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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM 10-K**

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(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2021

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 001-39532

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**Humacyte, Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**85-1763759**

(I.R.S. Employer Identification No.)

**2525 East North Carolina Highway 54**

**Durham, NC**

(Address of principal executive offices)

**27713**

(Zip code)

**(919) 313-9633**

(Registrant's telephone number, including area code)

Securities registered pursuant to 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

Securities registered pursuant to 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports); and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer   
Non-accelerated filer

Accelerated filer   
Smaller reporting company   
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.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of June 30, 2021, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of common stock held by non-affiliates of the registrant was approximately \$102.4 million (based on the closing price of the registrant's common stock as reported on The Nasdaq Global Select Market on that date).

As of February 28, 2022, 103,004,572 shares of common stock, par value \$0.0001, were issued and outstanding.

#### **DOCUMENTS INCORPORATED BY REFERENCE**

None.

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## FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. “Forward-looking statements,” as that term is defined in the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the “Exchange Act”) are statements that are not historical facts and involve a number of risks and uncertainties. These statements include, without limitation, statements regarding the financial position, business strategy and the plans and objectives of management for future operations. These statements constitute projections, forecasts and forward-looking statements, and are not guarantees of performance. Such statements can be identified by the fact that they do not relate strictly to historical or current facts. When used therein, words such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “strive,” “would” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Such statements are based on the beliefs of, as well as assumptions made by and information currently available to, our management.

Forward-looking statements may include, for example, statements about:

- 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 plans and ability to execute product development, process development and preclinical development efforts successfully and on our anticipated timelines;
- our ability to use our proprietary scientific technology platform to build a pipeline of additional product candidates;
- the characteristics and performance of our bioengineered human, acellular tissue-based vessels (“HAVs”);
- our plans and ability to obtain marketing approval from the U.S. Food and Drug Administration (“FDA”) and other regulatory authorities, including the European Medicines Agency (“EMA”), for our bioengineered HAVs and other product candidates;
- 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 ongoing V005 Phase II/III clinical trial and V007 Phase III clinical trial;
- the outcome of our ongoing discussions with the FDA concerning the design of our ongoing V005 Phase II/III clinical trial, including determination of trial size;
- 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. (“Fresenius Medical Care”) 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 COVID-19 pandemic on our business, including our manufacturing efforts, and our preclinical studies and clinical trials.

We caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. Any forward-looking statement is based on information current as of the date of this Annual Report on Form 10-K and speaks only as of the date on which such statement is made. Actual events or results may differ materially from the results, plans, intentions or expectations anticipated in these forward-looking statements as a result of a variety of factors, many of which are beyond our control. More information on factors that could cause actual results to differ materially from those anticipated is included from time to time in our reports filed with the Securities and Exchange Commission (the “SEC”), including, but not limited to, those described in the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in this Annual Report on Form 10-K. We disclaim any obligation, except as specifically required by law, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

## PART I

### Item 1. Business

#### Business Overview

##### *Executive Summary*

Humacyte, Inc. is pioneering the development and manufacture of off-the-shelf, universally implantable, bioengineered human tissues with the goal of improving the lives of patients and transforming the practice of medicine. We believe our technology has the potential to overcome limitations in existing standards of care and address the lack of significant innovation in products that support tissue repair, reconstruction and replacement. We are leveraging our novel, scalable technology platform to develop proprietary, bioengineered, acellular human tissues for use in the treatment of diseases and conditions across a range of anatomic locations in multiple therapeutic areas.

We are initially using our proprietary, scientific technology platform to engineer and manufacture human acellular vessels, or HAVs. Our investigational HAVs are designed to be easily implanted into any patient without inducing a foreign body response or leading to immune rejection. We are developing a portfolio, or “cabinet”, of HAVs with varying diameters and lengths. The HAV cabinet would initially target the vascular repair, reconstruction and replacement market, including vascular trauma; arteriovenous (“AV”) access for hemodialysis; peripheral arterial disease (“PAD”); and coronary artery bypass grafting (“CABG”). In addition, we are developing our HAVs for pediatric heart surgery and the delivery of cellular therapies, including pancreatic islet cell transplantation to treat Type 1 diabetes. We will continue to explore the application of our technology across a broad range of markets and indications including the development of urinary conduit, trachea, esophagus and other novel cell delivery systems.

We believe there is substantial clinical demand for safe and effective vascular conduits to replace and repair blood vessels throughout the body. Vascular injuries resulting from trauma are common in civilian and military populations, frequently resulting in the loss of either life or limb. Existing treatment options in the vascular repair, reconstruction and replacement market include the use of autologous vessels and synthetic grafts, which we believe suffer from significant limitations. For example, the use of autologous veins to repair traumatic vascular injuries can lead to significant morbidity associated with the surgical wounds created for vein harvest and prolonged times to restore blood flow to injured limbs, leading to an increased risk of amputation and infection. Synthetic grafts are often contraindicated in the setting of vascular trauma due to higher infection risk that can lead to prolonged hospitalization and limb loss. Given the competitive advantages our HAVs are designed to have over existing vascular substitutes, we believe that HAVs have the potential to become the standard of care and lead to improved patient outcomes and lower healthcare costs.

As of December 31, 2021, our HAVs have been implanted in approximately 471 patients. We are currently conducting Phase II and Phase III trials of our 6 millimeter HAV across two therapeutic indications, vascular trauma and AV access for hemodialysis, as well as continuing long-term follow up of patients in our Phase II PAD studies. We were granted Fast Track designation by the FDA for our 6 millimeter HAV for use in AV access for hemodialysis in 2014. We also received the first Regenerative Medicine Advanced Therapy (“RMAT”) designation from the FDA, for the creation of vascular access for performing hemodialysis, in March 2017. In addition, in 2018 our HAV product candidate 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. Upon completion of our Phase III trials, we intend to submit a Biologics License Application (“BLA”) to the FDA for an indication in vascular trauma in 2022 or 2023 and AV access for hemodialysis in 2023.

We have developed a novel paradigm for manufacturing human tissues that is intended to mimic key aspects of human physiology. We have an 83,000 square foot bioprocessing facility housing our modular manufacturing process with the ability to manufacture HAVs of different diameters and lengths at commercial scale. As we continue to expand production, we believe we will have the ability to take advantage of economies of scale to reduce costs of production. We believe our established, controlled manufacturing process demonstrates a significant competitive advantage in the regenerative medicine market.

Our technology is protected by our patent portfolio, which includes certain patents licensed from parties as well as intellectual property generated internally at Humacyte. Our patent portfolio is comprised of 15 families of patents, many of which generally relate to the scaffolds used to make our vessels, the composition of our vessels and systems and methods of manufacturing our vessels. For more information, see “— Intellectual Property” below.

We intend to continue to shape our commercial and distribution strategy by indication and pursue collaborations with partners in markets where such partners provide strategic opportunities in launching our product candidates and enabling access to specific patient populations.

Our world-class senior management team and board of directors will be instrumental in helping us achieve our goals. Our President and Chief Executive Officer, Laura Niklason M.D., PhD., who founded Legacy Humacyte (as defined below), is an internationally respected physician scientist and a world leader in regenerative medicine technologies. Dr. Niklason is also a member of three national academies — Inventors, Medicine and Engineering. Our current Chairman of the Board is Kathleen Sebelius, the former Secretary of the Department of Health and Human Services (“HHS”), and the former Governor of Kansas.

### ***Merger***

On August 26, 2021 (the “Closing Date”), Humacyte, Inc. (“Legacy Humacyte”), a Delaware corporation, and Alpha Healthcare Acquisition Corp. (“AHAC”), a Delaware corporation, consummated a merger pursuant to that certain Business Combination Agreement, dated as of February 17, 2021 (the “Merger Agreement”), by and among Legacy Humacyte, AHAC and Hunter Merger Sub (“Merger Sub”), a Delaware corporation and wholly owned subsidiary of AHAC. As contemplated by the Merger Agreement, Merger Sub merged with and into Legacy Humacyte, with Legacy Humacyte continuing as the surviving corporation and as a wholly owned subsidiary of AHAC (the “Merger”). On the Closing Date, AHAC changed its name to Humacyte, Inc. and Legacy Humacyte changed its name to Humacyte Global, Inc.

Unless the context indicates otherwise, references in this Annual Report on Form 10-K to the “Company,” “Humacyte,” “we,” “us,” “our” and similar terms refer to Humacyte, Inc. (formerly known as Alpha Healthcare Acquisition Corp.) and its consolidated subsidiaries (including Humacyte Global, Inc.) following the Merger. References to “AHAC” refer to Alpha Healthcare Acquisition Corp. prior to the Merger.

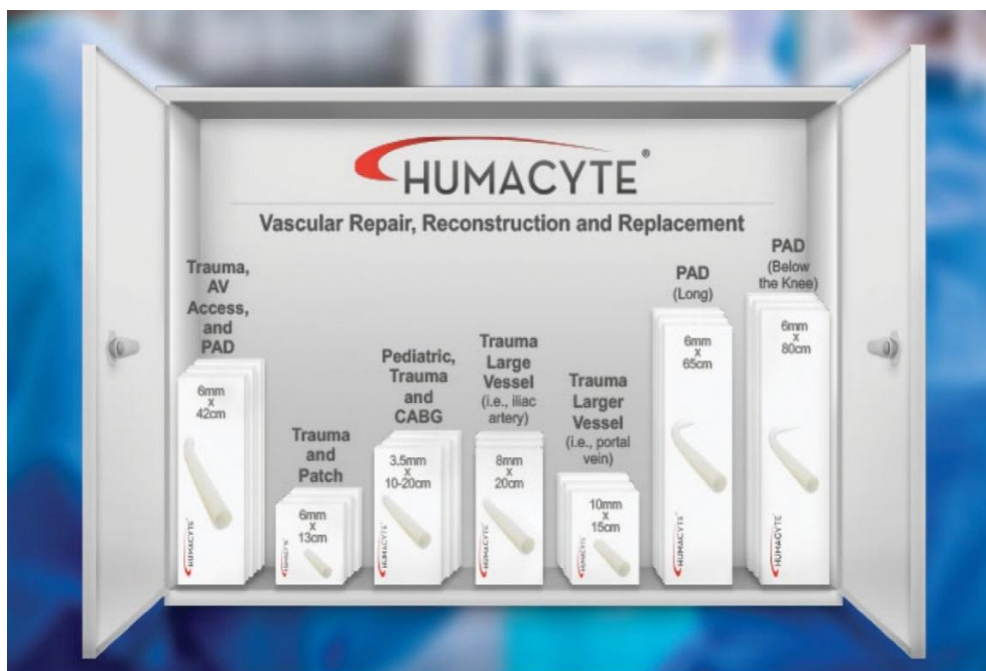
### ***Our Approach***

We have developed an approach that relies on two key complementary elements to address the significant market opportunity for the global treatment of patients in need of vascular replacement, repair and reconstruction, vascular access for dialysis and potential future indications including complex tissue and organ replacement and treatment of Type-1 diabetes:

- our proprietary scientific and engineering technology platform allows us to grow human tissues, which are ultimately decellularized and therefore expected to be non-immunogenic and universally implantable; and
- our novel, scalable manufacturing paradigm is designed to allow us to produce thousands of HAVs per year at the time of commercial launch, with the ability to expand manufacturing to meet expected future global demand and the planned expansion of our pipeline of product candidates.

In the first employment of these platform and manufacturing approaches, we intend to develop a readily available “cabinet” of HAVs of varying diameters and lengths to address the significant unmet needs across multiple potential indications in vascular repair, reconstruction and replacement.

