-201-389-0920 Conference ID #: 13749485
Call me™ Feature (avoid waiting for operator):	Click Here
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, advanced tissue constructs, 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 product candidates, a portfolio of ATEVs, are currently in late-stage clinical trials targeting multiple vascular applications, including vascular trauma repair, arteriovenous (AV) access for hemodialysis, and peripheral artery disease. A Biologics License Application for the ATEV in the vascular trauma indication is currently under review by the FDA and was granted Priority Review. 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 ATEV for AV access in 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. Humacyte's 6mm ATEV for urgent arterial repair following extremity vascular trauma and for advanced PAD also have received an RMAT designations. The ATEV 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, the outcome of the FDA's review of our BLA seeking approval of the ATEV in the vascular trauma indication; the statements regarding the initiation, timing, progress, and results of our preclinical and clinical trials; the anticipated characteristics and performance of our ATEV; our ability to successfully complete preclinical and clinical trials for our ATEVs; the anticipated benefits of the ATEV relative to existing alternatives; the anticipated commercialization of our ATEVs and our ability to manufacture at commercial scale; the implementation of our business model and strategic plans for our business; and the timing or likelihood of regulatory filings, acceptances, and approvals. 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, 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 described under the header "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023, and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, each filed by Humacyte with the SEC, and in future 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. Except as required by law, we have no current intention of updating any of the forward-looking statements in this press release. 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 September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	22,926	18,552	67,943	56,370
General and administrative	7,307	6,070	18,367	17,495
Total operating expenses	30,233	24,622	86,310	73,865
Loss from operations	**(30,233)**	**(24,622)**	**(86,310)**	**(73,865)**
Other income (expense), net:				
Change in fair value of contingent earnout liability	(8,489)	(1,144)	(38,653)	(11,708)
Other expense (net)	(480)	(229)	(2,798)	(97)
Total other expense, net	(8,969)	(1,373)	(41,451)	(11,805)
Net loss and comprehensive loss	**$ (39,202)**	**$ (25,995)**	**$ (127,761)**	**$ (85,670)**
Net loss per share, basic and diluted	$ (0.33)	$ (0.25)	$ (1.10)	$ (0.83)
Weighted-average shares outstanding, basic and diluted	119,408,565	103,444,246	115,623,616	103,357,087

Humacyte, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	September 30, 2024	**December 31, 2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 20,571	$ 80,448
Prepaid expenses and other current assets	2,434	2,830
Total current assets	23,005	83,278
Restricted cash	50,209	209
Property and equipment, net	24,250	26,791
Finance lease right-of-use assets, net	16,013	17,313
Other long-term assets	1,287	632
Total assets	**$ 114,764**	**$ 128,223**

Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 6,903	$ 6,490
Accrued expenses	11,151	9,340
Other current liabilities	2,888	2,613
Total current liabilities	20,942	18,443
Contingent earnout liability	76,569	37,916
Revenue interest liability	62,117	38,600
Finance lease obligation, net of current portion	14,379	16,293
Other long-term liabilities	4,478	3,425
Total liabilities	**178,485**	**114,677**
Stockholders' equity (deficit)		
Common stock and additional paid-in capital	601,354	550,860
Accumulated deficit	(665,075)	(537,314)
Total stockholders' equity (deficit)	(63,721)	13,546
Total liabilities and stockholders' equity (deficit)	**$ 114,764**	**$ 128,223**

Source: Humacyte, Inc