#### **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

#### FORM 8-K

#### CURRENT REPORT Pursuant to Section 13 OR 15(d) of

The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 10, 2022

#### Humacyte, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

001-39532 (Commission File Number)

85-1763759 (I.R.S. Employer Identification Number)

2525 East North Carolina Highway 54 Durham, NC

(Address of principal executive offices)

(919) 313-9633

(Registrant's telephone number, including area code)

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425) 

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12) Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)) 

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to 12(b) of the Act:

		Name of each exchange on which
Title of each class	Trading Symbol(s)	registered
Common Stock, par value \$0.0001 per share	HUMA	The Nasdaq Stock Market LLC
Redeemable Warrants, each whole warrant exercisable for one share of	HUMAW	The Nasdaq Stock Market LLC
Common Stock at an exercise price of \$11.50		

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company 🗵

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.  $\Box$ 

27713

(Zip code)

#### Item 7.01 Regulation FD Disclosure.

Attached hereto as Exhibit 99.1 and incorporated in this Item 7.01 by reference is an updated corporate slide presentation that will be used by Humacyte, Inc. during meetings with members of the investment community and other third parties.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section and shall not be incorporated by reference into any registration statement or other document filed pursuant to the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise expressly stated in such filing.

#### Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Description
Corporate Presentation.
Cover Page Interactive Data File (embedded within the Inline XBRL document).

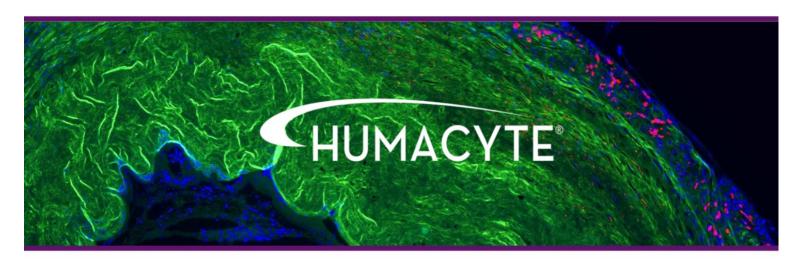
#### SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

#### HUMACYTE, INC.

By: /s/ Dale A. Sander Name: Dale A. Sander Title: Chief Financial Officer, Chief Corporate Development Officer and Treasurer

Date: January 10, 2022



### **Universally Implantable Regenerative Human Tissue**

Humacyte, Inc.



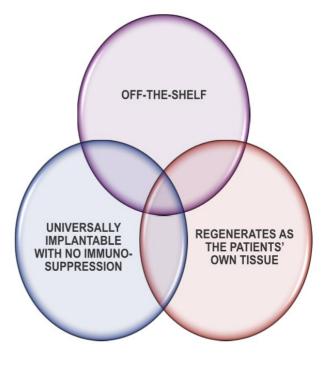
#### DISCLAIMER

These slides and the accompanying oral presentation contain forward-looking statements. All statements, other than statements of historical fact, included in these slides and the accompanying oral presentation are forward-looking statements reflecting management's current beliefs and expectations. In some cases, you can identify forward-looking statements by terminology such as "will," "anticipate," "expect," "believe," "intend" and "should" or the negative of these terms or other comparable terminology. Forward-looking statements in these slides and the accompanying oral presentation include, but are not limited to, statements about the initiation, timing, progress and results of our clinical trials; the anticipated characteristics and performance of our human acellular vessels (HAVs), our ability to successfully complete, clinical trials for our HAVs; the anticipated benefits of our HAVs relative to existing alternatives; our plans and ability to commercialize our HAVs and our ability to manufacture at commercial scale; the implementation of our business model, strategic plans for our business; the scope of protection we are able to establish and maintain for intellectual property rights covering our HAVs and related technology; estimates of our expenses, health economics, future revenues, capital requirements and our needs for additional financing; the timing or likelihood of regulatory filings and approvals; the outcome of our ongoing discussions with the FDA on whether trial size must be increased in our V005 clinical trial; timing, scope and rate of reimbursement for our HAVs; our estimated available market opportunity; our ability to maintain and establish collaborations; our financial performance; developments relating to our competitors and our industry; and statements regarding our markets, including the estimated size and anticipated growth in those markets. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. The potential risks and uncertainties that could cause actual results to differ from the results predicted include, among others, those risks and uncertainties included under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Form S-1 filed with the Securities and Exchange Commission on October 22, 2021 and subsequent annual reports, quarterly reports and other filings made with the Securities and Exchange Commission from time to time. Any forward-looking statements contained herein are based on assumptions that we believe to be reasonable as of the date hereof. Except as required by law, we assume no obligation to update these forward-looking statements, even if new information becomes available in the future.