*Illustration of our Proposed HAV “Cabinet” for Vascular Repair, Reconstruction, and Replacement*

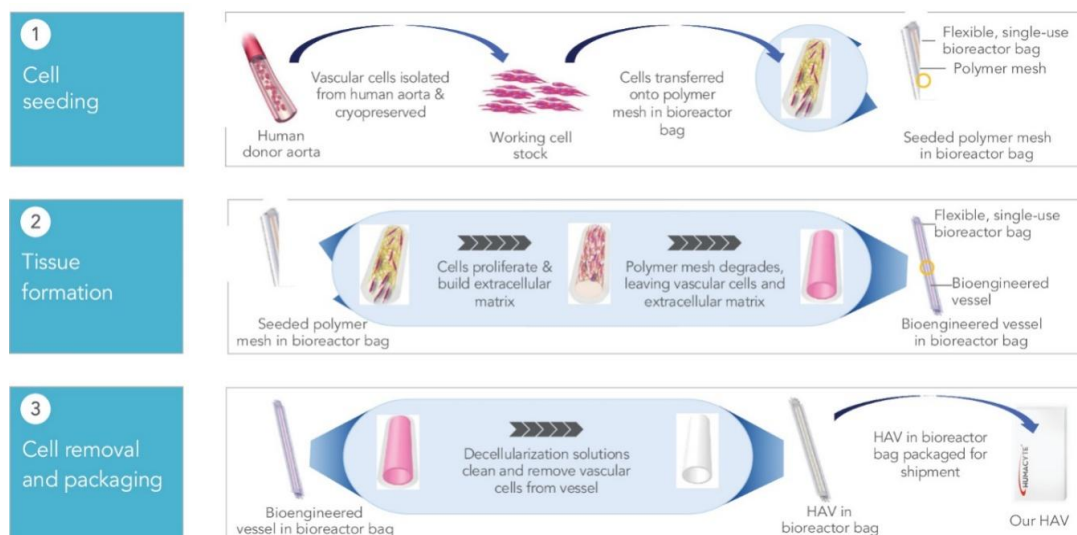


***Our Proprietary Scientific Technology Platform***

Our proprietary scientific technology platform uses primary human aortic vascular cells from a working cell stock, isolated from donor tissues and cryopreserved. The working cell stock is expanded using traditional cell culture techniques, and the cells are transferred onto a biocompatible, biodegradable polymer mesh within a flexible, single-use bioreactor bag. Over the course of weeks, the cells proliferate and build extracellular matrix while the polymer mesh degrades. The resulting bioengineered vessel is comprised of the aortic vascular cells and their deposited extracellular matrix. After completion of the culture period, we decellularize the bioengineered vessel using a proprietary combination of solutions. The resulting HAV retains the extracellular matrix constituents and, therefore, the biomechanical properties of the bioengineered vessel, but is cleansed of the cells and cellular components that could induce a foreign body response or immune rejection following implantation. Our functionally closed system allows for the HAV to be grown, decellularized and ultimately shipped within the same flexible bioreactor bag. Our HAVs are designed to be shipped to hospitals, trauma centers and outpatient surgical settings, where they can then be stored at refrigerated temperatures for immediate use by removing each HAV from its packaging.



The following image summarizes key information about our proprietary scientific technology platform:

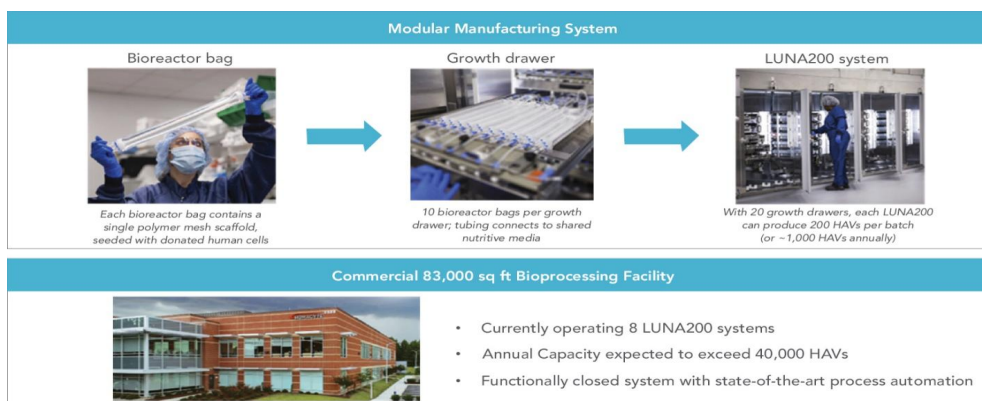


### ***Our Novel Manufacturing Paradigm***

We have developed a novel paradigm for manufacturing human tissues that is intended to mimic key aspects of human physiology. Our proprietary manufacturing process was designed with a modular approach allowing us to produce HAVs in smaller batches for clinical trials and scale out to larger batches for commercial manufacturing. The system used in our clinical trials from 2016 to 2021, including our Phase III trials, utilized a single tray within one growth drawer holding 10 HAVs per batch. In 2021 we commenced supplying our ongoing clinical trials with HAVs produced in our current, commercial-scale LUNA200 system, which consists of 20 growth drawers per production unit for a total of 200 HAVs per batch. Each growth drawer is capable of producing ten 42cm HAVs, each of which is contained within an individual bioreactor bag. Inside a LUNA200, a tubing network connects all HAVs, allowing the entire system to share nutritive media. In this way, a single LUNA200 can produce up to 200 HAVs (42cm in length) per batch while maintaining the critical operating parameters, such as biomechanical pulsing, that affect growth.

A thorough comparability assessment was performed to evaluate HAV batches produced in the single drawer system and used in Phase III studies versus the 20-drawer LUNA200 system. The study assessed 22 separate comparisons on the identity, strength, quality, purity, and potency of the HAV product. In this study, we observed that HAVs produced in the LUNA200 system were comparable to HAVs used in our Phase III trials. Additionally, a crossover study, called V011, completed enrollment of 30 subjects to evaluate HAVs that are manufactured on Humacyte's commercial LUNA200 platform with the primary goal to evaluate the safety, efficacy and immunogenicity of the LUNA200-manufactured HAVs. Thus far in this trial we have observed comparable safety profile between HAV used in previous studies and the HAV manufactured in the LUNA200 commercial system. The results of the comparability assessment and the 30-day results from the V011 crossover study were submitted to the FDA. In 2021, the FDA authorized the use of HAVs produced in the commercial LUNA200 system to supply our ongoing clinical trials. We plan to also use the LUNA200 system for anticipated commercial launches of the HAV if it is approved.

Our current 83,000 square foot manufacturing facility has space to further expand manufacturing capacity as needed to over 40 LUNA200 systems. Currently, eight LUNA200 systems are installed and operational.



We believe that the LUNA200 can produce HAVs in diameter sizes from 3mm to 10mm and lengths from 10cm to 42cm, making the equipment suitable for the varied array of product candidates in our pipeline. We intend to introduce a 13cm-long HAV line extension after commercial launch of the 42cm HAV for surgeries that require shorter segments of HAV in the setting of vascular trauma and repair. Using our existing LUNA200 manufacturing equipment without modification, we believe we have the ability to generate 400 HAVs (13cm in length) or 200 HAVs (42cm in length) per manufactured batch. We have designed our manufacturing system to be functionally closed, to utilize single-use disposable materials with aseptic connections, and to be fully automated, which allows us to control and maximize HAV production.

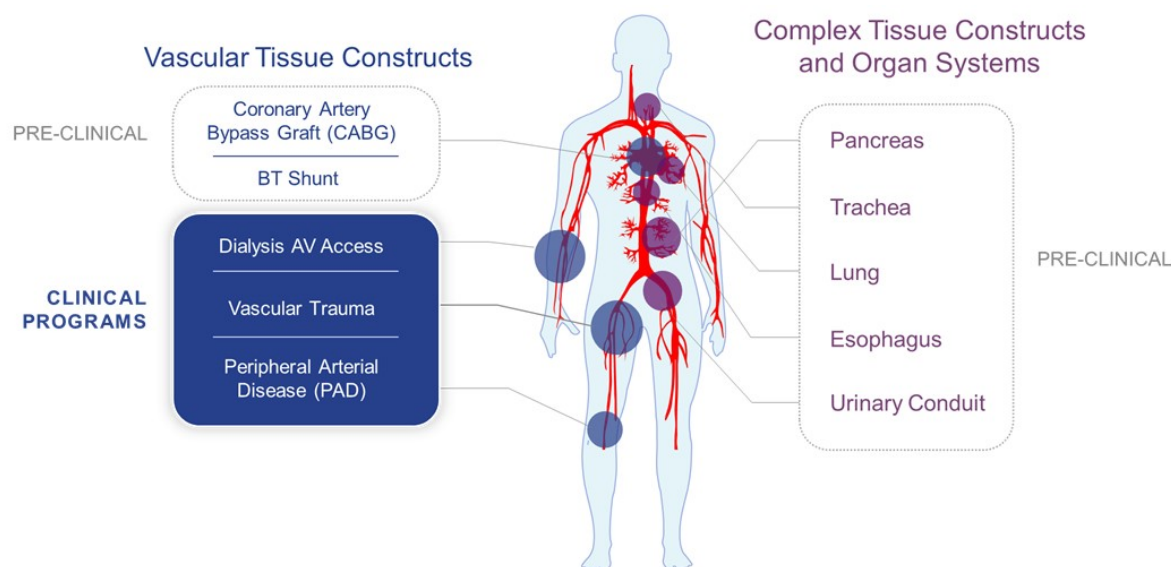
Based on observations to date, the HAV has withstood maximal pressures that are comparable to those reported for native arteries. For example, the human aorta is reported to have rupture strengths around 1,400 mmHg, while human cerebral arteries rupture around 1,800 mmHg. We have observed HAVs withstanding maximal pressures of approximately 3,200 mmHg before rupturing, making their mechanical properties on par with native human blood vessels.

### ***Our Market Opportunity***

We are a biotechnology company with Phase III clinical trials in two indications and a strong pipeline for additional products and indications. Additionally, we have had significant interest from surgeons to use our HAV in life and limb saving surgeries as demonstrated by their requests to the FDA to use our HAV in multiple expanded access (compassionate use) cases where no alternative was available.

### ***Our Initial Market Opportunity in Vascular Repair, Reconstruction and Replacement***

We believe there is a significant market opportunity for our technology across a number of important clinical areas within vascular reconstruction and replacement including vascular trauma, AV access for hemodialysis, peripheral arterial disease, and adult cardiac surgery. To treat these diseases and conditions, patients often require invasive cardiovascular surgery, which involves the use of alternative vascular synthetic materials or autologous vessels harvested from elsewhere in the body. For more information about our evaluation of market opportunity, see "Risk Factors — Risks Related to the Development and Commercialization of Our Product Candidates — The sizes of the market opportunities for our product candidates have not been established with precision and are estimates that management believes to be reasonable. If these market opportunities are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the relevant patient population, our revenue and ability to achieve profitability might be materially and adversely affected."



**Vascular Trauma:** Arterial injuries resulting from vascular trauma are common in military and civilian populations, frequently resulting in the loss of life or limb. In military populations, as the rate of battlefield fatalities has been declining due to faster evacuations and more robust protection from body armor, the rate of survivable vascular injuries has been increasing. In civilian populations, trauma injuries are primarily caused by motor vehicle accidents, gun violence, mass casualty terrorist attacks, stabbings and blunt trauma. We estimate that central or peripheral vascular injuries in civilian patients account for approximately 150,000 of all injuries reported in global trauma patients. Furthermore, these injuries account for greater than 20% of all trauma-related deaths.

Civilian patients with central or peripheral vascular injuries are estimated to account for approximately 75,000 of all injuries reported in trauma patients in the United States, inclusive of urgent and iatrogenic vascular trauma injuries. However, these injuries account for greater than 20% of all trauma-related deaths.

We believe our HAVs will be a promising alternative that can address critical gaps in existing treatment options for acute vascular injuries due to trauma. We are developing our HAVs with the goal of providing an effective solution in all time-constrained surgical environments and in resource-limited, infection prone battlefield environments. The ability to create immediately available, non-immunogenic, universally implantable material that is less susceptible to infection represents a clinically significant advantage over existing options.

**Arteriovenous Access for Hemodialysis:** An estimated \$5 to \$6 billion per year is spent on hospital admissions in hemodialysis patients with infection and access complications. In 2017, there were nearly 500,000 patients receiving hemodialysis in the United States. Annually, at least 160,000 existing or new dialysis patients require a new AV access in the U.S. and an additional 150,000 patients require a new AV access in Europe and Japan.

Hemodialysis patients are a chronically ill patient population, suffering an average of 1.8 hospital admissions, three visits to the emergency department, and four days hospitalized for infections each year. The two most common causes of hospital admissions in hemodialysis patients are infection and access complications, resulting in an estimated total spend of \$5 billion to \$6 billion per year. For hemodialysis patients, an infected access can lead to sepsis, which is life threatening, is the most expensive cause for hospitalization in the United States and carries at least a 10% overall mortality rate.

We believe that our HAVs, when used as AV access for hemodialysis, can decrease infections and dialysis access failures, which would improve patient outcomes and lower the burden of dialysis costs on the healthcare system. We expect to file a BLA with the FDA, seeking approval for the use of HAV in AV access for hemodialysis, and to target our commercialization efforts particularly toward those patients who are at high risk of fistula failure or non-maturation, or for those patients at high risk of vascular access infection.

**Peripheral Artery Disease (PAD):** PAD is a cardiovascular disease of blood vessels located outside the brain and heart. PAD occurs when plaque builds up in arteries that carry blood to the head, organs, and limbs. PAD usually affects arteries in the legs, but it can also affect arteries that carry blood from heart to head, arms, kidneys, and stomach. We believe our

HAVs can be used as a bypass conduit in patients with PAD. Peripheral arterial bypass procedures are common with as many as 160,000 PAD related procedures reported annually in the U.S. and over 550,000 annual PAD procedures estimated globally. Expanding into markets outside the U.S., annual peripheral bypass procedures are nearly 170,000 per year in Europe, and approximately 220,000 per year in Asia.

