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): February 29, 2024

Humacyte, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-39532**	**85-1763759**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification Number)

2525 East North Carolina Highway 54 **Durham, NC**	**27713**
(Address of principal executive offices)	(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 Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which 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 Common Stock at an exercise price of $11.50	**HUMAW**	**The Nasdaq Stock Market LLC**

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 8.01. Other Events.

On February 29, 2024, Humacyte, Inc. (the "Company") made available an investor presentation (the "Investor Presentation"), which the Company expects to use in connection with investor calls and/or conferences. A copy of the Investor Presentation is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Humacyte, Inc. Investor Presentation February 2024
104	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.

Date: February 29, 2024

By: /s/ Dale A. Sander

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

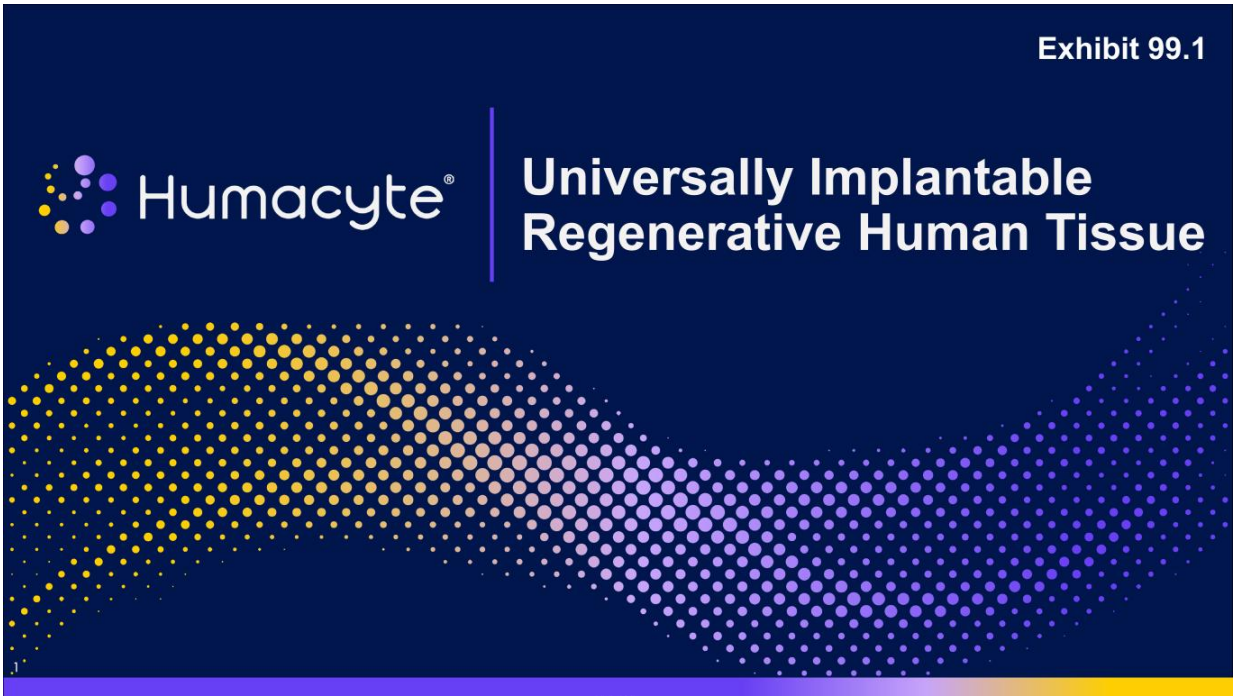
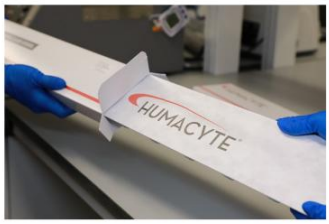


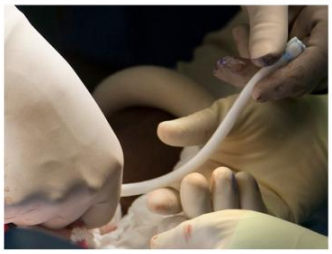
Exhibit 99.1
Humacyte®
Universally Implantable
Regenerative Human Tissue

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 our plans and ability to execute product development, process development and preclinical development efforts successfully and on our anticipated timelines; our plans, anticipated timelines and ability to obtain marketing approval from the U.S. Food and Drug Administration ("FDA") and other regulatory authorities, including the European Medicines Agency, for our bioengineered human acellular vessels ("HAVs") and other product candidates, including our Biologics License Application seeking approval of the HAV in urgent arterial repair following extremity vascular trauma when synthetic graft is not indicated and when autologous vein use is not feasible; our ability to design, initiate and successfully complete clinical trials and other studies for our product candidates and our plans and expectations regarding our ongoing or planned clinical trials, including for our V007 Phase 3 clinical trial; the outcome of our ongoing discussions with the FDA concerning the design of our clinical trials; our anticipated growth rate and market opportunities; the potential liquidity and trading of our securities; our ability to raise additional capital in the future; our ability to use our proprietary scientific technology platform to build a pipeline of additional product candidates; the characteristics and performance of our HAVs; our plans and ability to commercialize our HAVs and other product candidates, if approved by regulatory authorities; the expected size of the target populations for our product candidates; the anticipated benefits of our HAVs relative to existing alternatives; our assessment of the competitive landscape; the degree of market acceptance of HAVs, if approved, and the availability of third-party coverage and reimbursement; our ability to manufacture HAVs and other product candidates in sufficient quantities to satisfy our clinical trial and commercial needs; our expectations regarding our strategic partnership with Fresenius Medical Care Holdings, Inc. to sell, market and distribute our 6 millimeter HAV for certain specified indications and in specified markets; the performance of other third parties on which we rely, including our third-party manufacturers, our licensors, our suppliers and the organizations conducting our clinical trials; our ability to obtain and maintain intellectual property protection for our product candidates as well as our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others; our ability to maintain the confidentiality of our trade secrets, particularly with respect to our manufacturing process; our compliance with applicable laws and regulatory requirements, including FDA regulations, healthcare laws and regulations, and anti-corruption laws; our ability to attract, retain and motivate qualified personnel and to manage our growth effectively; our future financial performance and capital requirements; our ability to implement and maintain effective internal controls; and the impact of the overall global economy and increasing interest rates and inflation on our business. 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 10-K filed with the Securities and Exchange Commission on March 24, 2023 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.

