



Navigating Translation of Engineered Tissues

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September 2021

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; the commercialization of 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; 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; statements regarding our markets, including the estimated size and anticipated growth in those markets. The HAVs are investigational and have not been approved by the FDA for any indication to date. 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. Except as required by law, we assume no obligation to update these forward-looking statements, even if new information becomes available in the future.

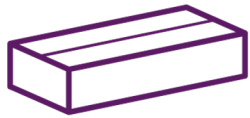
TRANSLATION OVERVIEW

Humacyte is pioneering the development and manufacture of off-the-shelf, universally implantable, bioengineered human tissues

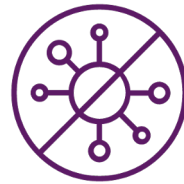


KEY FEATURES OF HUMACYTE TECHNOLOGY

Potential benefits of HAVs evaluated in completed and ongoing clinical trials across multiple indications



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



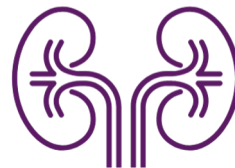
HAV is highly
resistant to infection



No evidence of
immunogenicity



Host cells repopulate
the HAV

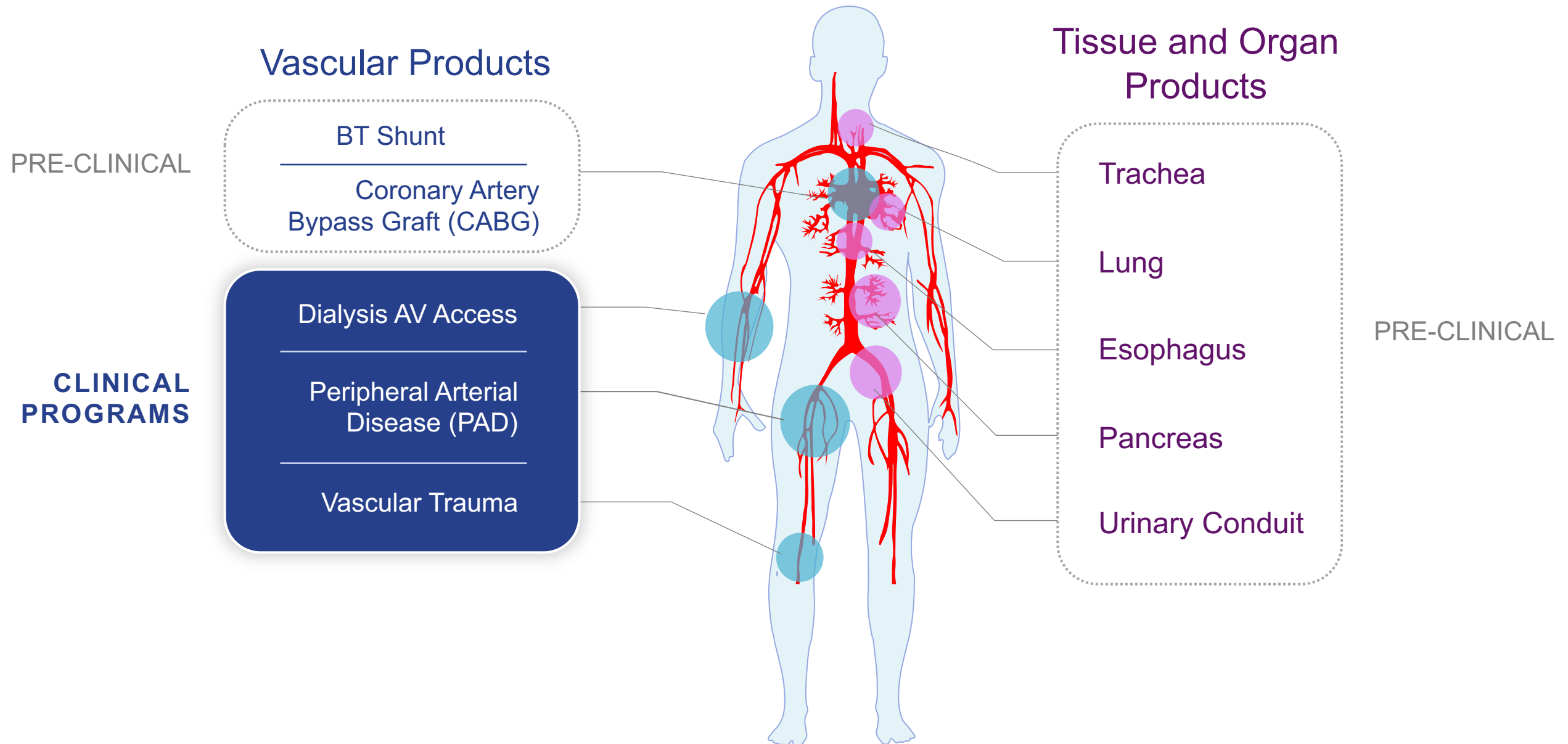


For ESRD patients,
accessible for dialysis
access within one
month of implantation