While endovascular techniques have become available over the past ten years to treat an array of vascular occlusions, depending on the nature and length of the blockage these types of treatment options have met with both mixed success and durability compared to conventional surgical bypass. Both angioplasty and stenting procedures provide near term success, however long-term durability has remained a question.

**Type 1 Diabetes:** Type 1 diabetes, caused by auto-immune destruction of insulin-producing cells in the islets of the pancreas, is a devastating disease affecting more than 1.2 million people in the United States, and costing at least \$10 billion to \$14 billion annually. In Europe, the number of patients suffering with Type 1 diabetes is estimated at approximately 2.2 million. Even with the newer insulin delivery technologies, less than one-third of patients achieve consistent target blood sugar levels.

Pancreas transplantation is limited due to the associated morbidity and cost of the whole pancreas organ transplantation procedure. As an alternative to pancreas transplantation, the “Edmonton Protocol” has been developed whereby insulin producing cells are transplanted into the portal vein in the liver. However, the majority of the injected cells are lost to inflammation and clotting, and only 16% of Type 1 diabetes patients who receive the Protocol are cured long term.

We believe our HAVs present a means to deliver a therapeutic number of pancreatic islets to patients with Type 1 diabetes. Pancreatic islets are embedded on the outer surface of our HAV and implanted as an AV graft, analogous to the outpatient procedure done for hemodialysis access. After implantation, the islets have the potential to sense blood glucose and then respond by secreting appropriate levels of insulin to maintain glucose levels in the blood. We have termed this new paradigm for pancreatic islet cell delivery the “Biovascular Pancreas.” Proof-of-concept studies in rodents and pigs have shown promise that the BVP can reduce glucose levels. Studies in non-human primates are planned.

We believe that a reliable, low-risk, and easily implantable islet cell delivery method that could ensure the survival and functionality of a therapeutic number of islet cells in a human adult would be transformational for the treatment of Type 1 diabetes.

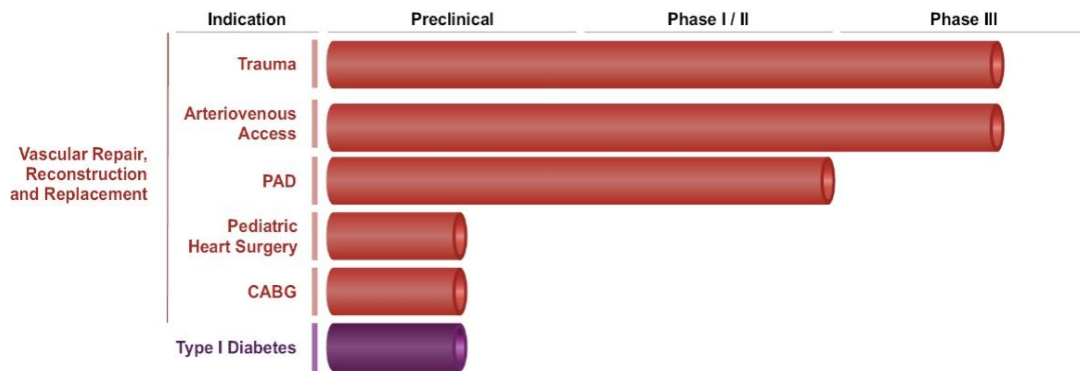
**Coronary Artery Bypass Graft (“CABG”):** CABG is a surgery used to treat a blockage or narrowing of one or more of the coronary arteries to restore the blood supply to the heart muscle. We believe our HAVs can replace existing vascular substitutes and improve patient outcomes, particularly in obese patients or those suffering from diabetes, in whom the risks of saphenous vein harvesting are more substantial. CABG procedures are common, with 350,000 CABG procedures reported annually in the U.S. and over 765,000 annual CABG procedures globally.

Typically, a CABG operation involves the use of both the patient’s own artery and vein. In patients who are obese, have diabetes, or who are very elderly, there are higher risks for vein harvest complications, including failure to heal the vein harvest incision, infection, and prolonged swelling of the operative leg. Furthermore, complications from the vein harvest incision site are more common than complications from the chest incision in CABG patients. It is estimated that approximately 20% of patients requiring bypass surgery have no suitable grafts available, with sources reporting as high as 45% of CABG patients are without suitable autologous vein.

**Pediatric Heart Surgery:** We are developing a smaller diameter HAV product for use in pediatric heart surgery as a Blalock Taussig (“BT”) shunt. The BT shunt is a surgical procedure that is used to increase pulmonary blood flow for the treatment of babies born with a complex congenital heart defect called Tetralogy of Fallot, a common type of “blue baby syndrome”. In 2018, there were 4 million babies born in the United States and approximately 1,500 to 2,000 of these babies were born with Tetralogy of Fallot. The BT shunt is a life-saving procedure for these babies, and we plan to submit an orphan drug application for use of our HAV as a BT shunt for infants born with cyanotic congenital heart defects. Although 3 – 4mm inner diameter expanded polytetrafluoroethylene (“ePTFE”) grafts are currently used as the most common BT shunt, they suffer from limitations that impact morbidity and mortality in these infants.

***Our Clinical and Pre-Clinical Stage Product Pipeline***

The following table highlights key information about our current product pipeline:



We began clinical evaluations of our HAVs in December 2012, with the enrollment of the first Phase II patient in our V001 hemodialysis access trial in Europe. Since then, we have completed one Phase II trial in the United States, and currently have seven trials either actively enrolling or in long-term follow-up. HAVs have been implanted in approximately 79 clinical centers in six countries around the world, and by more than 100 practicing surgeons.

Overview of Clinical Trials Assessing the Safety and Efficacy of the HAV in Multiple Indications

Clinical Trial Number	Indication	Begin Enrollment	Design/Phase	Number of Subjects	Status	Outcomes**
<b>Vascular Trauma</b>						
V005	Vascular Trauma	2018	Phase II/III Single-arm Historical Comparator Unblinded	Targeting 75± total 47 total (32 lower extremity) enrolled as of December 31, 2021	Enrolling	Trial is currently enrolling
<b>Dialysis Access</b>						
V001	Dialysis Access	2012	Phase II Single-arm	40	10-year follow-up ongoing	30-day PP: 95% 6-month SP: 100% 12-month SP: 97% 60-month SP: 58% Infection Rate/yr: 0% Number of Rejections: 0
V003	Dialysis Access	2013	Phase II Single-arm	20	Complete 2-year follow-up	30-day PP: 95% 6-month SP: 89% 12-month SP: 81% Infection Rate/yr: 4% (1 event) Number of Rejections: 0
V006	Dialysis Access	2016	Phase III Prospective Randomized Blinded	355 total; 177 received HAV 178 received ePTFE	5-year follow-up ongoing	30-day PP HAV: 93% 12-month SP HAV: 82% 24-month SP HAV: 67% 12-month SP ePTFE: 80% 24-month SP ePTFE: 74% Infection Rate HAV/yr: 0.93% Infection Rate ePTFE/yr: 4.5% Number of HAV Rejections: 0
V007	Dialysis Access	2017	Phase III Prospective Randomized Blinded	Target 240 total; 207 enrolled (as of December 31, 2021)	Enrolling	Trial is currently enrolling
V011	Dialysis Access	2019	Phase II (LUNA200 manufacturing system)	30	3-year follow-up ongoing	30-day PP: 97% 30-day SP: 100% 12-month SP: 83% Infection Rate HAV/yr: 0% Number of HAV Rejections: 0
<b>Peripheral Arterial Disease</b>						
V002	Peripheral Arterial Disease	2013	Phase II Single-arm	20	10-year follow-up ongoing	30-day PP: 100% 6-month SP: 84% 12-month SP: 84% Infection Rate/yr: 0% Number of Rejections: 0
V004	Peripheral Arterial Disease	2016	Phase II Single-arm	15	5-year follow-up ongoing	30-day PP: 100% 6-month SP: 86% 12-month SP: 64% Infection Rate/yr: 0% Number of Rejections: 0 Number of Amputations: 0

\*\* PP: Primary Patency, which is the interval of time of access placement until any intervention designed to maintain or reestablish patency, access thrombosis, or the time of measurement of patency, i.e. patent without interventions.

SP: Secondary Patency, which is the interval from the time of access placement until abandonment, i.e. patent with or without interventions.

As of December 31, 2021, approximately 471 patients worldwide have received our HAVs for the treatment of trauma, AV access for hemodialysis, PAD, and in expanded access cases resulting in approximately 971 subject-years of exposure to the HAV. Our cumulative HAV exposure is approximately 805 subject-years in the hemodialysis access population, 116 subject-years in the PAD population, and 50 subject-years in the arterial trauma population. The longest our HAV has been in a patient and used for dialysis is more than eight years and there have been more than 100,000 estimated dialysis

sessions using our HAVs. Additionally, a total of 17 expanded access/compassionate use cases have been granted by the FDA. Throughout all of these trials, we have observed that our HAVs functioned as intended and provided functional blood flow to affected limbs. We have also observed consistent durability with a strong tolerability profile. Furthermore, we have observed no evidence of clinically relevant immunologic reactions to our HAVs, supporting the potential use of our HAVs as off-the-shelf, universally implantable, bioengineered human tissues.

Overall, the HAV has functioned well and as intended, across eight different clinical trials in three clinical indications. The HAV has been implanted in approximately 471 patients, across approximately 79 clinical sites in six countries, over more than eight years (as of December 31, 2021). Rates of primary and secondary patency were similar across trial designs and disease states, with 30-day primary patency ranging from 95% – 100%. Six-month secondary patency ranges from 84% – 100%, and 12-month secondary patency ranges from 81% – 97%, across multiple clinical trials, disease states, and patient age ranges and demographics.

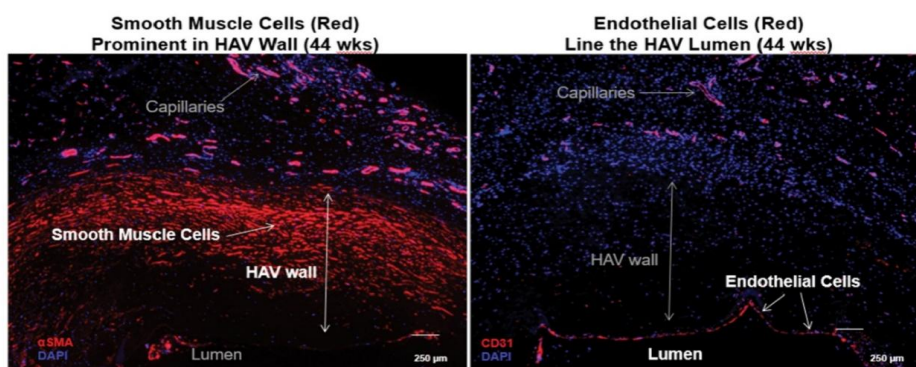
We have observed zero instances of clinical rejection of the HAV in any clinical trial over the past eight years, suggesting that the HAV was not immunologically rejected after implantation.

Based on clinical trial results to date, we have observed that the HAVs were highly resistant to infection, with an infection rate averaging approximately 1.3% per patient-year in our AV access trials, and low infection rates currently in our trauma and PAD trials. Vascular graft infections are a potentially serious complication and can result in adverse outcomes such as sepsis, hospitalization, long-term antibiotic use, repeat procedures and even death.

#### *HAVs Remodel with Host Cells After Implantation*

Additionally, based on clinical samples obtained during our Phase II AV access trials and published in three peer reviewed journals, *The Lancet* in 2016, *Science Translational Medicine* in 2019, and in the *Journal of Vascular Surgery* in 2020, we observed that the HAV became populated with healthy, vascular cells from the patient. As described in these publications, over time the patient's cells have been observed to transform the HAV into a multi-layered living tissue similar to native blood vessels. In these trials we have also observed ongoing cellular repair of HAV tissues that had been previously injured during cannulation with dialysis needles, which suggests that the recellularized HAV may be capable of self-healing. The image below shows an HAV that had been implanted in a hemodialysis patient for 44 weeks, that had developed alpha-actin positive vascular smooth muscle cells throughout the wall (red staining in the left-hand panel), and had developed a layer of CD31+ endothelial cells on the inner luminal surface of the HAV (line of red endothelial cells indicated in the right-hand panel).