### LEADING REGENERATIVE MEDICINE WITH THE DEVELOPMENT OF BIOENGINEERED HUMAN TISSUES AND ORGANS





#### CATEGORY-DEFINING INNOVATION DESIGNED TO TRANSFORM THE TREATMENT OF LIFE-THREATENING INJURIES AND DISEASE



#### HUMACYTE: THE PROMISE OF REGENERATIVE MEDICINE

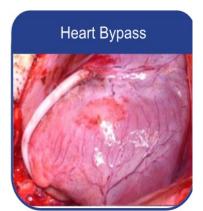
- Broad platform of universally implantable bioengineered human tissues
- Markets estimated to exceed \$150 billion:
  - Dialysis, peripheral artery disease, trauma, diabetes, coronary bypass
- First company to receive FDA RMAT designation. DOD priority product.
- Planned 2022 BLA filing in vascular trauma, 2023 BLA filing in AV access for dialysis<sup>1</sup>
- Commercial-scale manufacturing in place
- Publicly traded (Nasdaq: HUMA) with \$735 million raised, including \$175 million in equity investments from Fresenius Medical Care

'Subject to ongoing discussions with the FDA about trial design and number of subjects to be enrolled



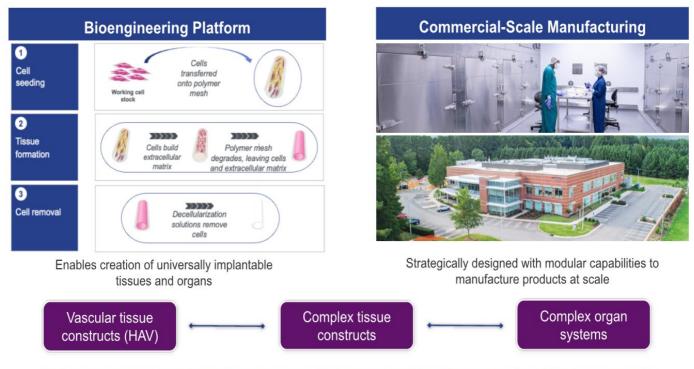








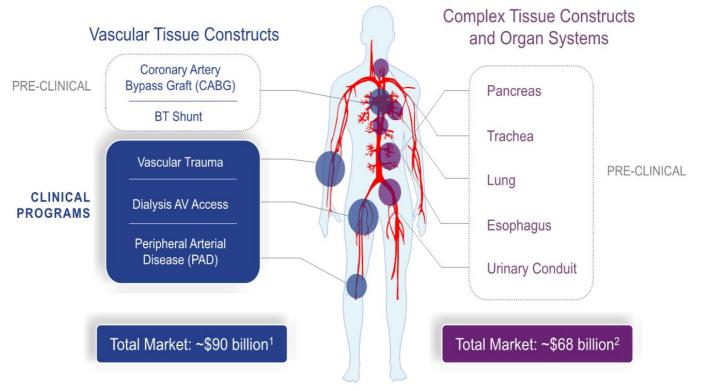
### PLATFORM AND MANUFACTURING ENABLE BROAD PIPELINE OF REGENERATIVE MEDICINE PRODUCTS



#### **OUR PLATFORM ENABLES DEVELOPMENT OF A BROAD RANGE OF PRODUCTS**



#### **OUR PIPELINE ADDRESSES EXTENSIVE MARKET OPPORTUNITIES**



<sup>1</sup>Vascular Products: CABG market estimate from Coronary Artery Bypass Graft (CABG) Market By Type, Crystal Market Research, with remaining market estimates from Triangle Insights Group and Humacyte Internal Data. <sup>2</sup>Tissue and Organ Products: Market estimate for diabetes (pancreas) is estimated global human insulin market revenue from 2015 to 2021, Statista, and Worldwide Industry for Insulin Delivery Systems to 2025, Research and Markets Remaining estimates are Humacyte Internal estimates.