Humacyte is a Leader the Field of Regenerative Medicine:
Investigational Bioengineered Tissues & Organs





- Off-the-shelf
- Universally implantable with no immuno-suppression
- Observed to regenerate as the patient's own tissue

Category-Defining Innovation that Creates New Tissues

Universally Implantable Regenerative Human Tissue

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Potential First-in-Class Technology & Manufacturing Platform

Large addressable markets
(trauma, dialysis, peripheral artery disease, diabetes, coronary bypass)

Nearing Potential Market Launch

BLA granted Priority Review by FDA
in February 2024 for HAV in vascular trauma with August 10, 2024 PDUFA date

Commercial-Scale Manufacturing

Commercial-scale manufacturing in place with annual capacity of up to 40,000 HAVs in existing facility

Validated through Multiple Partnerships

MAYO CLINIC

U.S. DEPT OF DEFENSE

JDRF IMPROVING LIVES. CURING TYPE 1 DIABETES.

FRESENIUS MEDICAL CARE

Humacyte Leadership & Board

Humacyte

Leadership Team


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


Dale Sander
Chief Financial Officer, Chief Corporate Development Officer


Heather Prichard, PhD
Chief Operating Officer


Shamik Parikh, MD
Chief Medical Officer


Cindy Cao
Chief Regulatory Officer


BJ Scheessele
Chief Commercial Officer


Sabrina Osborne
Executive Vice President, Business Strategy & People


William Tente, MS
Executive Regulatory Fellow


Harold Alterson
Senior Vice President, Quality

Board of Directors

Kathleen Sebelius
Chair of the Board

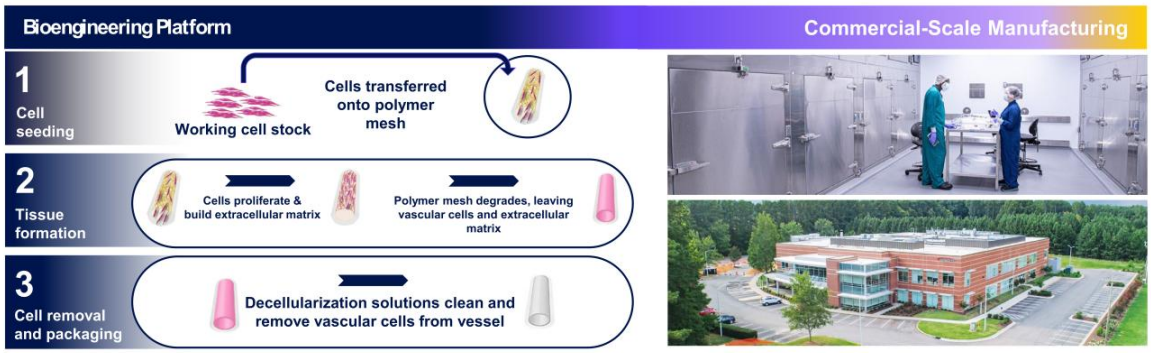
Gordon M. Binder
Emery N. Brown, MD, PhD
Michael T. Constantino
Brady W. Dougan
Charles Bruce Green, MD
Laura E. Niklason, MD, PhD
Todd M. Pope
Diane Seimetz, PhD
Rajiv Shukla
Max Wallace, JD
Susan Windham-Bannister, PhD

Prior Experience

Ascentage Pharma
AstraZeneca
AVITA Medical
Biogen
bluebirdbio
Bristol Myers Squibb
U.S.Department of Heath and Human Services
Duke University School of Medicine
Johnson & Johnson
KRIYA THERAPEUTICS
NOVARTIS
novo nordisk
SANDOZ A Novartis Division
sanofi
Yale University School of Medicine
GSK

Platform & Manufacturing:
Enable Broad Pipeline of Regenerative Medicine Products

Humacyte



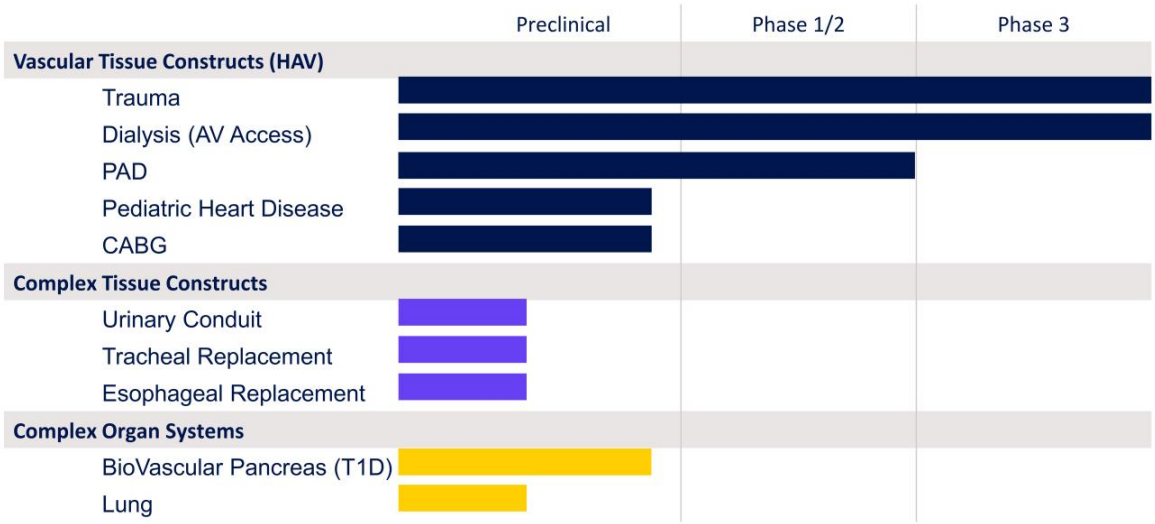
Enables creation of universally implantable tissues and organs