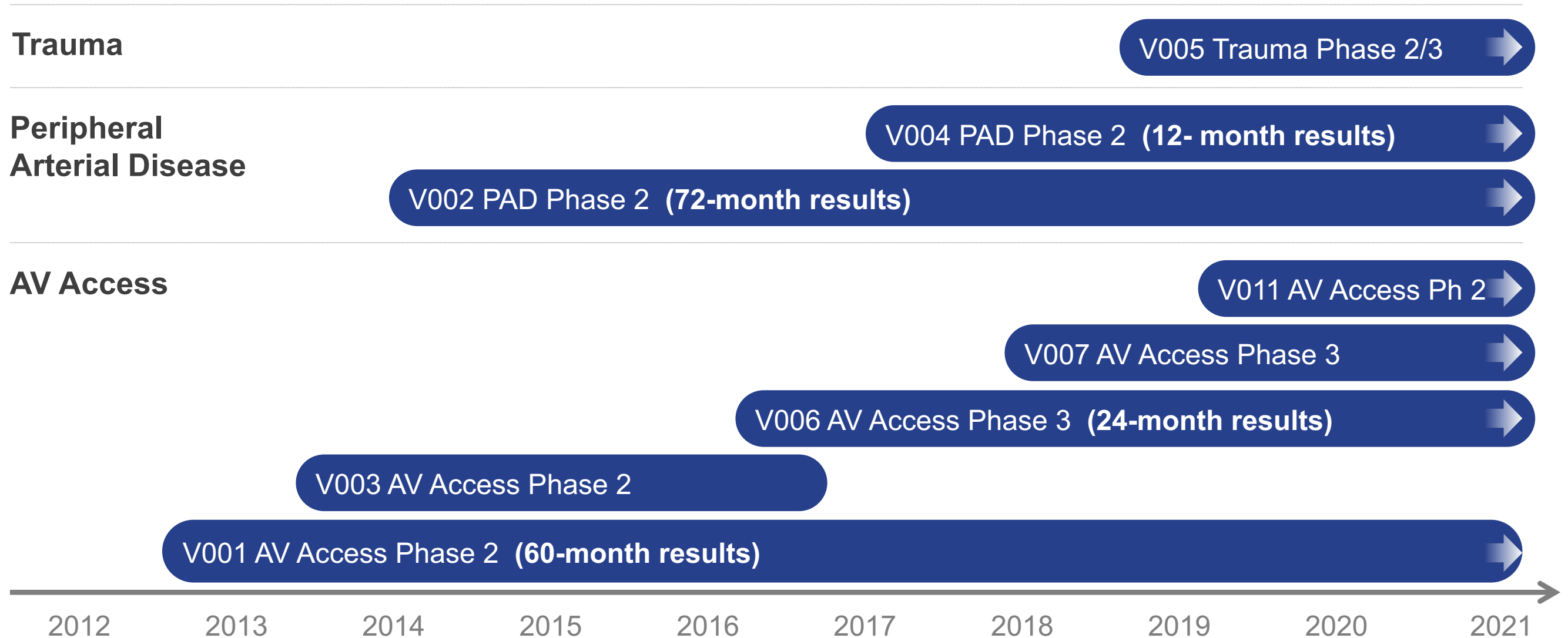


Long-term durability
is demonstrated in
ongoing studies

HUMACYTE'S PRODUCTS ARE BEING STUDIED TO TREAT DISEASE THROUGHOUT THE BODY



EXTENSIVE CLINICAL EXPERIENCE IN VARIED PATIENT COHORTS



HAVs have been implanted into hundreds of patients over more than 8 years.

LESSON #1: IF POSSIBLE, DESIGN PHASE 1 FOR SAFETY AND EFFICACY READOUTS

As trials of other cell therapies have shown, (some types of MSC, for example) simple safety does not create much value, in and of itself:

- Most cell therapies are deemed safe at the Phase 1 stage
- You don't learn much about your product in advance of Phase 2 or 3
- Huge investment of time and money to get into humans with new therapy

Advantages of building some Efficacy readout into Phase 1:

- Magnitude of therapeutic effect helps with Phase 2/3 trial design