#### PIPELINE WITH MULTIPLE POTENTIAL COMMERCIAL LAUNCHES

	Preclinical	Phase 1/2	Phase 3
Vascular Tissue Constructs (HAV)			
Trauma			
AV Access			
PAD			
Pediatric Heart Disease			
CABG			
Complex Tissue Constructs			
Urinary Conduit			
Tracheal Replacement			
Esophageal Replacement			
Complex Organ Systems			
BioVascular Pancreas			
Lung			
All milestone dates are only management estimates based on currently available data			



### Vascular Tissue Constructs: HUMAN ACELLULAR VESSEL (HAV)





HUMACYTE<sup>®</sup>

#### POTENTIAL BENEFITS OF HAVS IN COMPLETED AND ONGOING CLINICAL TRIALS IN MORE THAN 460 PATIENTS ACROSS MULTIPLE INDICATIONS



Off-the-shelf, immediately available with 18-month shelf life



Long-term durability



No evidence of immunogenicity



Multiple diameters and lengths



#### HUMACYTE<sup>®</sup>

### HAV REPOPULATES WITH THE PATIENT'S OWN CELLS, POTENTIALLY ENABLING INFECTION RESISTANCE AND SELF-HEALING



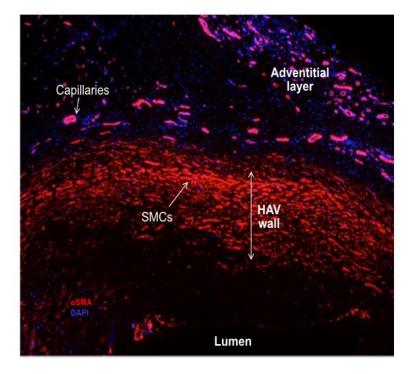
Host cells repopulate the HAV



HAV is highly resistant to infection



HAV may have the ability to self-heal after host cell repopulation





### HAV Repair of Vascular Trauma

Phase 2/3 Trial Underway







#### **CIVILIAN AND WARTIME VASCULAR TRAUMA INJURIES THREATEN** LIFE AND LIMB



Used ePTFE graft routed extra-anatomic to popliteal artery.

ePTFE graft subsequently became Infected and limb was amputated.

- Alarhayem, A.Q., al, Journal of Vascular Surgery 2019; 69: 1519-1523. Kauvar, D.S., et al, Journal of Vascular Surgery 2011; 53: 1598-603. Siracuse, J.J. et al, Journal of Vascular Surgery 2013: 57: 700-705. Andercou, O., et al, Medicine 2018; 97:27(et1350).



- Harvesting vein adds an hour or . more of operative time<sup>1</sup>
- Delayed revascularization . significantly increases amputation risk
- Rate of amputation in lower-limb . trauma ranges from 5-15%

#### Limitations of Current Standard of Care



- 50% infection rate<sup>3</sup> .
- Mortality rate when ePTFE is . infected:8-30%4
- . Median length of stay 11 days it re-admitted for graft infection
- Amputation rate is 8-15%



#### THE HAV IN VASCULAR TRAUMA - DESIGNED TO SAVE LIVES AND LIMBS

#### HAV Expected Improved Patient Outcomes in Trauma

- Off the shelf: Immediately available to the surgeon.
   Eliminates the time required to harvest a vein
- Outstanding primary patency
- Substantial reduction in rate of Infection compared to ePTFE
- Excellent limb salvage (reduced rate of amputation)



