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)
2525 East North Carolina Highway 54
Durham, NC
(Address of principal executive offices)

001-39532
(Commission File Number)

85-1763709
(I.R.S. Employer
Identification Number)

27713
(Zip code)

(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:

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

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. ☐
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 13 or 15(d) 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.

<table>
<thead>
<tr>
<th>Exhibit Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>99.1</td>
<td>Corporate Presentation</td>
</tr>
<tr>
<td>104</td>
<td>Cover Page Interactive Data File (embedded within the Inline XBRL document).</td>
</tr>
</tbody>
</table>
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.

Date: January 10, 2022

By: /s/ Dale A. Sander

Name: Dale A. Sander
Title: Chief Financial Officer, Chief Corporate Development Officer and Treasurer
Universally Implantable Regenerative Human Tissue

Humacyte, Inc.
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 dialysis¹

- Commercial-scale manufacturing in place

- Publicly traded (Nasdaq: HUMA) with $735 million raised, including $175 million in equity investments from Fresenius Medical Care

¹Subject 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

**Bioengineering Platform**

1. **Cell seeding**
   - Working cell stock
   - Cells transferred onto polymer mesh

2. **Tissue formation**
   - Cells build extracellular matrix
   - Polymer mesh degrades, leaving cells and extracellular matrix

3. **Cell removal**
   - Decellularization solutions remove cells

Enables creation of universally implantable tissues and organs

**Commercial-Scale Manufacturing**

Strategically designed with modular capabilities to manufacture products at scale

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

- Vascular tissue constructs (HAV)
- Complex tissue constructs
- Complex organ systems
OUR PIPELINE ADDRESSES EXTENSIVE MARKET OPPORTUNITIES

Vascular Tissue Constructs

- Coronary Artery Bypass Graft (CABG)
- BT Shunt
- Vascular Trauma
- Dialysis AV Access
- Peripheral Arterial Disease (PAD)

Total Market: ~$90 billion\(^1\)

Complex Tissue Constructs and Organ Systems

- Pancreas
- Trachea
- Lung
- Esophagus
- Urinary Conduit

Total Market: ~$68 billion\(^2\)

---

\(^1\) Vascular Products - CABG: Market and demand for Coronary Artery Bypass Graft (CABG) calculated by Total Market Research, with market demand estimates from Triplane Health Group and Humacyte internal data.

# Pipeline with Multiple Potential Commercial Launches

<table>
<thead>
<tr>
<th>Vascular Tissue Constructs (HAV)</th>
<th>Preclinical</th>
<th>Phase 1/2</th>
<th>Phase 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trauma</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AV Access</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PAD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pediatric Heart Disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CABG</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Complex Tissue Constructs</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinary Conduit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tracheal Replacement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Esophageal Replacement</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Complex Organ Systems</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>BioVascular Pancreas</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

All milestone dates are only management estimates based on currently available data.
Vascular Tissue Constructs:
HUMAN ACELLULAR VESSEL (HAV)
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
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

Example of Complex Wartime Injury

Used ePTFE graft routed extra-anatomic to popliteal artery.

ePTFE graft subsequently became infected and limb was amputated.

Limitations of Current Standard of Care

Saphenous Vein Grafts

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

ePTFE Grafts

- 50% infection rate
- Mortality rate when ePTFE is infected: 8-30%
- Median length of stay 11 days if re-admitted for graft infection
- Amputation rate is 8-15%

References:
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

Low rates of amputation
Low rates of HAV infection despite multiple implants into contaminated wound beds
Zero instances of HAV rejection

Expected Milestones

| 2022 Completion of enrollment, top-line results |
| 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
HAV in AV Access for Dialysis

Phase 3 Trial Underway
TRADITIONAL METHODS OF AV ACCESS FOR HEMODIALYSIS

Current Estimates of Access in the US

~60% AV fistulas
Primary/AV Fistula (Autogenous)

~20% Catheters
Venous/Temporary Catheter

~20% Grafts
Secondary/Graft

Market targeted by ongoing V007 Phase 3 Trial

1 http://www.aekp.org/library/attachments/understandingyourhemodialysisaccessoptionsnew.pdf
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

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

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


FRESENIUS MEDICAL CARE
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)

**NCT03183245:**

Compare the Efficacy and Safety of Humacyte’s Human Acellular Vessel with that of an Autologous Arteriovenous Fistula in Subjects with End-Stage Renal Disease (currently enrolling)

30 centers in the US. HAV implanted in patients in need of dialysis access and who were suitable for single-stage arteriovenous fistula.