*Histological Images of HAV Repopulated with the Patient's Own Vascular Cells*



*Existing Options for Surgical Treatment of Vascular Disease Are Not Sufficient*

The table below contains a summary of the efficacy of autologous veins, ePTFE grafts, cryopreserved human cadaveric veins, and preserved bovine veins. For the treatment of vascular trauma, saphenous vein presents challenges in terms of time to procure the vein, and ePTFE grafts carry extremely high infection rates: 24% – 29% per patient year in the studies below. Similarly, autogenous fistulas and ePTFE grafts for dialysis access have low functional patencies at six and 12 months, and ePTFE is burdened with high rates of annual infection: 3% – 17% in the studies below. Both cryopreserved human cadaver vein, and preserved bovine veins, have low patency at 12 months, and also suffer from high rates of aneurysm formation. Lastly, for bypass of PAD, vein has acceptable patency but is not available for all subjects, while ePTFE carries lower patencies and higher infection risk, and bovine vein becomes aneurysmal at unacceptably high rates.

*Published Studies in Vascular Surgery*

We derived the data in the table below from data contained in certain published papers on vascular trauma, hemodialysis and PAD between 2002 and the present. These data are from different studies and thus are not directly comparable. In addition, many of these papers reported on additional endpoints that are not included in the table below.

Clinical Indication	Type of Conduit	Year	Number of Patients	Published Secondary Patency Outcome	Infection (per patient-year)	Rejection Outcome
Vascular Trauma	Saphenous Vein (autologous)	2002–2012	24	12 months: ~78% function	4%	N/A
		2014	152	30 days: ~90% function		
	ePTFE (synthetic graft)	2002–2012	25	12 months: ~50% function	24%	N/A
		2005	14 of 95	30 days: ~79% function	29%	
Hemodialysis Access	Fistula (autogenous)	Post-2005	2,800	12 months: 75%	2%	N/A
		2019	14892	6 months: 51%		
		2017	6,439		N/A	4%
		2018	602		6 months: 61%	N/A
	ePTFE (synthetic graft)	2013	128		6 months: ~60%	N/A
		2019	> 400		N/A	3% – 17%
		2020	> 3,000		12 months: 70%	9%
	Cryovein (cryopreserved human cadaver vein)	2002	45		12 months: 80%	N/A
	2004	49	12 months: ~65% Aneurysm rate: 18%	0%	~100%	
	Procol (bovine vein)	2005	186	12 months: 66% Aneurysm rate: 3.2%	5.3%	N/A
Peripheral Arterial Disease	Saphenous Vein (autologous)	2008	60	12 months: ~86%	N/A	N/A
	ePTFE (synthetic graft)	2008	61	12 months: ~80%	N/A	N/A
		2013	101	12 months: 76% – 89%		
		2011	273		12 months: 81%	
		2013	496		N/A	3.8%
	Procol (bovine vein)	2008	7		6 months: 50% 12 months: 50% Aneurysm Rate: 29%	N/A






**Proposed Indication #1: Use of HAV to Repair Vascular Trauma**

*Overview of Vascular Trauma*

Arterial injuries resulting from vascular trauma are common in military and civilian populations, frequently resulting in the loss of life or limb. In military populations, as the rate of battlefield fatalities has been declining due to faster evacuations and more robust protection from body armor, the rate of survivable vascular injuries has been increasing. In civilian populations, trauma injuries are primarily caused by motor vehicle accidents, gun violence, mass casualty terrorist attacks, stabbings and blunt trauma. Consequently, we believe there is an increasingly urgent unmet need for novel materials that are immediately available for permanent vascular repair for both civilian and military vascular trauma.

*Options in Surgical Treatment of Vascular Trauma*

Saphenous Vein Grafts	ePTFE Grafts	Humacyte HAV
		
<ul style="list-style-type: none"><li>■ Harvesting vein adds an hour or more of operative time</li><li>■ Delayed revascularization significantly increases amputation risk</li><li>■ Amputation in lower-limb trauma ranges from 5-15%</li></ul>	<ul style="list-style-type: none"><li>■ &gt;50% infection rate</li><li>■ Amputation rate is 8-25%</li><li>■ Mortality rate when ePTFE is infected: 8-30%</li><li>■ Median length of stay 11 days if re-admitted for graft infection</li></ul>	<ul style="list-style-type: none"><li>■ Off the shelf; no need to harvest vein</li><li>■ Robust primary patency: 100% at 30 days</li><li>■ Data suggest meaningful reduction in rate of infection compared to ePTFE</li><li>■ Expected clinical improvement in limb salvage leading to significantly lower rate of amputation</li></ul>

Autologous vein is the preferred conduit for vascular repair. However, harvesting of autologous vein is not always feasible, due to damage to vein or lower limb, prior vein harvest, inadequate size of the vein or venous disease. Harvesting autologous vein is a serious operation that requires additional time and resources. Delaying the time from injury to operative intervention from less than one hour, to three hours or greater, more than doubles the risk of limb amputation. Limb amputation, in turn, almost triples the length of intensive care unit stay, nearly doubles the length of hospital stay, and is devastating to patient quality of life. Additionally, the morbidity associated with saphenous vein harvest includes surgical site infections, chronic pain, and limb swelling. Synthetic materials have been shown to be inferior to autologous vein in resistance to infection and durability and, therefore, are generally only used for vascular repair when autologous vein is not an option.

*Our Solution for Vascular Trauma*

We believe our HAVs will be a promising alternative that can address critical gaps in existing treatment options for acute vascular injuries due to trauma. We are developing our HAVs with the goal of providing an effective solution in all time-constrained surgical environments and in resource-limited, infection prone battlefield environments. The ability to create immediately available, non-immunogenic, universally implantable material that is less susceptible to infection represents a clinically significant advantage over existing options.

Humacyte has a strong working relationship with the Department of Defense (“DoD”) that has led to a partnership over the last decade to support their unmet need to reconstruct and repair vascular injuries through the development of our HAVs. As a result of this collaboration and partnership with the DoD, we anticipate Humacyte would supply HAVs for use in military hospitals to treat injured soldiers and veterans. The DoD assigned a priority designation to the HAV technology under Public Law 115-92. Under this law, FDA and DoD work together to expedite the development and review of critical technologies and therapies requested by DoD. Additionally, we have received an approximately \$7 million grant from the DoD for the continued development of our HAVs for vascular reconstruction and repair.

*Our Current Phase II/III Trial for Vascular Trauma*

**Trial Design:** Our ongoing V005 trial is a single-arm, multi-center, non-randomized clinical trial to evaluate the efficacy, safety and tolerability of our 6 millimeter HAV in replacement or reconstruction of vascular tissues in patients with life or limb-threatening vascular trauma. Since the V005 trial is a single-arm, non-randomized, open label study, we have the ability to track ongoing efficacy and safety. The current primary efficacy endpoint evaluates primary patency of the HAV at 30 days. Based on the results we have observed to date, and subject to discussions with the FDA regarding trial size, we expect that the final design of the trial will support the submission of a BLA in 2022 or 2023. We anticipate that analysis of data from V005 will focus on patients with lower extremity injuries. The final number of subjects to be enrolled and evaluated in the study is dependent on additional guidance from the FDA, but is currently estimated to approximate 75.

*Status of Phase III Trial of HAV in Vascular Trauma (as of December 31, 2021)*

Clinical Trial Number	Indication	Begin Enrollment	Design/Phase	Number of Subjects	Status	Outcomes**
V005	Vascular Trauma	2018	Phase II/III Single-arm Historical Comparator Unblinded	Targeting 75± total 47 total (32 lower extremity) enrolled as of December 31, 2021	Enrolling	Trial is currently enrolling

\*\* PP: Primary Patency, which is the interval of time of access placement until any intervention designed to maintain or reestablish patency, access thrombosis, or the time of measurement of patency, i.e. patent without interventions.

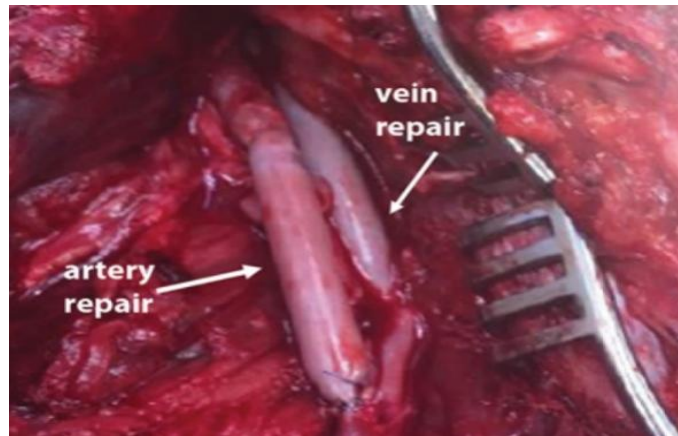
SP: Secondary Patency, which is the interval from the time of access placement until abandonment, i.e. patent with or without interventions.

**Current Trial Status:** During 2020, we increased the number of trial sites for the V005 trial in the United States, from seven to 20 sites. We are currently working to further expand sites in the United States, as well as add additional sites in Poland and Israel. Increasing the number of sites is expected to provide a broader patient cohort for enrollment in the trial, providing more extensive clinical exposure to differing types of vascular traumatic injury.

The range of trauma injuries in V005 has been broad, including penetrating trauma cases, blunt injury cases, and iatrogenic injuries. Mechanisms of injury have included motor vehicle accidents, gunshot wounds, industrial accidents, falls, and iatrogenic injuries from other interventional or surgical procedures. The HAVs have been placed throughout the body, including in the lower limbs, upper limb, and torso. The HAV has been used to repair the axillary artery, femoral artery, popliteal artery and vein, and the brachial artery in the V005 trial. Many of the injuries treated in the V005 trial, including industrial accidents, motor vehicle accidents, and some gunshot wounds, are contaminated injuries that are at elevated risk of graft infection. Nonetheless, as of December 31, 2021, there has been only one report of HAV infection in any V005 subject, despite a number of instances where the HAV has been implanted into contaminated surgical fields of acute vascular wounds. There have been several instances of local wound infections, but importantly only one of these instances has led to infection of the HAV material itself, which we believe represents a significant advantage of the HAV over ePTFE grafts, which have a higher propensity to become infected in contaminated or infected wound beds. There have been no reports of limb amputation that occurred as a result of HAV malfunction or loss of patency. The resistance to infection we have observed in trials to date is particularly important in traumatic injuries which are often caused by infected material (i.e., knife, car accident, blast injury).

In the figure below, a photograph is shown of an HAV that was used to repair both an artery and a vein in the knee of a patient who suffered a gunshot wound. This patient was doing well at the 30-day follow-up visit with both repairs remaining patent and functional.

*Intra-operative photograph of HAV repair of popliteal artery (left) and vein (right) in V005 subject.*

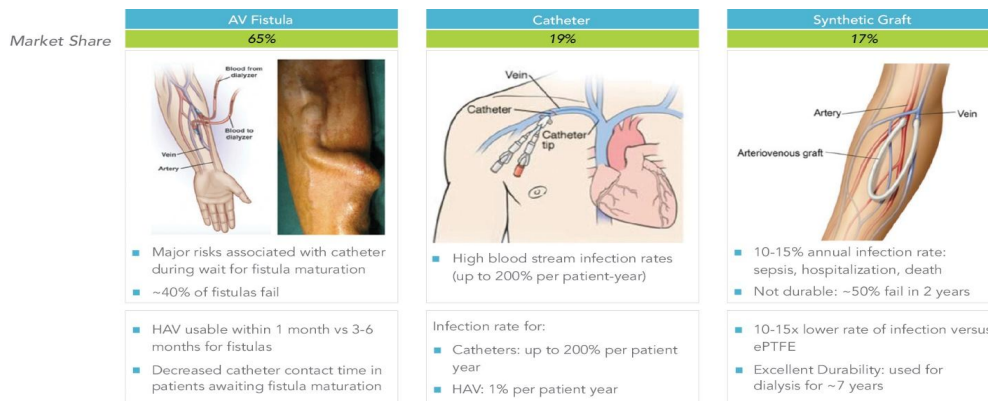


**Proposed Indication #2: Use of the HAV for Arteriovenous Access for Hemodialysis**

*Overview of Hemodialysis and Existing Methods of Arteriovenous Access for Hemodialysis*

End-stage renal disease (“ESRD”) develops when chronic kidney disease progresses to a point where either dialysis or a kidney transplant is required for the patient to survive. For hemodialysis to be conducted, a point of vascular access to the patient’s circulatory system must be created, termed vascular access, so that blood can be transported from the body to the dialyzer and then back to the body. The demand for vascular access conduits includes the need for both new hemodialysis patients who have progressed to ESRD requiring an initial access, and existing patients that require the replacement of their existing access. There are currently three traditional methods for obtaining vascular access for hemodialysis: an AV fistula, a synthetic graft, and a catheter. Each of these vascular access methods has substantial limitations, as outlined below:

*Three Traditional Methods for Obtaining Vascular Access for Hemodialysis*



**Fistula.** An AV fistula is created by surgically connecting a vein to an artery, typically in the patient’s arm. Fistulae are often considered the preferred means of access for hemodialysis due to lower infection rates of approximately 0.5% – 1.5% per patient-year as well as long-term durability. However, many patients are not suitable candidates for fistula placement, due to small vessel anatomy, advanced age, obesity or other comorbidities. Approximately 40% of patients who undergo surgery for fistula creation will not gain any benefit from the surgery because the fistula lacks sufficient vein enlargement and increased blood flow, a process called fistula maturation, that is necessary for hemodialysis. Additionally, during the period in which the fistula is maturing, catheters are generally used to provide the patient access for dialysis. There is a high risk of infection and morbidity, and health care cost, associated with prolonged catheter dependence while waiting for the fistula to mature.