#### **HAV Trauma Case Study**



Iliac Artery Bypass with HAV (Pelvis and Leg)

#### HAV Expected Economic Benefits

- The HAV's expected reduction in rate of infection, amputation and other complications drive reductions in costs:
- Average cost associated with complications in vascular trauma:
- Infection \$42,000
- Amputation \$90,000
- Harvest site infection \$20,000



### ONGOING V005 PHASE 2/3 TRIAL IN TRAUMA SHOWS ROBUST RESULTS TO DATE

- Single-arm, open label study in ± 75 patients; unblinded trial with historical database comparators
- 90-day endpoints of infection, amputation and survival
- Sites are Level-I Trauma centers in the US and Europe, including sites with high clinical volume, led by key opinion leaders (e.g. Denver, Baltimore Shock-Trauma).
- DOD Priority Designation
- Accelerated Approval Pathway
- 47 patients enrolled as of December 31, 2021

HAV performance to date in trial compares favorably to both saphenous vein and ePTFE historical reported literature

2022

**Completion of** 

enrollment, top-line results

## Low rates of HAV infection despite multiple implants into contaminated wound beds

Low rates of amputation

Zero instances of HAV rejection

Late-2022 File BLA for Vascular Trauma

2023 BLA approval for Vascular Trauma

'Subject to ongoing discussions with the FDA about trial design and number of subjects to be enrolled

Expected Milestones<sup>1</sup>





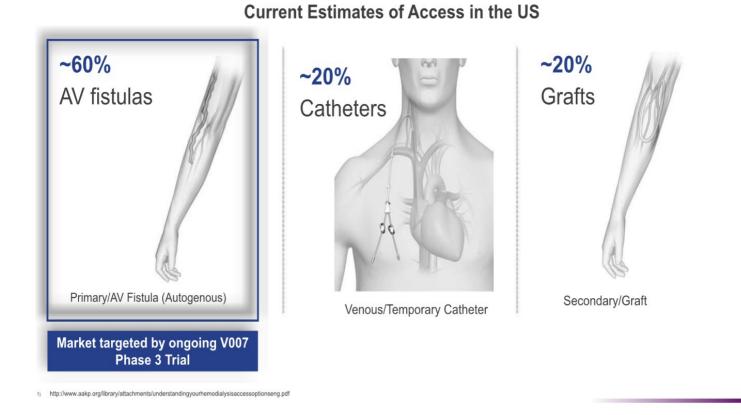
### HAV in AV Access for Dialysis

Phase 3 Trial Underway





#### TRADITIONAL METHODS OF AV ACCESS FOR HEMODIALYSIS



#### HAV IS DESIGNED TO ADDRESS FISTULA FAILURES, INFECTIONS



### Use of AV Fistula has Substantial Limitations





- ~40% of fistulas fail to mature
- Even the fistulas that do mature take 3-6 months to become usable for dialysis
- While fistulas are unusable patients are required to use catheters:
- Catheter infection rates are up to 200% per patient-year

<sup>1</sup> Lawson, J.H, et al, The Lancet 2016; 387: 2026-2034. <sup>2</sup> Halbert, R.J., et al, Kidney360 2020; doi: 10.34067/KID.003502020.

#### HAV is Designed to Address Substantial Unmet Need in AV Access

#### Expected Improved Patient Outcome:

- HAV usable for dialysis after only four weeks
- HAV reduces catheter contact time thereby reducing risk of catheter infection
- >90% of HAVs functional for dialysis at 6 months
- HAV infection rate is <1% per patient year</li>

#### Expected Economic Benefits:

- Expected reduction in catheter contact time, infection, and failure rate have potential to reduce cost including the following:
  - Infection \$45,000
  - Additional access procedures \$9,000



Our partner and shareholder FMC is the global market leader in the care of dialysis patients