Strategically designed with modular capabilities to manufacture products at scale

Vascular tissue constructs (HAV) ⟷ Advanced tissue constructs ⟷ Advanced organ systems

Our platform technology enables development of a broad range of product candidates

Pipeline with Multiple Potential Commercial Launches



HAV Observed to Repopulate with Patient's Own Cells
Potentially Enabling Infection Resistance & Self-Healing

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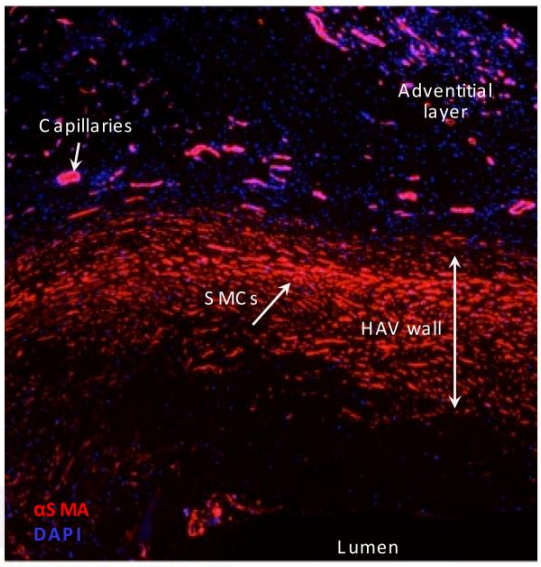
HAV Overview

- Host cells observed to repopulate the HAV[1]
- HAV observed to have low rates of infection
- HAV may have the ability to self-heal after host cell repopulation

More than 500 patients across multiple indications



Benefits of HAV

- Off-the-shelf, immediately available with 18-month shelf life
- Long-term durability
- Resistant to infection even in contaminated wound bed
- No evidence of immunogenicity

1. Kirkton, R.D., et al, Science Translational Medicine 2019; 11:eaau6934.


Vascular Trauma
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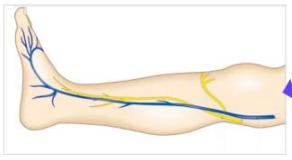
Vascular Injuries – Value Proposition for the HAV

- Common causes of vascular injuries include workplace injuries, car accidents, gunshots and stabbings, and sports injuries
- Currently available treatment options have significant drawbacks:

Shotgun Wound

Exit wound of a shotgun injury



1. Vein is the standard of care, but causes injury from harvest and takes valuable time, delaying revascularization

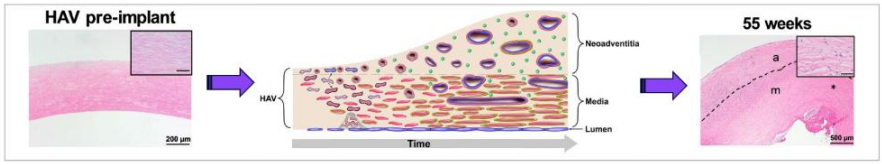
2. Synthetics are quick, but have infection risk and high rates of amputation

3. Amputation

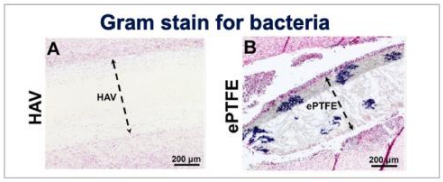
Why HAV for Traumatic Vascular Injury?

- **HAV is off the shelf and immediately available for implant**
  - In contrast to harvesting vein from the patient which can take an hour [1]

- **HAV repopulates with the patient's cells, becoming a living tissue** [2]



- **HAV is resistant to infection, compared to synthetic grafts** [3]



1: Zenati, M.S., et al, New England Journal of Medicine 2019; 380: 2.
2. Kirkton, R.D., et al, Science Translational Medicine 2019; 11:eaau6934.
3. Wang, J., et al, Journal of Vascular Surgery – Vascular Science 2023; 4: 100120.