### Enrollment:
- Target 240 total subjects
- 207 subjects enrolled as of December 31, 2021

### Comparators:
- Single-stage arteriovenous fistula in the upper extremity

### Duration:
- Each subject is followed for 24 months after implantation,

### Objectives:
- **Primary Efficacy:** Useability for dialysis at 6 months; Secondary patency at 12 months
- **Primary Safety:** Compare rates of interventions, infections, host remodeling, and dialysis efficiency

### Expected Milestones

<table>
<thead>
<tr>
<th>2022</th>
<th>2023</th>
<th>2023</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completion of enrollment</td>
<td>Top-line readout for V007 AV Access trial 12-month follow-up from last subject enrolled</td>
<td>File BLA for AV Access</td>
</tr>
</tbody>
</table>
SUPPORTIVE DATA FROM COMPLETED PHASE 2 AND PHASE 3 STUDIES OF HAV

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.

3. Akasaka, et al. 2010, JIS
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
Case Study: Using the HAV in patient with severe vascular disease.

- Case Study of using the HAV for Compassionate Use in 70-year-old patient with severe vascular disease.
- No vein was available to perform a bypass, as the vein was previously used for a CABG.
- A right distal superficial femoral artery-to-peroneal artery bypass was performed using an HAV.
- The patient’s postoperative course was unremarkable.
- At 1-year follow-up the angiography showed a patent graft without significant stenosis at the distal anastomosis.

**Two years after HAV implantation, the patient continues to do well and is walking.**

HAV results in critical limb ischemia to be presented at VESS meeting January 28, 2022.
HAV for Cardiac Bypass

Preclinical Program
SAPHEOUS VEIN GRAFT (SVG)

- Harvesting SVG from the patient is painful and complicated:
  - 41% have persistent numbness
  - 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’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 Innovation in Complex Organ Systems: BioVascular Pancreas for Type-1 Diabetes

Preclinical Program
- 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.
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
Anticipated Path to Market
Collaboration with Fresenius Medical Care

Global collaboration for Dialysis AV Access and PAD
2,500 dialysis centers in the US: largest provider of dialysis services in the U.S.
Leader in the management of outpatient surgical centers
Over 60 outpatient centers for vascular procedures

Direct Sales for Vascular Trauma

- Department of Defense supply depots
- Vascular Trauma is highly specialized market with 190 Level I Trauma centers
- Launch field sales force of up to 20 representatives
- Dual targeting of surgeons intended to create pull-through demand and hospital administrators to gain product placement in hospitals

Strategic Partnerships

- Large market potential of CABG and pancreas products expected to provide additional collaboration opportunities
- We will explore strategic partnerships for future products
## Commercial Manufacturing Scale – LUNA200 System

### Modular Manufacturing System

<table>
<thead>
<tr>
<th>Bioreactor bag</th>
<th>Growth drawer</th>
<th>LUNA200 system</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Bioreactor bag" /></td>
<td><img src="image2" alt="Growth drawer" /></td>
<td><img src="image3" alt="LUNA200 system" /></td>
</tr>
</tbody>
</table>

- Each bioreactor bag contains a single polymer mesh scaffold, seeded with donated human cells.
- 16 bioreactor bags per growth drawer; tubing connects to shared nutritive media.
- With 20 growth drawers, each LUNA200 can produce 200 HAVs per batch (or >1,000 HAVs annually). ²

### Commercial 83,000 sq ft Bioprocessing Facility

- Currently operating 8 LUNA200 systems.
- Annual Capacity expected to exceed 40,000 HAVs.
- Functionally closed system with state-of-the-art process automation.

### $1 billion in annual revenue potential from existing facilities with room for modular expansion

Source: Humacyte
HUMACYTE'S TEAM

LEADERSHIP TEAM

Laura E. Niklason, MD, PhD
Founder, President, Chief Executive Officer

Dale Sander
Chief Financial Officer, Chief Corporate Development Officer

Heather Pritchard, PhD
Chief Operating Officer

Juliana Blum, PhD
Co-Founder, Executive Vice President, Corporate Development

RJ Schvetsela
Chief Commercial Officer

William Tento, MS
Chief Regulatory Officer

Sabrina Osborne
Executive Vice President, Business Strategy & People

Scott Well, PhD
Vice President of Quality

BOARD OF DIRECTORS

Kathleen Sebelius - Chair of the Board
Gordon M. Binder
Emery N. Brown, MD, PhD
Michael T. Constantino
Brady W. Dougan
Laura E. Niklason, MD, PhD
Todd M. Pope
Rajiv Shukla
Max Wallace, JD
Susan Windham-Bannister, PhD

* HLT Member
# Upcoming Milestones for Humacyte

## 2022
- **HAV preclinical results in CABG** to be presented at Advanced Therapies Week meeting (January 2022)
- **HAV results in critical limb ischemia** to be presented at VESS meeting (January 2022)
- Completion of enrollment in V005 Vascular Trauma trial. Top-line trial results
- File BLA for Vascular Trauma
- **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

---

1 Subject to ongoing discussions with the FDA about trial design and number of subjects to be enrolled
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 dialysis¹

- Commercial-scale manufacturing in place

- Strong cash position ($240 million at September 30, 2021) to fund operations past major milestones

¹Subject to ongoing discussions with the FDA about trial design and number of subjects to be enrolled
Universally Implantable Regenerative Human Tissue

Humacyte, Inc.