#### **ONGOING PHASE 3 TRIAL IN DIALYSIS ACCESS VERSUS AV FISTULA (V007)**

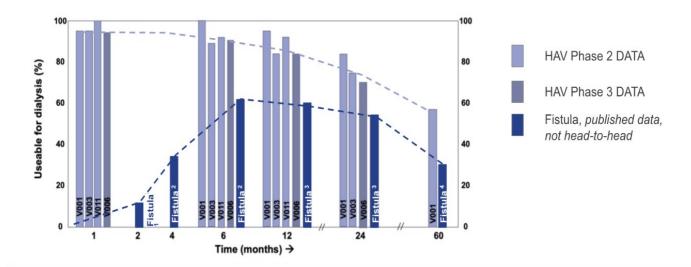


enrolled

#### HUMACYTE

SUPPORTIVE DATA FROM COMPLETED PHASE 2 AND PHASE 3 STUDIES OF HAV

HUMACYTE

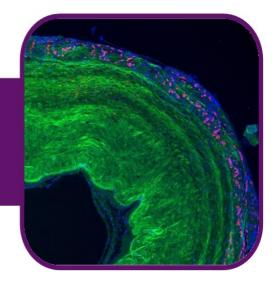


Completed studies of HAV as a conduit for hemodialysis compare well to published results for AV Fistula.

The V006 trial of HAV was conducted versus ePTFE. It did not meet its primary endpoint, which was secondary patency compared to ePTFE at 18 months. The secondary patency of the HAV was greater than that of ePTFE at 6 and 12 months, but lower at 18 and 24 months.

Woodside, Kenneth J., et. Al, American Journal of Kidney Diseases, Volume 71, Issue 6, 2018, Pages 793-801 Alton, M., et al. American J Kidney Disease 2018; 71: 677-689 Arhuidese, et al, 2018; JVS Lok, et al; 2013 CJASN





### HAV for Peripheral Arterial Disease

Phase 2 Program





#### PERIPHERAL ARTERIAL DISEASE (PAD)

Can progress to multiple leg arteries, further reducing circulation

#### **Critical Limb Threatening Ischemia**

- Tissue does not receive enough blood
  flow to survive
- If untreated, leads to tissue loss, gangrene, and ultimately amputation

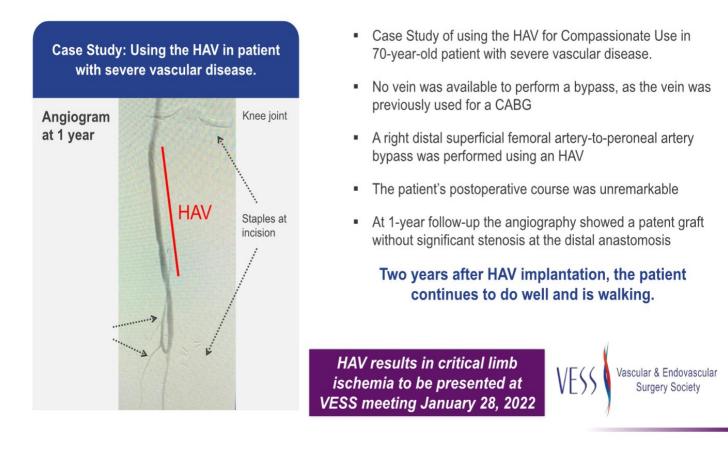
### Treatment requires restoration of blood flow

- Non-surgical, catheter-based intervention
- Surgical bypass

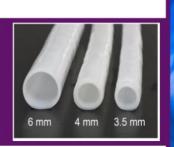




#### PERIPHERAL ARTERIAL DISEASE: RESTORING MOBILITY WITH HAV









### HAV for Cardiac Bypass

**Preclinical Program** 



#### POTENTIALLY TRANSFORMING CABG CARE: GREATER DURABILITY, LESS MORBIDITY



#### SAPHENOUS VEIN GRAFT (SVG)

- Harvesting SVG from the patient is painful and complicated:
  - 41% have persistent numbress
  - 32% develop infection
  - 23% have persistent swelling; worse in obese and diabetic patients; 2x worse in women
- SVGs do not last long enough: ~33% of patients will require one or more re-grafting procedures during their lifetimes