- Value proposition of the product is clearer to company and investors
- “Fail early” mentality: “if this does not work, then we should know now”

LESSON #2: SIZE MANUFACTURING AND CONTROLS FOR CLINICAL STAGE (full cGMP is not required for Phase 1, for example)

Phase 1 / 2

Phase 3

Phase 3 / Commercial

Modular Manufacturing System

Bioreactor bag



Bag contains a single polymer mesh scaffold



Growth drawer



10 bioreactor bags per growth drawer



LUNA200 system



LUNA200 can produce 200 HAVs per batch (or ~1,000 HAVs/yr)

Commercial 83,000 sq ft Bioprocessing Facility



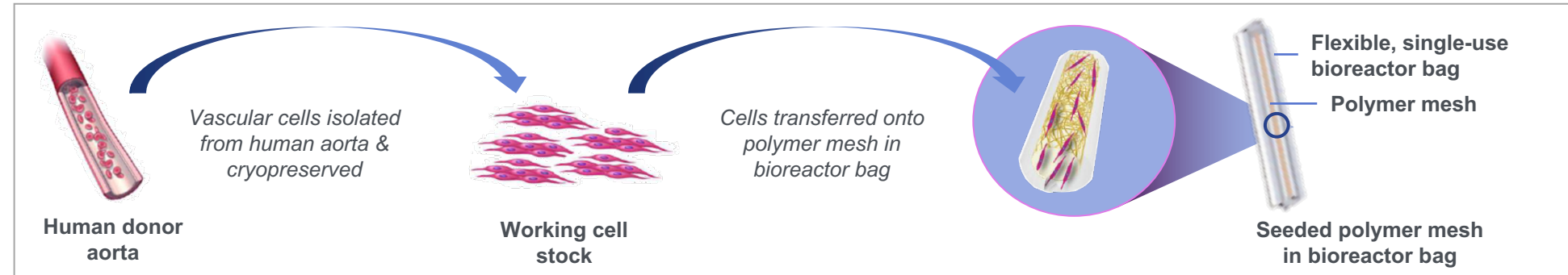
- Currently operating 8 LUNA200 systems
- Annual Capacity expected to exceed 40,000 HAVs
- Functionally closed system with state-of-the-art process automation

LESSON #3: RESPECT THE BIOLOGY AS YOU SCALE YOUR PROCESS

The Cells “Rule the Roost”