CLN-PRO-V005 Phase 2/3 Pivotal Trial

Human Acellular Vessel (HAV) in Vascular Trauma
(NCT03005418)

- Single-arm, open label trial
- Level 1 trauma centers in US and Israel
- Arterial injury repair

→ Primary endpoint 30-day patency in patients with extremity injuries

69 total patients enrolled as of data cut off
51 patients with extremity injuries – focus for BLA filing

- ALL patients had NO VEIN for repair, as assessed by treating surgeons
- Hence, patients would have received synthetic grafts, ligation of the bleeding vessel and/or amputation, had they not gotten the HAV.
- Extremity Injuries at high risk of contamination/infection[1]

- Historical Benchmarks
  - Systematic literature review of synthetics in vascular trauma
- Primary Comparison
  - 30-day endpoint of patency
- Secondary Comparisons
  - Infection rate
  - Amputation rate

Success Criteria
- Comparable (or higher) Patency
- Infection rate comparable or lower than Synthetic Grafts
- Amputation rate comparable or lower than Synthetic Grafts
- No unexpected safety signals

1: Prevaldi et al, 2016 World Journal of Emergency Surgery

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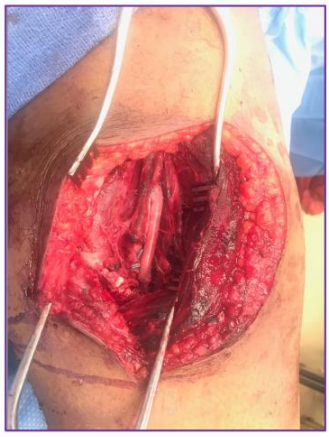
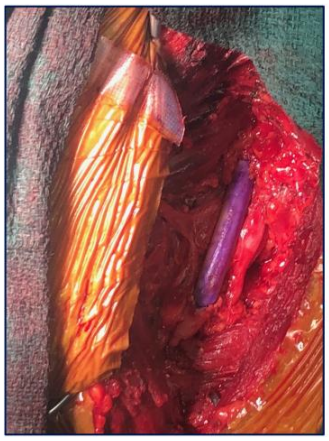
Example Vascular Injuries Treated in CLN-PRO-V005 Trial



Gunshot Wound



Industrial Accident

Knee Dislocation

V005 Trial: HAV vs Synthetic Graft Benchmarks

Endpoint	HAV Extremity (V005) %	Synthetic Graft Benchmark %
Secondary Patency	90.2%	78.9%
Conduit Infections	2.0%	8.4%
Amputations	9.8%	24.3%

V005 Trial was a Success and Met All Objectives

Observations from V005 trial:

- **Secondary Patency**
  - HAV performed better than historic benchmark
- **Conduit Infections**
  - HAV point estimate lower than historic benchmark
- **Amputations**
  - HAV performed better than historic benchmark

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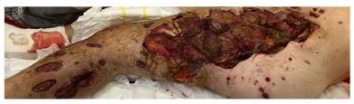
Ukraine Real World Experience of HAV Use in Vascular Repair

- 19 patients received a HAV
- 17 consented for data collection and study participation
- 16 patients had extremity trauma repair; one patient required HAV for Iatrogenic Trauma Repair
- Ukraine Humanitarian Experience presented at MHSRS[1] 2023 Annual meeting on August 14th 2023

Measure	V017 Trial Ukraine Extremity Patients (n=16)
30-day Patency	93.8%
Amputation	0.0%
Limb Salvage	100.0%
Conduit Infection	0.0%



Ukraine Patient Blast Injury

Pre-op CT Scan

HAV repair of Femoral artery

Walking once again (Day 113)

1: MHSRS - Military Health System Research Symposium

HAV Combined Results from V005 and V017 Trials

The FDA advised Humacyte to include in its BLA submission patient outcomes from V017 (the humanitarian program conducted in Ukraine)

Endpoint	HAV Extremity (V005 + V017 Meta Analysis) %	Synthetic Graft Benchmark %
Secondary Patency	91.5%	78.9%
Conduit Infections	0.9%	8.4%
Amputations	4.5%	24.3%

Combined V005 + V017 Results Further Supports HAV Performance Versus Synthetic Graft Benchmarks

- **Observations from combined V005 and V017 trials:**
- **Secondary Patency**
  - HAV performed better than historic benchmark
- **Conduit Infections**
  - HAV performed better than historic benchmark
- **Amputations**
  - HAV performed better than historic benchmark

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Priority Review of BLA and Planned Market Launch

- **BLA submitted to FDA** in December 2023
- Priority Review granted by FDA in February 2024
- PDUFA date of August 10, 2024
- Factors supporting Priority Review:
  - In May 2023 the **FDA granted Regenerative Medicine Advanced Therapy (RMAT)** designation for use of the HAV in urgent arterial repair following extremity vascular trauma
  - The HAV was assigned a **priority designation by the Secretary of Defense** under Public Law 115-92, enacted to expedite the FDA's review of products that are intended to diagnose, treat or prevent serious or life-threatening conditions facing American military personnel
- Planned market launch in 2nd Half 2024 if approved


AV Access
for Dialysis
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AV Access for Hemodialysis Has Substantial Limitations

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Estimates of Access (U.S.)

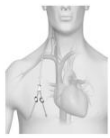
~60% AV fistulas

Primary/AV Fistula (Autogenous)

Market targeted by ongoing V007 Phase 3 Trial

~20% Catheters

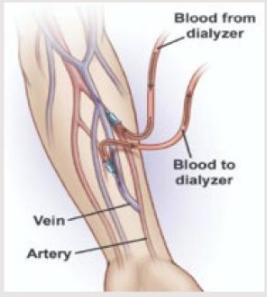
Venous / Temporary Catheter

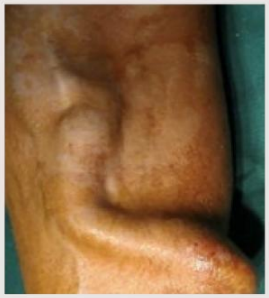


~20% Grafts

Secondary / Graft

Limitations of AV Fistulas (Current Standard of Care)





- ~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 Failures in AV Access

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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

RMAT

RMAT designation granted by FDA

HAV Expected Economic Benefits

- Expected reduction in catheter contact time, infection, and failure rate have potential to reduce costs, including the following:

Reduce Costs from Infection

Reduce Costs of Additional Access Procedures

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

Enrolled Phase 3 Trial in Dialysis: HAV vs. Fistula

V007 Phase 3 Trial Design: 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

- Subjects with end-stage renal disease in need of dialysis and suitable for single-stage arteriovenous fistula
- Target 240 total subjects

HAV

Trial enrollment completed (242 patients) in April 2023

Single-stage AV Fistula in Upper Extremity

> Endpoints
  > Efficacy: Useability for dialysis and patency during the first year
  > Safety: interventions, infections, etc.