**Catheters.** A catheter, which is tunneled underneath the skin and placed directly into a large vein in the patient, is generally the least desirable access solution. Given the time necessary for fistulae to mature, the vast majority of patients in

the United States begin hemodialysis using a catheter while awaiting fistula maturation. Catheters have rates of blood stream infections as high as 200% per patient-year, with high associated morbidity and health care costs.

**Synthetic graft.** A synthetic graft, typically made from ePTFE and sewn between an artery and vein in the patient’s arm, is generally used in patients who are not candidates for fistulae. The drawbacks of synthetic grafts include higher infection rates, which can be as high as 10% – 15% per patient-year, and gradual degradation of the non-healing ePTFE graft material caused by persistent needle punctures. A recent systematic meta-analysis measuring the functional patency of ePTFE grafts shows that, on average, only 70% of ePTFE dialysis access grafts remain functional one year after implantation.

*Distribution of Hemodialysis Access Modes in Use in the United States*

Access Type	Fistulae	Catheters	Synthetic Grafts
Incident Patients: At Initiation of Hemodialysis	16.7 %	80.3 %	3.0 %
Prevalent Patients: For Ongoing Hemodialysis	64.5 %	18.9 %	16.6 %

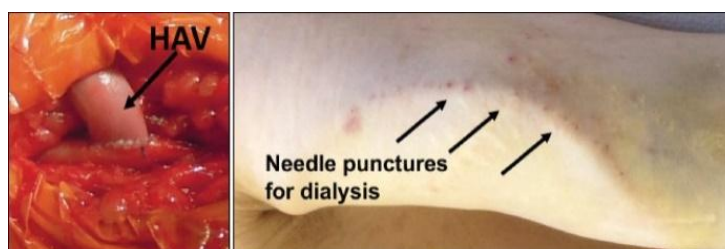
*Published Data in Hemodialysis Access*

We derived the data in the table below from data contained in certain published papers on hemodialysis between 2002 and the present. These data are from different studies and thus are not directly comparable. In addition, many of these papers reported on additional endpoints that are not included in the table below.

Clinical Indication	Type of Conduit	Year	Number of Patients	Published Secondary Patency Outcome	Infection (per patient-year)	Rejection Outcome
Hemodialysis Access	Fistula (autogenous)	Post-2005	2,800	12 months: 75%	2%	N/A
		2019	14,892	6 months: 51%	N/A	
		2017	6,439	N/A	4%	
	ePTFE (synthetic graft)	2018	602	6 months: 61%	N/A	
		2013	128	6 months: ~60%	N/A	N/A
		2019	> 400	N/A	3% – 17%	
Cryovein (cryopreserved cadaver vein)	2020	> 3,000	12 months: 70%	9%		
	2002	45	12 months: 80%	N/A	100%	
	2004	49	12 months: ~65% Aneurysm rate: 18%	0%	~100%	
	2005	186	12 months: 66% Aneurysm rate: 3.2%	5.3%	N/A	

**Overview of HAV Experience in Hemodialysis Access:** A table listing our clinical trials of the HAV in hemodialysis access is included below. We have implanted the HAV into approximately 372 total patients for hemodialysis access, for a total of more than 805 patient-years of exposure, as of December 31, 2021. Throughout these trials, we have observed consistent and sustained high primary patency rates, ranging from 95% – 100% at 30 days. Secondary patency of the HAV at 6 months ranges from 84% – 100%. Consistently, we have observed zero instances of clinical rejection of any HAV in any hemodialysis access trial.

*Implantation of HAV for Hemodialysis*



We have also observed in multiple clinical trials that our HAVs had a low infection susceptibility during use for hemodialysis, with a rate lower than 1% per patient-year across all studies. The low infection susceptibility we observed in our trials of our HAVs may be a result of the HAV’s potential to become a living tissue as it becomes populated by cells from the patient’s body. Since living tissues are known to have resisted infection due to interactions with host white blood cells and immunological defense systems, it is possible that the repopulated HAV resists infection for the same reasons that native arteries and veins resist infections, as is observed with autogenous fistulas.

We have also observed early evidence of potential healing from the cells that repopulate the HAV after needle puncture for hemodialysis. In examining HAV explanted segments we have observed healed needle cannulation tracts with cells expressing smooth muscle markers. This self-healing indicates that the HAV may have repaired itself while being used as a hemodialysis access, which we believe is a distinct feature not present in synthetic materials, and, to our knowledge, has not been observed before for any other regenerative medicine product.

*Our Current Phase II and Phase III Trials of the HAV in Hemodialysis Access*

Clinical Trial Number	Indication	Begin Enrollment	Design/Phase	Number of Subjects	Status	Outcomes**
V001	Dialysis Access	2012	Phase II Single-arm	40	10-year follow-up ongoing	30-day PP: 95% 6-month SP: 100% 12-month SP: 97% 60-month SP: 58% Infection Rate/yr: 0% Number of Rejections: 0
V003	Dialysis Access	2013	Phase II Single-arm	20	Complete 2-year follow-up	30-day PP: 95% 6-month SP: 89% 12-month SP: 81% Infection Rate/yr: 4% (1 event) Number of Rejections: 0
V006	Dialysis Access	2016	Phase III Prospective Randomized Blinded	355 total: 177 received HAV 178 received ePTFE	5-year follow-up ongoing	30-day PP HAV: 93% 12-month SP HAV: 82% 24-month SP HAV: 67% 12-month SP ePTFE: 80% 24-month SP ePTFE: 74% Infection Rate HAV/yr: 0.93% Infection Rate ePTFE/yr: 4.5% Number of HAV Rejections: 0
V007	Dialysis Access	2017	Phase III Prospective Randomized Blinded	Target 240 total; 207 enrolled (as of December 31, 2021)	Enrolling	Trial is currently enrolling
V011	Dialysis Access	2019	Phase II (LUNA200 manufacturing system)	30	3-year follow-up ongoing	30-day PP: 97% 30-day SP: 100% 12-month SP: 83% Infection Rate HAV/yr: 0% Number of HAV Rejections: 0

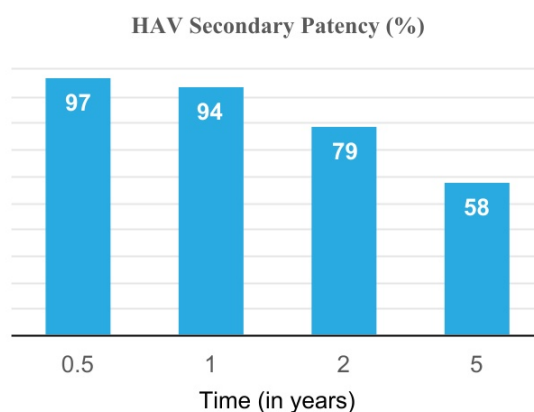
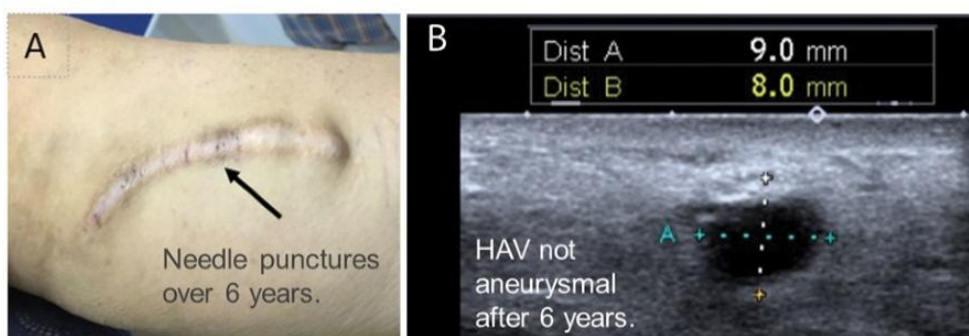
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SP: Secondary Patency, which is the interval from the time of access placement until abandonment, i.e. patent with or without interventions.

Long-Term Data from Early Phase II Trials in Hemodialysis: V001 and V003

**Phase II Trial Design and Current Outcomes:** We have completed or are in long-term follow-up on two open-label Phase II trials in 60 hemodialysis patients in the United States and Poland from December 2012 through May 2014, which we refer to as our V003 trial and V001 trial, respectively. Both the V001 and V003 studies were designed as single-arm trials to assess the safety and efficacy of the HAV for hemodialysis access, with assessments of patency at 6, 12, 18 and 24 months. In the 60 patients enrolled in these two studies, blood flow through all HAVs was appropriate for hemodialysis, averaging over 1,200 mL/minute. Secondary patency for the two combined trials was 97% at six months, 89% at 12-months, and 81% at 18-months. These results compare favorably to published reports of secondary patency for fistula of 51% – 61% at six months and 75% at 12 months. Long-term results from the V001 trial showing five-year secondary patency of 58% were published in the *European Journal of Vascular and Endovascular Surgery* companion journal *EJVES Vascular Forum* in February 2022, and patients from the V001 trial are currently in a 10-year follow-up period.

*Images and long-term results from Phase 2 V001 trial of HAV in AV Access*



Phase III V006 AV Access Study

**Trial Design:** Our V006 HUMANITY study is a prospective, multi-center, multinational, open-label, randomized, two-arm, comparative study. Eligible study subjects were randomized to receive either a HAV or a commercially available ePTFE graft and followed to 24 months post-implantation by routine study visits. After 24 months, subjects with a patent conduit are followed to five years post-implantation using a questionnaire at six-month intervals to ascertain patient and conduit status. The primary endpoint for the V006 HUMANITY trial was a non-inferiority analysis of secondary patency compared to ePTFE, to be assessed when all subjects are at least 18 months post-implantation. There were a total of 37 sites that participated in the study, enrolling a combined total of 355 subjects.

**24-Month Results:** The V006 study enrolled 355 subjects who were roughly equally matched in terms of demographics and co-morbidities. HAV subjects trended older ( $p=0.06$ ) and had more prior strokes ( $p=0.02$ ) than did ePTFE subjects.

Phase 3 V006 HUMANITY trial subject demographics

V006 Demographics (N=355)	ePTFE (n=178)	HAV (n=177)	p-value
Age(years)	59.9	62.6	0.06
Male (%)	49.4%	49.7%	NS
Caucasian (%)	65.2%	69.5%	NS
Black (%)	27.5%	24.9%	NS
Hispanic (%)	11.2%	14.7%	NS
Asian / Other (%)	3.4%	2.3%	NS
Body Mass Index (BMI)	29.2	28.9	NS
Hypertension (%)	79.8%	79.7%	NS
Cardiac Disease (%)	50.6%	57.1%	NS
Diabetes (%)	29.2%	32.8%	NS
Prior Stroke (%)	5.6%	12.4%	0.02

The secondary patency of the HAV was greater than that of ePTFE at six and 12 months but lower at 18 and 24 months, an outcome that had not been modelled in the V006 trial design. As per the pre-specified Cox Proportional Hazards test, the HAV did not achieve its primary efficacy endpoint regarding secondary patency. In terms of safety, the HAV had a statistically significant lower rate of conduit infections compared to ePTFE. Substantial differences in antibiotic use and need for hospitalization for infection were also noted in the V006 trial, all favoring the HAV. The safety advantage of the HAV over ePTFE may be clinically important as infection and sepsis are the second most common cause of death in dialysis patients.