# 

Humacyte HAV

#### HUMACYTE'S HAV

- Does not require tissue harvest from the patient
- Immediately available and avoids morbidity of vein harvest
- Particularly important to avoid vein harvest in diabetics, women, and the overweight
- Durable and highly uniform in diameter and quality

### SURGEONS KNOW WHAT THEY ARE GETTING EACH TIME



HUMACYTE

HAV preclinical results in CABG to be presented at Advanced Therapies Week January 28, 2022



Humacyte Innovation in Complex Organ Systems: BioVascular Pancreas for Type-1 Diabetes

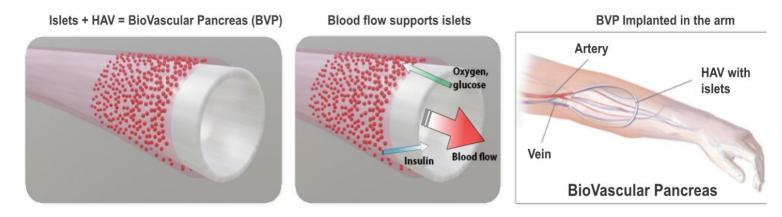
#### **Preclinical Program**







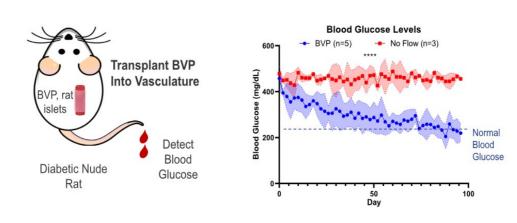
#### **BIOVASCULAR PANCREAS MAY DELIVER CURATIVE ISLETS TO DIABETICS**



- Islets die after implantation under the skin, or after injection into the abdomen, due to lack of oxygen and nutrients.
- Without a blood supply, pancreatic islets cannot survive transplantation.
- Humacyte's HAV is being developed as a means to provide oxygen and nutrients to islets that are coated on the outside of the vessel: a "BioVascular Pancreas", or BVP
- Once implanted in the vasculature, blood flow supplies oxygen and nutrients to islets, via diffusion through the HAV wall.
- Islets survive and secrete insulin. One 42-cm HAV can accommodate all of the islets in an entire human pancreas.

### BIOVASCULAR PANCREAS NORMALIZED GLUCOSE IN DIABETIC ANIMALS

- Diabetic rodents implanted with BVPs containing rat islets, then followed for blood glucose levels
- All treated animals normalized glucose over time. All sham-treated animals ("No Flow") remained diabetic
- Collectively, these data support the potential of a BioVascular pancreas to provide an effective method for transplanting pancreatic islets that produce insulin for the treatment of type 1 diabetes.



Moving into large-animal preclinical studies

#### Volume 12: 1-18





### Anticipated Path to Market





#### **COMMERCIALIZATION STRATEGY**





#### COMMERCIAL MANUFACTURING SCALE – LUNA200 SYSTEM



Source: Humacyte

HUMACYTE<sup>®</sup>

#### HUMACYTE'S TEAM



1



#### UPCOMING MILESTONES FOR HUMACYTE





HAV preclinical results in CABG to be presented at Advanced Therapies Week meeting (January 2022)

Completion of enrollment in V005 Vascular Trauma trial. Top-line trial results<sup>1</sup> HAV results in critical limb ischemia to be presented at VESS meeting (January 2022)

File BLA for Vascular Trauma<sup>1</sup>

Completion of enrollment of V007 Phase 3 trial in AV Access vs. fistula

Publications and presentations (multiple clinical and preclinical publications & presentations, including preclinical biovascular pancreas results)

2023

Top-line readout for V007 AV Access trial (12-month follow-up from last subject enrolled) BLA approval for Vascular Trauma U.S. commercial launch in Vascular Trauma File BLA for AV Access