> Duration
  > Subjects followed for 24 months after implantation

> Sites
  > 30 centers in the U.S.

> Timelines
  > Top-line readout expected in 2024 (12-month follow-up from last subject enrolled)

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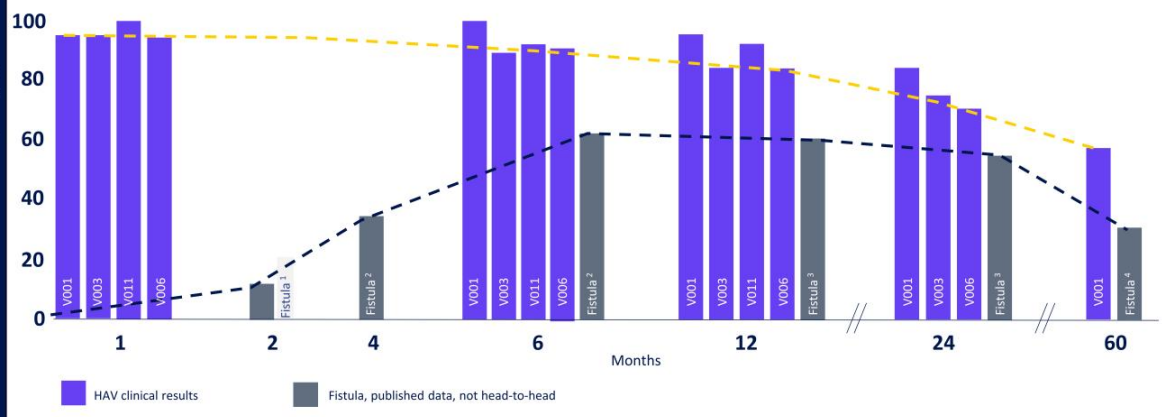
Supportive Data From Completed Phase 2 & Phase 3 Studies of HAV



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.

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


Peripheral Arterial Disease (PAD)
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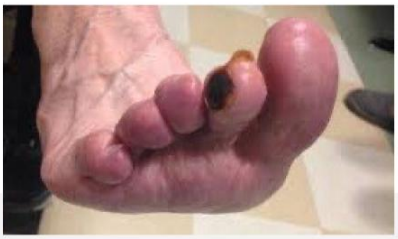
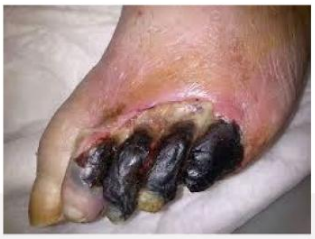
Peripheral Artery Disease (PAD)

Can progress to multiple leg arteries, further reducing circulation



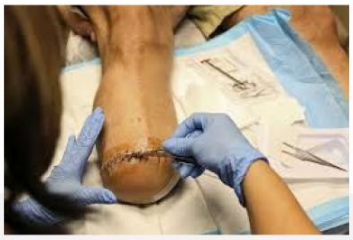
Critical Limb Threatening Ischemia

- 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



For the 40% of PAD patients who do not have an ipsilateral saphenous vein for arterial bypass, HAV may represent a promising means of revascularization and limb salvage

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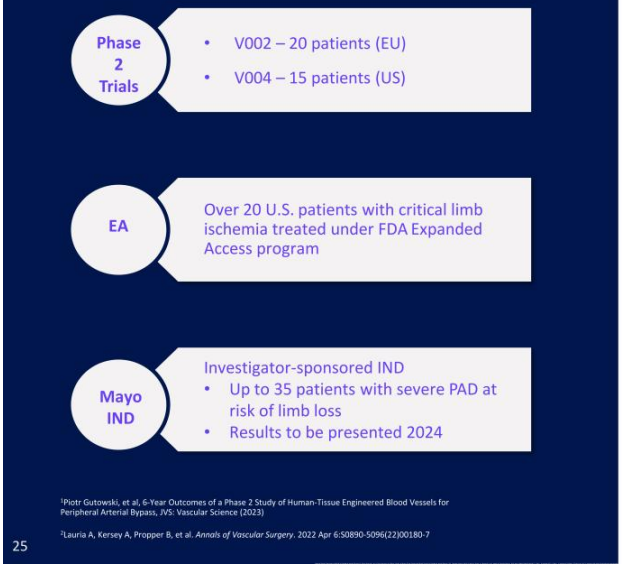
Current Clinical Experience with HAV in Peripheral Arterial Disease



[1]Piotr Gutowski, et al, 6-Year Outcomes of a Phase 2 Study of Human-Tissue Engineered Blood Vessels for Peripheral Arterial Bypass, JVS: Vascular Science (2023)

[2]Lauria A, Kersey A, Propper B, et al. *Annals of Vascular Surgery*. 2022 Apr 6:50890-5096(22)00180-7

- Six-year results from V002 published in *Journal of Vascular Surgery – Vascular Science*[1]
- Publication of First Eight Expanded Access Cases in *Annals of Vascular Surgery*[2]
- Preliminary results presented at Midwestern Vascular Surgical Society Meeting in September 2023 showing 86% limb salvage rate