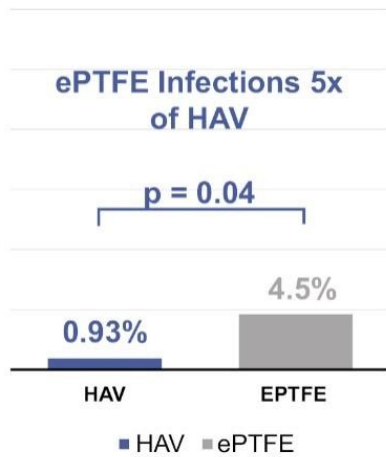
Phase 3 V006 HUMANITY trial secondary patency results

Secondary Patency	6 months	12 months	18 months	24 months
HAV HUMANITY [Mean (95% CI)]	92%(87 – 95%)	82% (75 – 87%)	73% (65 – 79%)	67% (59 – 74%)
ePTFE HUMANITY [Mean (95% CI)]	87% (81 – 85%)	80% (73 – 85%)	77% (70 – 83%)	74% (67 – 81%)

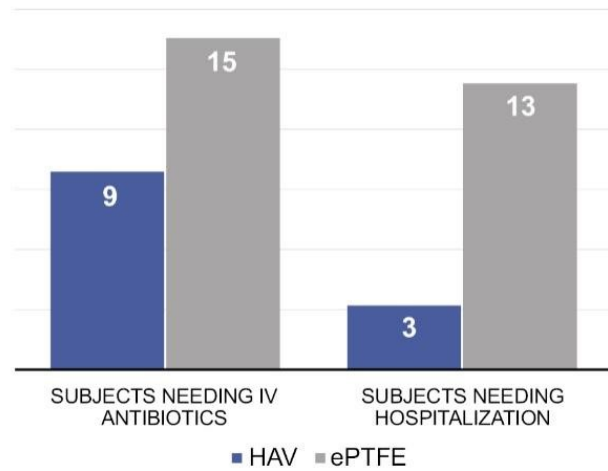
Cox Proportional Hazards Model for Time to Loss of Secondary Patency					
Treatment Group (HAV vs ePTFE)		Hazard Ratio		Non-inferiority Margin Hazard	Non-inferiority Demonstrated (Yes/No)
		Estimate	95% CI		
	12 months	0.869	(0.528, 1.431)	1.491	Yes
	24 months	1.284	(0.867, 1.903)	1.488	No

Phase 3 V006 HUMANITY trial rates of infection

Phase 3 HUMANITY Infection Rates



Consequences of Access Infection in V006



The reported SAEs related to the HAV and ePTFE in the V006 trial, in this patient population, which typically has a high prevalence of existing medical conditions, are detailed in the table below.

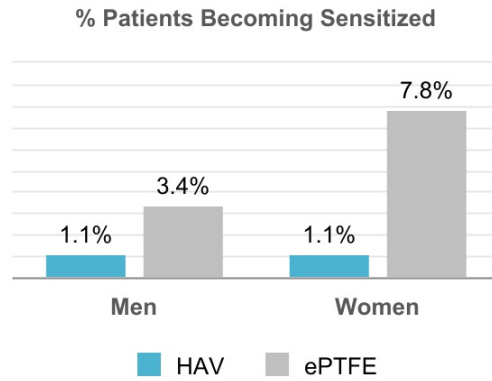
SAEs Reported in V006 Phase III Clinical Study in AV Access

Description of SAE	Number of SAEs (% of total subjects)	
	HAV	ePTFE
Number of subjects in V006 study	177	178
General disorders and administration conditions:		
Implant site extravasation	0(0.0)%	1(0.6)%
Infections and infestations:		
Vascular access site infection	0(0.0)%	5(2.8)%
Injury, poisoning and procedural complications:		
Anastomotic stenosis	1(0.6)%	(0.0)%
Vascular access site hematomas	1(0.6)%	(0.0)%
Vascular access site hemorrhage	0(0.0)%	3(1.7)%
Vascular access site pain	1(0.6)%	0(0.0)%
Vascular access site pseudoaneurysm	10(5.6)%	0(0.0)%
Vascular access site rupture	2(1.1)%	0(0.0)%
Vascular access site thrombosis	41(23.2)%	28(15.7)%
Skin and subcutaneous tissue disorders:		
Skin necrosis	0(0.0)%	1(0.6)%
Vascular disorders:		
Steal syndrome	2(1.1)%	2(1.1)%
Subclavian vein occlusion	0(0.0)%	1(0.6)%
Vascular stenosis	34(19.2)%	27(15.2)%
Venous stenosis	3(1.7)%	9(0.0)%



Through an Analysis of Panel Reactive Antibodies (“PRA”) in the V006 trial, we observed that subjects that received the ePTFE grafts were more likely to develop antibodies against human tissues, and to become more difficult to crossmatch for a future kidney transplant, than were patients who received the HAV. While the cause of this improvement in patient responses with the HAV is not clear, this may have been related to the lower number of severe infection events in HAV patients as compared to ePTFE patients in V006. The percentage of women becoming sensitized (i.e. cPRA values > 20%) was notably higher in the ePTFE group than the HAV group.

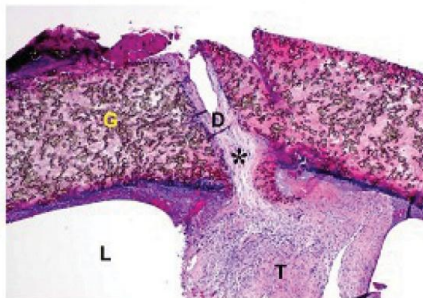
*Phase 3 V006 HUMANITY trial % of patients developing antibodies against human tissues*



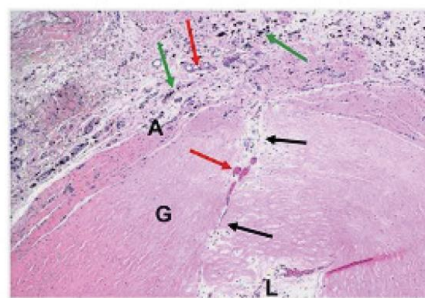
We also observed differences in the remodeling of the HAV and ePTFE implants in the V006 trial. Consistent with earlier observations from Phase II studies, microscopic examination of samples from HAV and ePTFE subjects suggest that the HAVs may have repopulated with host cells and microvasculature, while ePTFE grafts did not repopulate with cells and, in certain cases, fractured at sites of needle cannulation for hemodialysis (“G” is graft; “D” is defect; “T” is thrombus (clot); “L” is lumen; and “A” is adventitia):

*Phase 3 V006 HUMANITY trial microscopic examination of samples from ePTFE and HAV subjects*

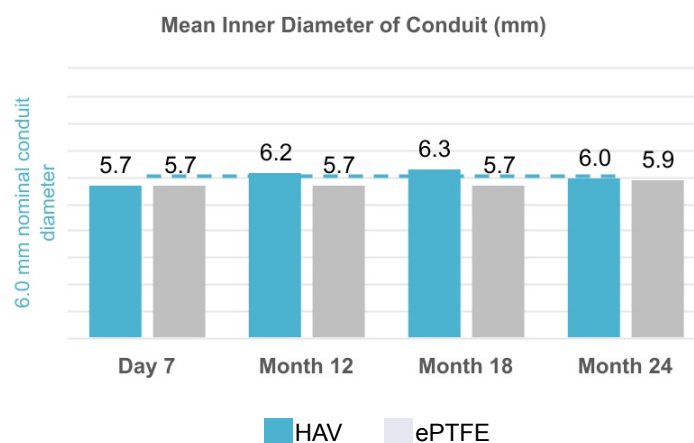
**PTFE: Patient V006-1167-001\_B, 13 months.**



**HAV: Patient V006-1199-023, 13 months.**



Comparison of flow rates within the HAV and ePTFE conduits revealed similarities in blood flow and diameter over the 24-month period of the trial. Bar graphs below display average blood flow rate, maximal blood flow rate, and mid-graft diameters, all of which were measured by periodic ultrasound examinations. Diameters of the HAV remained close to the nominal 6.0 millimeter diameter. Average blood flow rates exceeded 1.0 liters/minute, which is generally considered suitable for efficient hemodialysis.

*Phase 3 V006 HUMANITY trial blood-flow rates and vessel diameters*

Overall, although the primary efficacy endpoint concerning secondary patency was not met, the HAV performed in the V006 trial as was expected, based upon HAV performance in previous Phase II trials in hemodialysis and in other clinical applications. This outcome was due at least in part to unexpectedly high patency of the ePTFE grafts, particularly after 12 months. While the cause of this unexpectedly high patency is not clear, it is possible that study-mandated ultrasounds and examinations may have led to more aggressive vigilance with ePTFE grafts to maintain patency. In addition, the age and comorbidities of HAV subjects in V006 was somewhat worse than for ePTFE subjects.

In the V006 trial, the HAV displayed significantly fewer infections than did the ePTFE grafts. This was associated with fewer instances of immune sensitization in HAV subjects as compared to ePTFE subjects, which could translate to easier kidney transplantation at future times. Similar to prior studies, we observed that the HAV had good durability, blood flow rates and diameters similar to ePTFE grafts, and also host cell remodelling that was superior to that of ePTFE grafts.

#### Phase III V007 AV Access Study

**Trial Design:** We are currently enrolling a Phase III trial, called V007, in 240 patients with ESRD. V007 is a Phase III, prospective, multi-center, open label, randomized, two-arm comparative study conducted in the United States. The V007 trial is designed to assess the usability of the HAV for dialysis at six and 12 months as a comparison to autogenous fistulas, which are known to exhibit a high rate of early maturation failure of approximately 40% at six months. Patients in the study are randomized to receive either the HAV for vascular access or an autogenous AV fistula. The objective of V007 is to compare the safety and efficacy of our 6 millimeter HAV to autogenous AV fistula for functional hemodialysis access.

Eligible study subjects in V007 are randomized to receive either an HAV or an autogenous fistula and followed to 24 months post-implantation by routine study visits. After 24 months, patients with functional accesses will be followed for up to five years. Efficacy endpoints include useability for dialysis at six and 12 months, as well as a comparison of secondary patency via a time-to-event analysis of all subjects at 12 months. Additional safety endpoints include the rate of dialysis access-related infections for HAV and fistula subjects.

**Current Trial Status:** As of December 31, 2021, there were 207 patients enrolled in the V007 trial, out of a target enrollment of 240 total. We currently expect to complete the V007 trial in time to support a BLA filing for the use of HAV in AV access for hemodialysis in 2023.

#### ***Proposed Indication #3: Peripheral Arterial Disease***

PAD involves partial or complete occlusion of blood vessels in the peripheral circulation and is a major cause of morbidity and mortality in the developed world. Patients with severe PAD undergo peripheral arterial bypass surgery where a conduit is implanted above and below the area of the arterial obstruction, to provide a “bypass” route for blood to flow around the blocked artery. The vast majority of these operations are performed in the lower limb. Other surgical alternatives include minimally invasive approaches such as stenting and angioplasties that are suitable for smaller atherosclerotic lesions and can delay — but oftentimes not prevent — the ultimate need for surgical revascularization.

*Published Data in PAD*

We derived the data in the table below from data contained in certain published papers on PAD between 2008 and the present. These data are from different studies and thus are not directly comparable. In addition, many of these papers reported on additional endpoints that are not included in the table below.

Clinical Indication	Type of Conduit	Year	Number of Patients	Published Secondary Patency Outcome	Infection (per patient-year)	Rejection Outcome
Peripheral Arterial Disease	Saphenous Vein (autologous)	2008	60	12 months: – 86%	N/A	N/A
	ePTFE (synthetic graft)	2008	61	12 months: – 80%		
		2013	101	12 months: 76% – 89%	N/A	N/A
		2011	273	12 months: 81%		
	2013	496	N/A	3.8%		
Procol (bovine vein)		2008	7	6 months: 50%	N/A	N/A
				12 months: 50%		
				Aneurysm Rate: 29%		

We have observed strong patency rates and no reported cases of infection for the HAV in PAD in clinical studies to date. We are developing our 6 millimeter HAV for use as a bypass conduit for patients with PAD. We are conducting two Phase II trials to evaluate the safety and efficacy of our 6 millimeter HAV for use as a bypass conduit with PAD, which we refer to as our V002 and V004 trials. For both of these Phase II trials, the HAV is being implanted as a femoral popliteal bypass graft in patients with PAD.

*Our Current Phase II Trials of the HAV in PAD*

Clinical Trial Number	Indication	Begin Enrollment	Design/Phase	Number of Subjects	Status	Outcomes**
V002	Peripheral Arterial Disease	2013	Phase II Single-arm	20	10-year follow-up	30-day PP: 100%
					ongoing	6-month SP: 84%
						12-month SP: 84%
						Infection Rate/yr: 0%
						Number of Rejections: 0
V004	Peripheral Arterial Disease	2016	Phase II Single-arm	15	5-year follow-up	30-day PP: 100%
					ongoing	6-month SP: 86%
						12-month SP: 64%
						Infection Rate/yr: 0%
						Number of Rejections: 0
						Number of Amputations: 0

\*\* PP: Primary Patency, which is the interval of time of access placement until any intervention designed to maintain or reestablish patency, access thrombosis, or the time of measurement of patency, i.e. patent without interventions.