All milestone dates are only management estimates

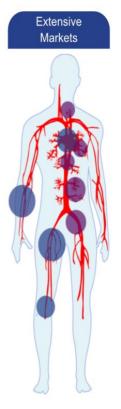
Subject to ongoing discussions with the FDA about trial design and number of subjects to be enrolled

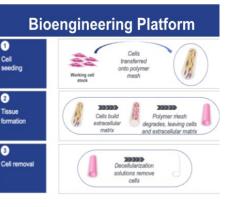


#### THE PROMISE OF REGENERATIVE MEDICINE

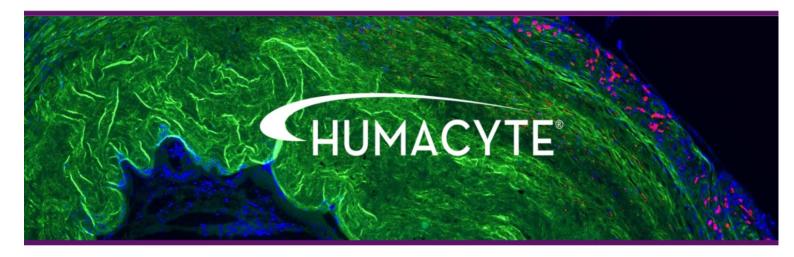
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- Markets estimated to exceed \$150 billion:
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- First company to receive FDA RMAT designation. DOD priority product.
- Planned 2022 BLA filing in vascular trauma, 2023 BLA filing in AV access for dialysis<sup>1</sup>
- Commercial-scale manufacturing in place
- Strong cash position (\$240 million at September 30, 2021) to fund operations past major milestones

Subject to ongoing discussions with the FDA about trial design and number of subjects to be enrolled









### **Universally Implantable Regenerative Human Tissue**

Humacyte, Inc.





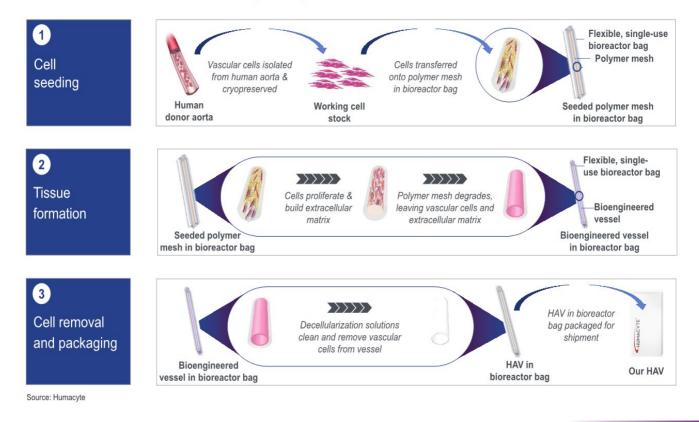






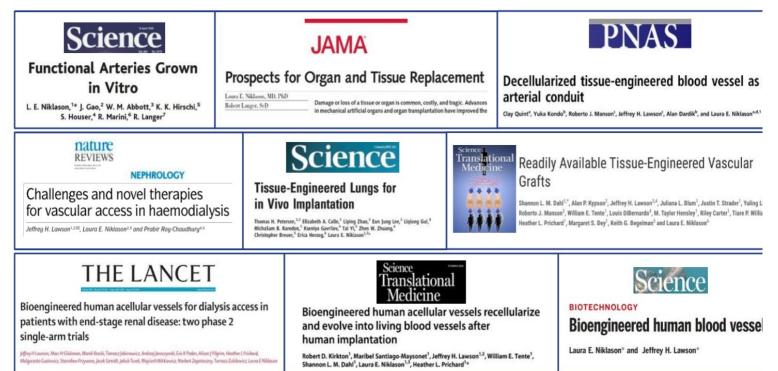
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#### HUMAN ACELLULAR VESSELS (HAVs)



#### HUMACYTE IS BASED ON BREAKTHROUGH SCIENCE





SCIENCE VALIDATED BY EXTENSIVE TOP-TIER PEER REVIEWED PUBLICATIONS