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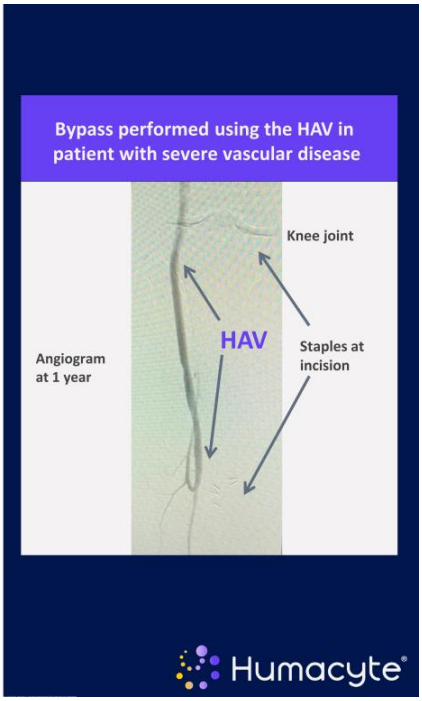
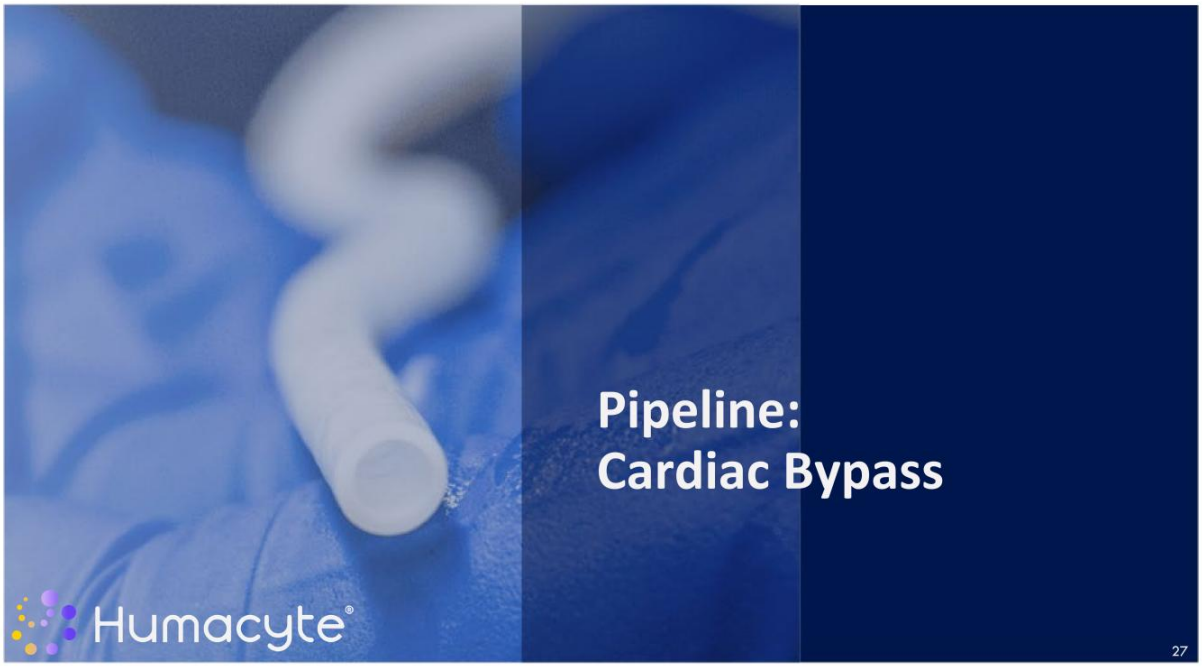
Expanded Access Case Study: Restoring Mobility with HAV

- The HAV was used under compassionate use program in 70-year-old patient with severe vascular disease
- No vein was available to perform a bypass, as the vein was previously harvested 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 HAV without significant stenosis at the distal anastomosis
- **Four years after HAV implantation, the patient continues to do well and is walking.**

VESS Vascular & Endovascular Surgery Society

This case was included in HAV results in critical limb ischemia presented at VESS meeting in January 2022




Pipeline:
Cardiac Bypass
Humacyte®
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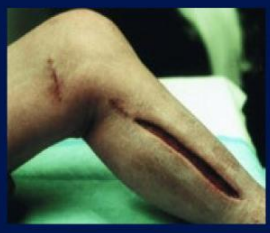
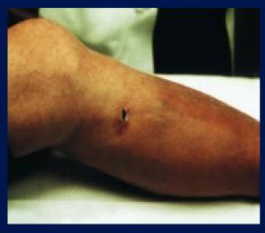
Potentially Transforming CABG Care: Greater Durability, Less Morbidity





- Saphenous 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®

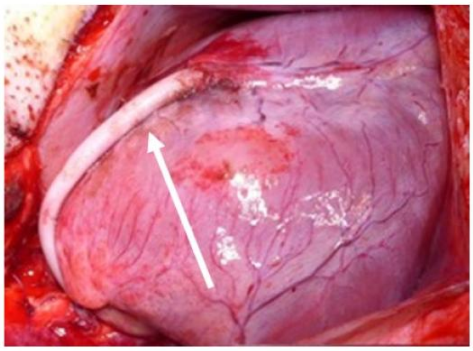
CABG Preclinical Results

American Heart Association. Scientific Sessions

Next Steps in CABG Development

Proceeding to IND enabling non-clinical studies to support first-in-human clinical trials

- Testing of HAV in baboon model has transitioned to right coronary artery (RCA) as distal target
- Results showing HAV maintained patency and exhibited host-cell remodeling through six months