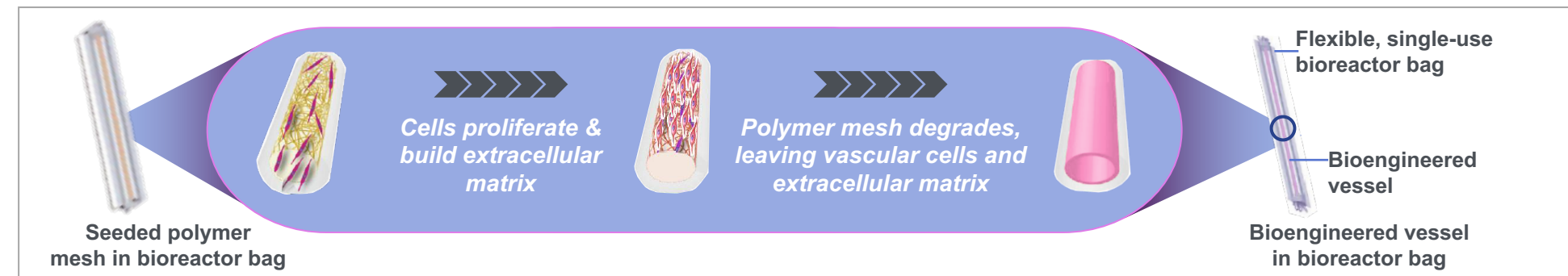
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Cell seeding



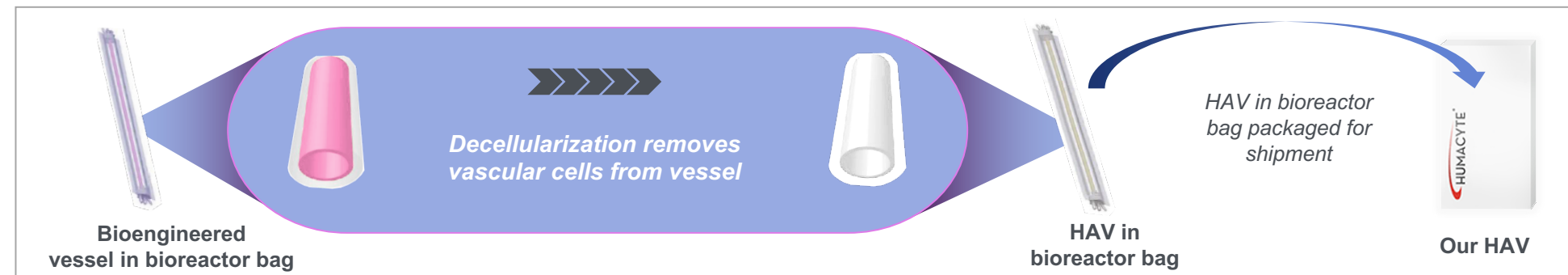
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Tissue formation



3

Cell removal and packaging



LESSON #4: The Hammer and the Nail: Find the *RIGHT NAIL* to hit with your *HAMMER*

Potential Use of the HAV in Acute Vascular Trauma

Saphenous Vein Grafts



- Harvesting vein adds an hour or more of operative time ¹
- Delayed revascularization significantly increases amputation risk

ePTFE Grafts



- > 50% infection rate ³
- Mortality rate when ePTFE is infected: 8-30%⁴
- Median length of stay 11 days if re-admitted for graft infection

Humacyte HAV



- Off the shelf; no need to harvest vein
- Outstanding primary patency
- Data suggest meaningful reduction in rate of infection compared to ePTFE

1) Alarhayem, A.Q., et al, Journal of Vascular Surgery 2019; 69: 1519-1523.

2) Kauvar, D.S., et al, Journal of Vascular Surgery 2011; 53: 1598-603.

3) Siracuse, J.J. et al, Journal of Vascular Surgery 2013; 57: 700-705.