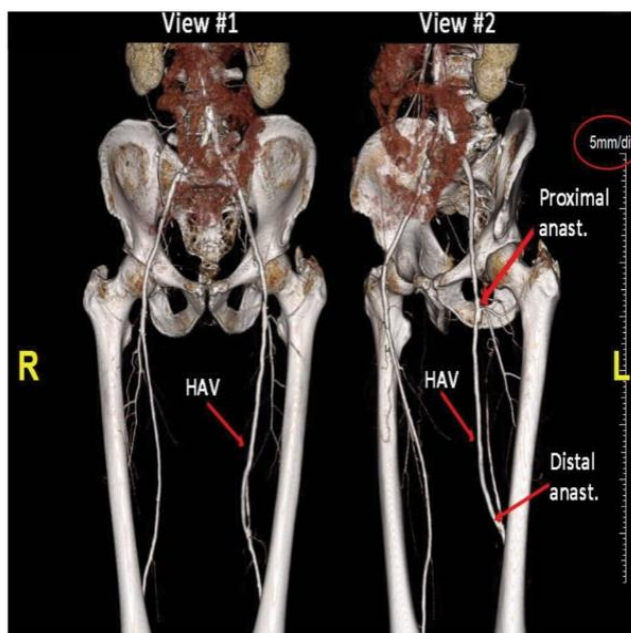
SP: Secondary Patency, which is the interval from the time of access placement until abandonment, i.e. patent with or without interventions.

**Trial Design:** Both our V004 and V002 trials are prospective, open-label, single treatment arm, multi-center studies. We enrolled 20 patients in our V002 trial in Poland, and 15 patients in our V004 trial in the United States. Both trials have the primary objectives of evaluating the safety of the HAV as a femoral-to-popliteal bypass graft, and determining the primary, primary assisted, and secondary patency over 12 and 24 months.

**Current Trial Status and Outcomes:** V002 enrolled a total of 20 patients between the ages of 54 and 79 at three clinical sites. 24-month results of the V002 trial were published in 2020. After censoring for three deaths (none of which were determined to be related to the HAV or the implant procedure), we observed 24-month primary, primary assisted and secondary patency rates of 58%, 58%, and 74%, respectively. We observed through ultrasound data that the HAVs were mechanically stable during the follow-up period and did not develop aneurysmal dilatation in any patient. Overall, we also determined through the histological assessment of explanted specimens that there were normal vascular cells within the HAV and there was no infection or signs of immunological reaction to the graft.

There have been no HAV-related infections reported during the V002 trial as of December 31, 2021, and no amputations of the treated extremity. A sub-set of seven V002 subjects consented for long-term follow-up computerized tomography (“CT”) angiograms, which were obtained at 48 to 52 months after HAV implantation. In all cases, the HAV maintained normal architecture and function. A representative image is shown below, taken 50 months post-implantation. Proximal and distal anastomoses of HAV with recipient’s vasculature are noted, as is the scale bar on the right-hand side of each image. The image presents two views of the same subject, and shows uniform HAV diameter along the length of the implant.

*A CT Angiogram from a V002 Subject at 51 months after HAV implantation*



Patients in the V002 trial are currently in long-term follow-up out to ten years. For the V002 trial, six-year long-term follow-up data were compiled in March 2021, which confirmed durability of the HAV in the arterial circulation. For HAV patients in the V002 trial, there were also no reports of conduit infections, and no reports of amputations of the operative limb.

*Long-term results from V002 Phase II study in PAD*

Result from V002 Phase 2 Trial in PAD (as of April 2021)	Pre-Op	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	Avg
Secondary Patency	—	84%	74%	73%	66%	60%	<b>60%</b>	—
Ankle-Brachial Index (median)	0.64	0.90	0.96	—	1.07	0.98	0.94 (n=2)	0.97 (post-op)
HAV Infection Rate	—	0%	0%	0%	0%	0%	<b>0%</b>	0%

The V004 trial enrolled 15 subjects in the United States, with the 12-month follow-up of the last enrolled patient occurring in December 2020. Patients in the V004 trial included Rutherford 4 and 5 subjects, with severe, debilitating limb ischemia. (Rutherford 4 and 5 patients are classified as patients with pain at rest due to limb ischemia (stage 4), and those patients suffering tissue loss in the limb as a result of ischemia (stage 5)). In addition, enrollment in V004 required that no autologous vein be available for bypass. Hence, the subjects enrolled in the V004 trial had severe and debilitating limb ischemia due to PAD and had no autologous vein that was suitable for lesion bypass and revascularization.

*12-month results from V004 Phase II study in PAD*

Result from V004 Trial (as of April 2021)	Pre-Op	6 mos	12 mos
Secondary Patency	—	86%	64%
Ankle-Brachial Index (median)	0.51	0.85	0.90
Rate of Amputation	—	0%	0%
VascuQol Quality of Life Assessment	3.1	5.6	5.9

In the V004 trial, HAV secondary patency was 86% at 6 months, and 64% at 12 months. While lower than patency values observed in the V002 trial, patients in the V004 trial had more severe PAD, which is associated with poorer arterial “run-off” and higher propensity for conduit occlusion. Assessment of Quality of Life by the validated VascuQol assessment demonstrated an increase in overall quality of life for V004 patients at 6 and 12 months. In addition, ankle-brachial index, a measurement of blood pressure in the operative limb, was increased at 6 and 12 months. There were no infections of the HAV reported in the V004 trial, despite the severity of the PAD and the often-associated tissue infection that can accompany this disease. There were zero reports of clinical HAV rejection. Lastly, there were zero reported amputations of any operative limb in the first 12 months of follow-up.

The SAEs reported for the HAV in our V002 and V004 Phase II clinical studies in PAD in 35 subjects, a patient population which typically has a high prevalence of existing medical conditions, are summarized in the table below.

*SAEs Reported in V002 and V004 Phase II Clinical Studies in PAD*

Description of SAE	Number of SAEs (% of total subjects)
Number of subjects in V002 and V004 studies	N=35
Arterial bypass thrombosis	3(8)%
Anastomotic stenosis	1(3)%
Graft Thrombosis	2(6)%
Vascular Graft Complication	1(3)%

Published literature reports of patients with Rutherford stage 4 and 5 PAD and no autologous vein available for revascularization show that outcomes can include amputation. For Rutherford 4,5 patients with no vein and no revascularization procedure, amputation rates at 6 months are reported at 31%. For stage 4,5 patients who do undergo saphenous vein revascularization, the amputation rate at one year is approximately 10%. The lack of amputation for stage 4,5 patients in the V004 trial at one year, none of whom had saphenous vein for revascularization, supports the use of the HAV in severe PAD.

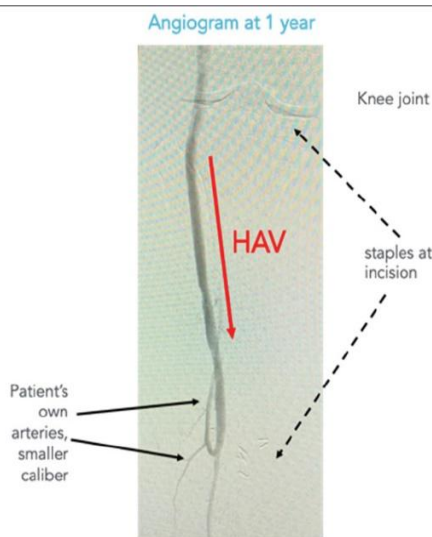
*Examples of the Use of Our 6 millimeter HAVs in Expanded Access Cases*

The FDA has granted use of the HAV in 17 special expanded access cases through December 31, 2021. Each of these compassionate use cases was conducted under an individual, investigator-initiated IND with the FDA. Two cases are highlighted below.

*70-year-old with Critical Limb Ischemia*

The patient is a 70-year-old male with critical limb ischemia and no vein available to perform a bypass, as the vein was previously used for a CABG. He underwent a successful bypass with the HAV. Imaging at one year demonstrated a patent graft.

- Case Study of using the HAV for Compassionate Use in patient with severe vascular disease.
- The patient was a 70-year-old male with critical limb ischemia
  - 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
- Nearly 2 years after HAV implantation, the patient continues to do well and is walking



Angiogram at 1 year

Knee joint

HAV

staples at incision

Patient's own arteries, smaller caliber

#### *42-year-old with Infected Dacron Graft*

An HAV was used in a 42-year-old female to replace an 8 mm Dacron iliac artery bypass graft that had become infected. The patient refused harvesting of the femoral vein for reconstruction and requested the HAV. The patient was seen at one, three, six, nine, and 12 months after HAV implantation. At all visits, the HAV appeared normal with unobstructed patency. Flow and velocities were normal. At three months, the patient was released to full activity. At six and 12 months, the graft was functioning well. At one-year imaging, the HAV was patent and appeared remarkably similar to the patient's native blood vessels. The patient had no signs of infection in the HAV and continues to have no limitations or complications during normal activity or exercise.

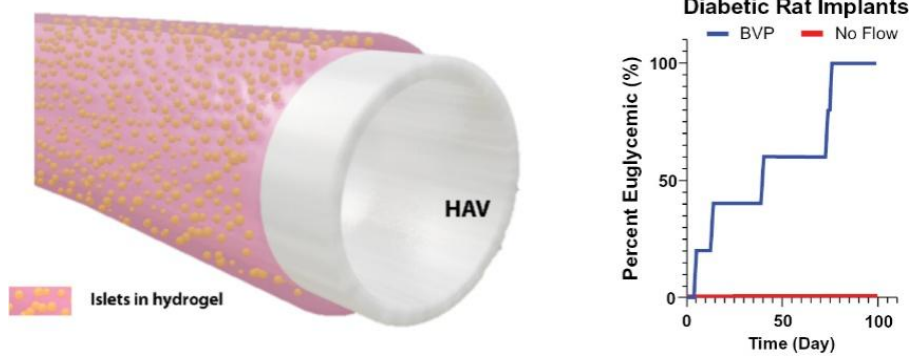
#### **Preclinical Pipeline**

##### *Pancreatic Islet Transplantation for Type 1 Diabetes ("Biovascular Pancreas")*

The Biovascular Pancreas ("BVP") is a modification of Humacyte's HAV product, leveraging the HAV to deliver therapeutic cells to within close proximity of the patient's bloodstream. We believe that the HAV extracellular matrix material is both highly biocompatible, as evidenced by adaptive cellular repopulation after implantation, and also highly angiogenic, as evidenced by extensive formation of microvessels surrounding the HAV in vivo. These attributes mean that the HAV may serve as a suitable conduit for delivering large numbers of therapeutic cells to a patient.

Pancreatic islets, which sense blood glucose and respond by secreting insulin, are destroyed by an auto-immune attack in patients with Type I diabetes. The outer surface of our 42cm HAV has sufficient surface area to accommodate a monolayer of approximately 800,000 human pancreatic islets, which is approximately the number in an entire adult pancreas, and can reverse diabetes and restore glucose control.

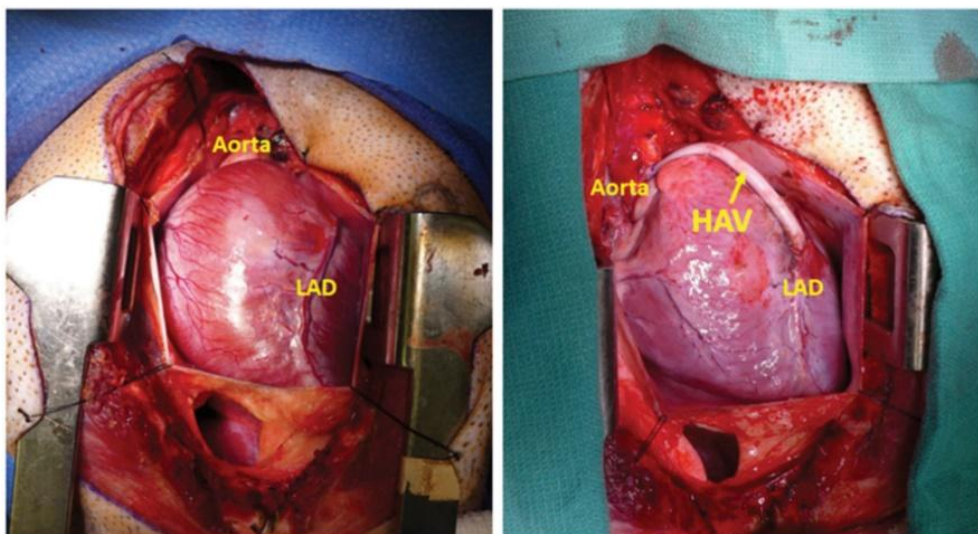
We have performed mathematical modelling studies that predict, we believe, that a 42cm HAV could maintain viability of a therapeutic number of islets after implantation of the HAV into the arterial bloodstream, or after implantation as an AV conduit similar to that used for hemodialysis access. Bioreactor experiments have confirmed these mathematical conclusions. Furthermore, we have implanted rat-sized BVPs into the aortas of diabetic rats, and observed that the BVP could restore normal glucose levels in all treated animals, while control animals (“No Flow” in red in figure below) did not restore glucose control. Studies in large animal models are planned as the next step in the development of this product candidate.