Humacyte HAV in Baboon

Humacyte®

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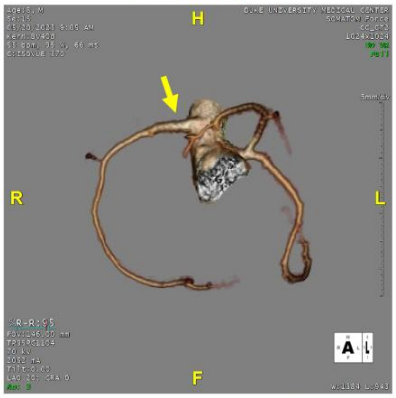
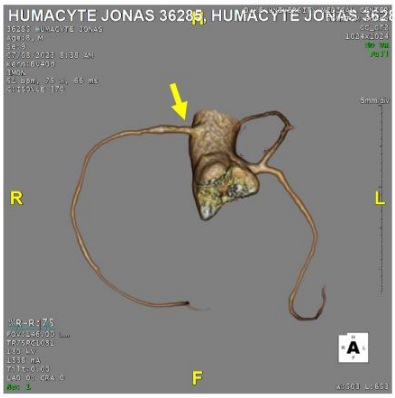
Primate – CABG Angiography – Adaptive Remodeling:

Humacyte

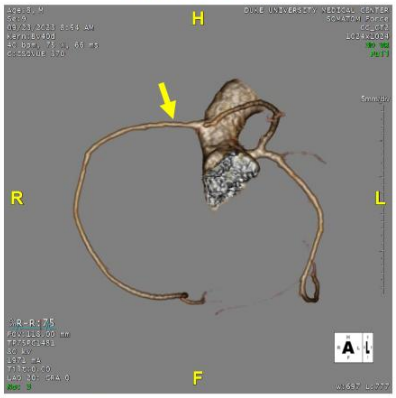
1 Month



3 Months



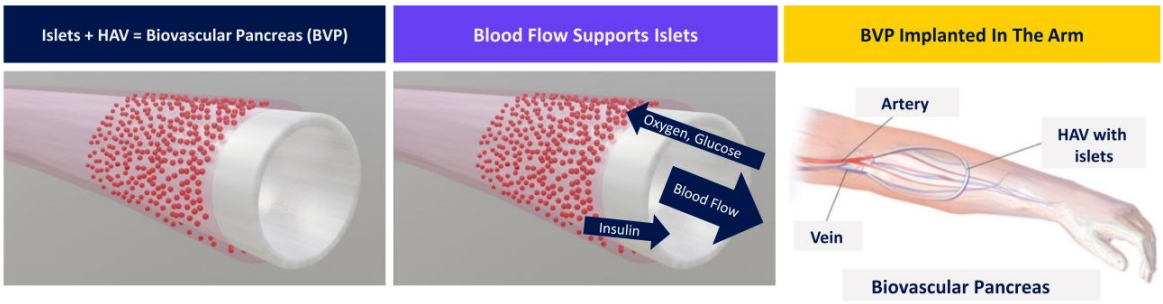
6 Months



Jonas – Left Ventricular Function (%)			
Pre-Op	1-Month	3-Month	6-Month
70%	73%	74%	73%


Pipeline:
BioVascular Pancreas
Humacyte®
31

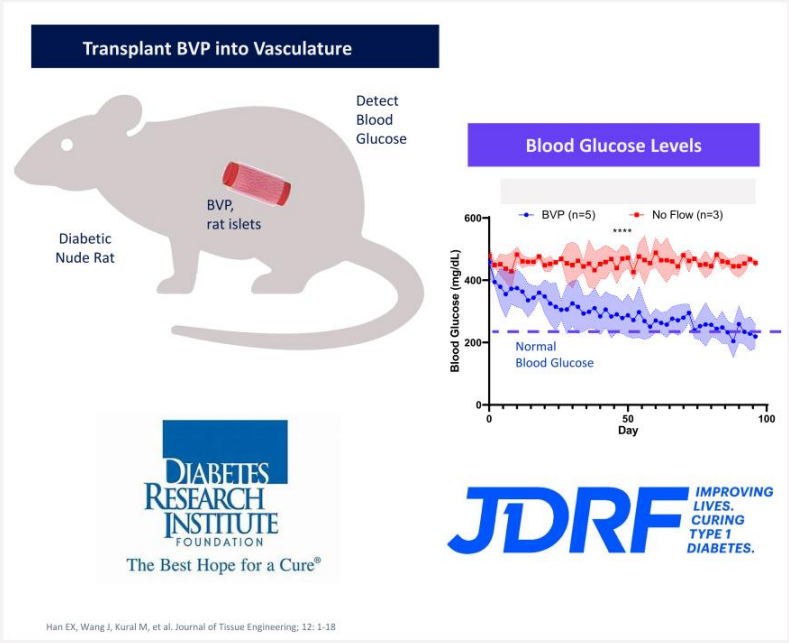
Biovascular Pancreas May Deliver Curative Islets to Diabetics



- Islets die after injection into the liver, due to lack of oxygen and nutrients
- Humacyte's HAV is being developed as a means to provide oxygen and nutrients to islets that are coated on the outside: "Biovascular Pancreas" (BVP)
- Once implanted in the vasculature, blood flow supplies oxygen and nutrients to islets
- One 42-cm HAV is expected to accommodate all the islets in an entire human pancreas

Biovascular Pancreas Normalized Glucose in Diabetic Animals

- Diabetic rodents implanted with BVPs
- All treated animals normalized glucose over time. All sham-treated animals ("No Flow") remained diabetic



DIABETES RESEARCH INSTITUTE FOUNDATION
The Best Hope for a Cure®

JDRF IMPROVING LIVES. CURING TYPE 1 DIABETES.