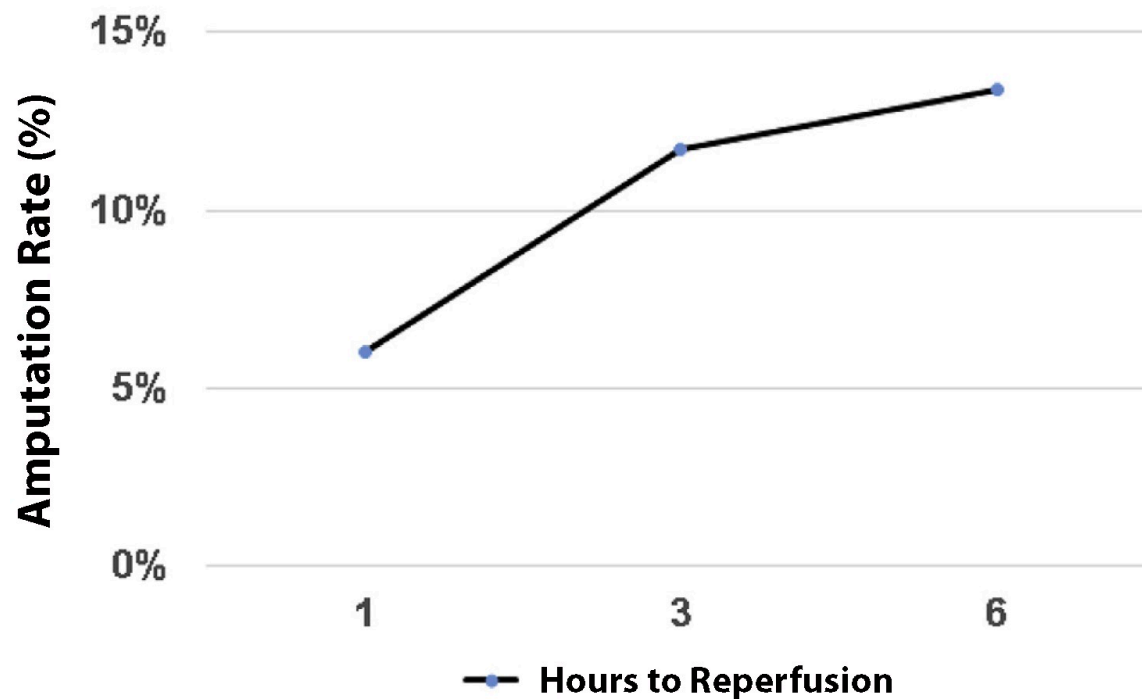
4) Andercou, O., et al, Medicine 2018; 97:27(e11350).

Source: Humacyte

LESSON #4 (cont)

IN TRAUMA, TIME TO RE-VASCULARIZATION IS CRITICAL

Amputation Risk and Revascularization Time



- In vascular trauma: **quicker revascularization significantly reduces risk of amputation.** ¹
- **Extending time to revascularization** to 6 hours (“clinical standard”) doubles rate of amputation compared to 1 hour.
- **Steep increase in amputation rate** as revascularization time approaches 3-4 hours after initial injury. ²
- **Lower extremity trauma** comprises the clear majority of civilian and military vascular trauma.
- With current standard of care (vein, ePTFE), **overall amputation rate is approximately 13%.** ²
- ePTFE rarely used; saphenous vein takes an hour to harvest.

1) Alarhayem A.Q. et al, 2019; *Journal of Vascular Surgery*
 2) Glass, G. et al. 2009; *Journal of Plastic and Reconstructive Surgery*.

LESSON #5: KEEP YOUR HAND IN, IF POSSIBLE

Blending Pre-Existing Science with Commercial / Manufacturing Know-How

Technical hurdles will come in abundance as you develop a new therapy

- Resolute focus on what will constitute a therapeutic effect
- Navigate continuous pressures to speed timelines and reduce costs
- No substitute for therapeutic efficacy: the Cells Rule the Roost
- Amazingly, almost all technical problems are solvable, with sufficient effort (!!!)

Philosophy on Biotech Success Has Evolved Over the Last Decade

- Prior mantra was “get the founder out, the the experts in”
- Scientific founder’s value is in keeping the science on track, avoiding the “kool-aid”
- **Flexibility in clinical problem, trial design, speed of scale-up is important**
- **Flexibility on the science, or on product quality, will never win the day**

THANK YOU !!!

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