Han EX, Wang J, Kural M, et al. Journal of Tissue Engineering; 12: 1-18

Humacyte®

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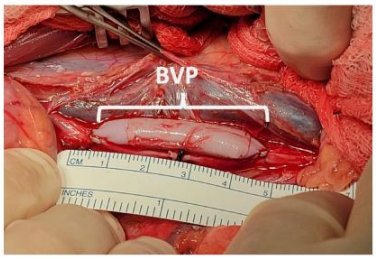
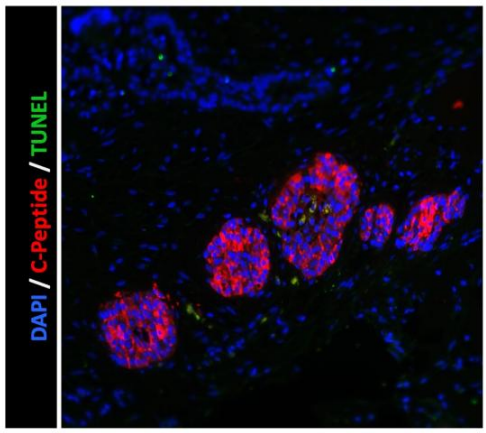
Primate BVP – Islets Survive, and Produce Insulin

- In this model, the BVP is produced by harvesting islets from one animal, and creating a BVP comprising human HAV and primate islets
- Animal receives the primate-islet BVP into the aorta
  - 25,600 islet equivalents
  - Corresponds to a potentially curative number of islets in a human



Islets survive for weeks after implantation, continue making insulin (c-peptide).




Anticipated
Path to Market
Humacyte®
35

Our Technology Addresses Compelling Unmet Needs in Attractive Markets

Humacyte

Vascular Tissue Constructs

Complex Tissue Constructs and Organ Systems

Pre-Clinical

Coronary Artery Bypass Graft (CABG)

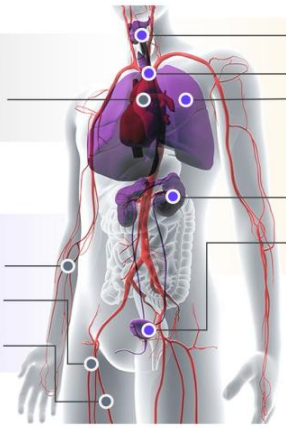
BT Shunt

Clinical Programs

Dialysis AV Access

Vascular Trauma

Peripheral Arterial Disease (PAD)



Trachea

Esophagus

Lung

Pancreas

Urinary Conduit

Pre-Clinical

Preparing for Strong Commercial Launch

Humacyte

Vascular Trauma is a Concentrated Market

US DEPT OF DEFENSE

- Majority of trauma vascular repair performed at Level 1 centers
- Approximately 200 level 1 trauma centers in U.S.
- Clear call point as majority of cases performed by vascular surgeons
- Humacyte expects DoD to stockpile for deployment to sites of conflicts

Compelling Health Economic Value Proposition for HAV

- Budget Impact Model expected to support economic benefit of HAV
- Costs associated with complications in vascular trauma potentially avoided with HAV:
  - Amputation
  - Infection
  - Harvest Site Infection
- Opportunity for incremental CMS and private pay NTAP payment

Experienced Hospital / Surgical Sales Professionals

- Estimate we can reach market with fewer than 20 sales representatives
- Direct force expected to secure hospital approvals through VACs and also drive adoption by vascular surgeons

FRESENIUS MEDICAL CARE

Strategic Collaboration

- Large shareholder with $175 million invested in Humacyte
- Global collaboration for HAV in trauma, dialysis and PAD
- Largest provider of renal care services in the U.S.

Commercial Manufacturing Scale – LUNA200 System

Bioreactor bag

Each bioreactor bag contains a single polymer mesh scaffold, seeded with banked human cells

Growth drawer

10 bioreactor bags per growth drawer; tubing connects to shared nutritive media

LUNA200 System

Each LUNA200 can produce 200 HAVs per batch (or ~1,000 HAVs annually) [1]

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

Humacyte®

Anticipated 2024 Milestones

Completed in 2023

Vascular Trauma (HAV):

- *Completion and positive results from V005 Phase 2/3 trial* ✓
- *Positive Ukraine humanitarian trauma results* ✓
- ***BLA submission*** ✓

Completion of enrollment of Phase 3 HAV dialysis trial ✓

Positive Phase 2 results from PAD trial conducted by Mayo Clinic ✓

Preclinical BVP results showing survival and function of islets ✓

Anticipated for 2024

Vascular Trauma (HAV):

- BLA filing acceptance by FDA
- FDA approval
- U.S. commercial launch

Top-line results V007 HAV dialysis (AV Access) Phase 3 trial

Publication of Mayo Clinic HAV Phase 2 trial results in severe PAD

BioVascular Pancreas (BVP) for type-1 diabetes:

- Results from preclinical studies showing survival and function of islets cells in large animals and diabetes models

Results from large animal studies of small-diameter HAV in Cardiac Bypass Surgery (CABG)

Publications & Presentations
(Multiple other clinical and preclinical publications and presentations expected for 2024)

All milestone dates are only management estimates

The Promise of Regenerative Medicine

Bioengineering Platform

Broad platform of universally implantable off-the-shelf bioengineered human tissues and organs

Extensive Markets

Platform targets extensive markets across multiple indications

Commercial Scale Manufacturing

Existing facilities expected to support anticipated commercial launch with room for modular expansion

Humacyte®


Humacyte
Universally Implantable
Regenerative Human Tissue
Thank You
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