### Coronary Artery Bypass Graft (CABG)

Evaluation of 3- and 4mm diameter HAVs for coronary artery bypass is ongoing at Humacyte. Our initial pilot studies have included the use of our engineered vessels for CABG in canines, demonstrating functional patency and adequate blood flow for up to one month. To further evaluate the utility and durability of the HAV in a large animal model, we have initiated a preclinical study at Duke University to evaluate the use of our small diameter HAV for CABG in adult primates (baboons). The goal of this study is to assess patency and function for six to 12 months, as well as host responses and cellular remodeling. We anticipate that this study will provide sufficient in vivo data to support an IND filing for a Phase I clinical trial in adult CABG. As of December 31, 2021, we have implanted a 3.5mm HAV CABG from the aorta to the left anterior descending coronary artery in five baboons. HAVs are followed by ultrasound imaging of the heart, and angiographic imaging of the conduits. In January 2022, results from this preclinical study were presented at *Advanced Therapies Week* where we reported that the HAV maintained patency and exhibited host-cell remodeling and regeneration in the non-human primate model.

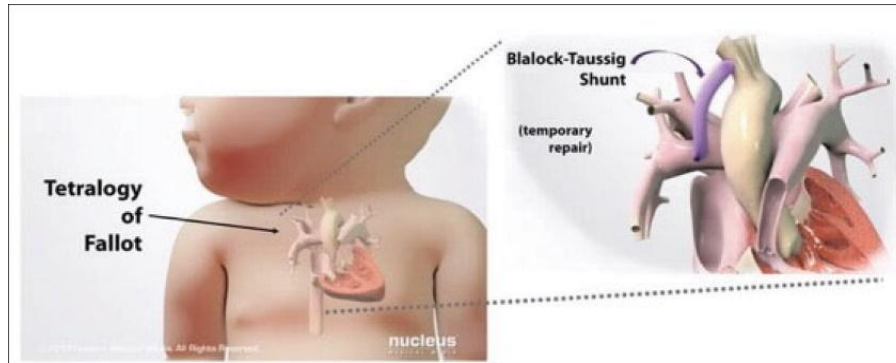
*Before (left) and after (right) implantation of HAV CABG in baboon*



*Pediatric Heart Surgery: Modified Blalock-Taussig-Thomas (mBTT) Shunt*

Tetralogy of Fallot is a relatively common congenital heart defect, that is often treated using a modified Blalock-Taussig-Thomas (“mBTT”). To support a potential future IND filing with the FDA, we have evaluated the use of our HAV as an mBTT shunt for up to six months in juvenile primates at the Research Institute at Nationwide Children’s Hospital in Columbus, Ohio.

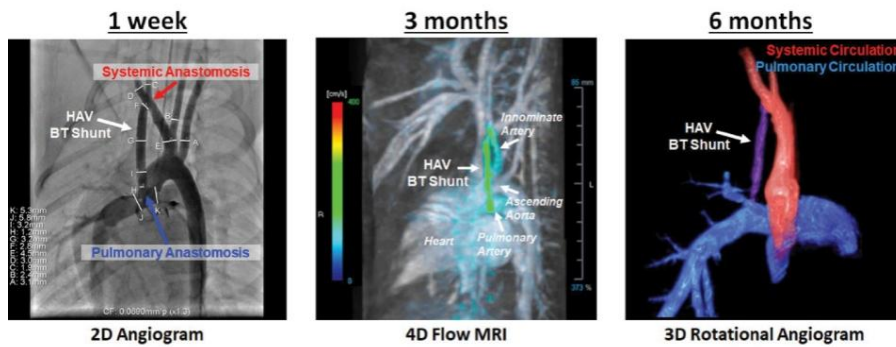
*BT Shunt Implant Schematic*



In November 2021, the results for this preclinical study were presented at the American Heart Association’s Scientific Sessions 2021 meeting. In this study, five non-immunosuppressed juvenile primates were surgically implanted with the 3.5mm diameter HAVs as mBTT shunts. The 3.5mm HAVs were implanted into primates as mBTT shunts using standard surgical techniques, and the animals were studied for three to six months. Each of the HAVs remained patent during the study and exhibited repopulation with vascular cells. Two of the primates showed a stronger xenogeneic to the human HAV material.

The 3.5mm diameter HAV has smaller product dimensions but is manufactured using a similar process as Humacyte’s 6mm HAV system currently being evaluated in clinical trials in vascular trauma, AV access for hemodialysis, and PAD. We believe that the production of the functional 3.5mm HAV is indicative of the potentially broad application of our proprietary bioengineered tissue platform and manufacturing processes.

*Imaging of 3.5mm HAV mBTT shunt in juvenile primate followed for 6 months*



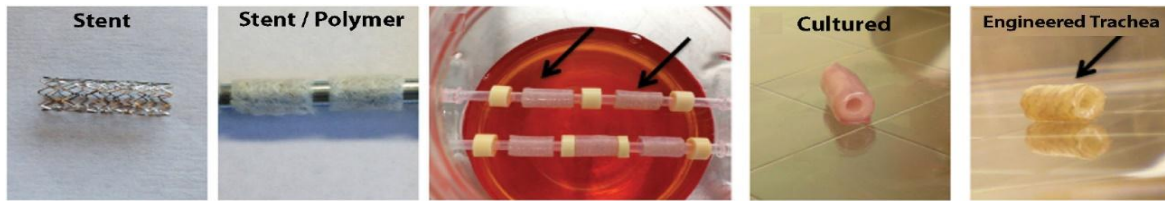
*Engineered Trachea for Treatment of Severe Airway Injuries*

Each year in the United States, approximately 4,000 operations are performed to repair or reconstruct the trachea or mainstem bronchi. But unlike most other connective tissues in the body — such as blood vessel, bone, skin and tendon — there currently are no replacements for tracheal tissue that are in widespread clinical use. For long tracheal or bronchial defects, some sort of tracheal replacement is often needed, yet none exists currently. The lack of a functional tracheal conduit commits patients to, sometimes, slow suffocation.



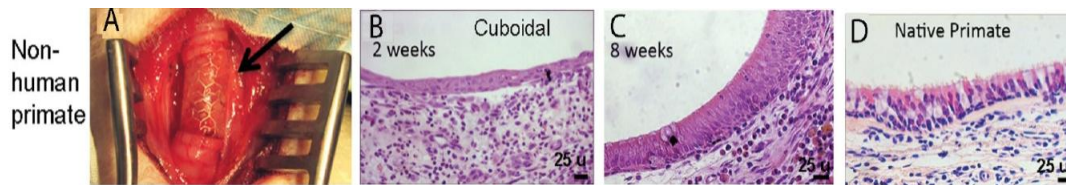
We have modified the HAV production process to enable the embedding of a biocompatible medical-grade stent within the wall of the engineered vessel. Combining a non-degradable stent with the degradable polymer scaffold used for HAV production results in a composite scaffold that can be seeded with smooth muscle cells and grown in culture. After decellularization, the engineered trachea consists of the extracellular matrix contained in the HAV, along with an embedded stent that prevents the collapse of the engineered airway with inspiration or neck movements.

*Summary of Process to Generate Engineered Tracheas*



In models where engineered tracheas were implanted into rats and non-human primates, we have observed that the implants repopulate with cells from the host, including cuboidal respiratory epithelium that lines the native airway progressively from two to eight weeks after implantation. We have further observed that the engineered tracheas can function out to two months. Future studies in large animal models are planned.

*Photograph (A) of Implantation of Engineered Trachea into Non-Human Primate Airway; Microscope Imaging of Cells Repopulating the Trachea after 2 and 8 weeks (B, C)*



*Engineered Whole Lung Organs*

End-stage lung disease is the fourth leading cause of death in the U.S., and lung transplantation remains severely limited by donor organ shortages. Dr. Niklason's laboratory at Yale University has pioneered the development of using decellularized native lungs, combined with targeted recellularization of the lung scaffolds within biomimetic bioreactors, to produce whole lungs that are capable of exchanging gas. Gas exchange for several hours has been observed in studies in rodents. Efforts to scale-up the technology to human-sized organs are ongoing.

*Structure of Lung, Scaffold for Lung Engineering, and Implanted Engineered Lung*



## ***Manufacturing***

We have developed a novel paradigm for manufacturing human tissues that mimics key aspects of human physiology. Recognizing that commercial scale production capacity of bioengineered tissue has been non-existent, we prioritized the development of a scalable, reproducible, commercial biomanufacturing process. At our 83,000 square foot manufacturing facility in Durham, North Carolina, we have industrialized this concept and created a scalable modular manufacturing process that enables us to engineer our HAVs in commercial quantities in a system designed for cGMP compliance.

Our proprietary manufacturing process was designed with a modular approach allowing us to produce HAVs in smaller batches for clinical trials and scale out to larger batches for commercial manufacturing.

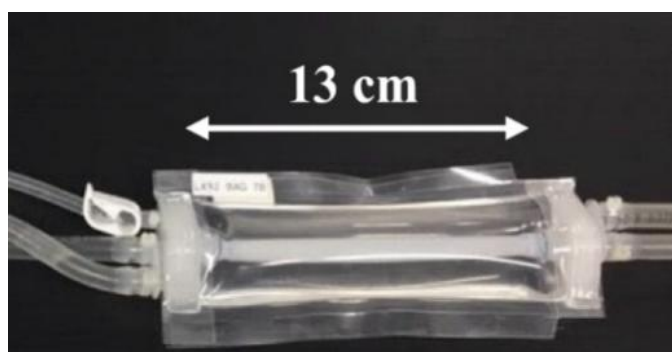
The system used in our clinical trials since 2016, including all Phase III trials, utilizes a single tray within one growth drawer holding ten HAVs per batch. These batches were manufactured at a contract manufacturer. The current, commercial-scale LUNA200 system utilizes 20 growth drawers holding ten HAVs each for a total of 200 HAVs per batch. This system is planned to be utilized for ongoing Phase III trials and for subsequent anticipated commercial launches once approved.

Our manufacturing process utilizes our LUNA200 system, consisting of 20 “growth drawers.” Each growth drawer is capable of producing ten 42cm HAVs and each HAV remains contained within an individual bioreactor bag. Inside a LUNA200, a closed tubing network connects all 20 growth drawers as well as the ten bioreactor bags in each drawer, allowing the entire system to share cells and nutritive media. In this way, a single LUNA200 can produce up to 200 HAVs per batch while maintaining the critical operating parameters that direct growth, creating a gross capacity of approximately 900 HAVs per system annually.

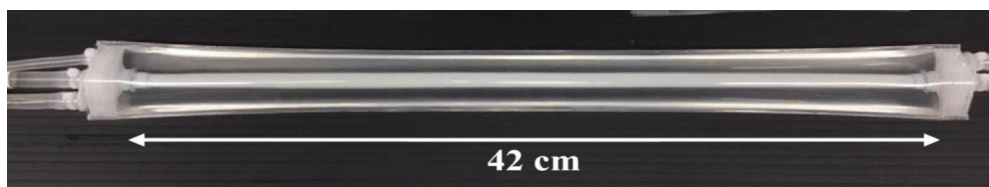
A thorough comparability assessment was performed to evaluate HAV batches produced in the single drawer system and used in Phase III studies versus the 20-drawer LUNA200 system. The study assessed 22 separate comparisons on the identity, strength, quality, purity, and potency of the HAV product. In this study, we observed that HAVs produced in the LUNA200 system were comparable to HAVs used in our Phase III trials. Additionally, a crossover study, called V011, completed enrollment of 30 subjects to evaluate HAVs that are manufactured on Humacyte’s commercial LUNA200 platform with the primary goal to evaluate the safety, efficacy and immunogenicity of the LUNA200-manufactured HAVs. Thus far in this trial we have observed comparable safety profile between HAV used in previous studies and the HAV manufactured in the LUNA200 commercial system. The results of the comparability assessment and the 30-day results from the V011 crossover study were submitted to the FDA. In 2021, the FDA authorized the use of HAVs produced in the commercial LUNA200 system to supply our ongoing clinical trials. We plan to also use the LUNA200 system for anticipated commercial launches of the HAV if it is approved.

We have designed the LUNA200 to have the ability to produce HAVs in diameter sizes from 3mm to 10mm and lengths from 10cm to 42cm, making the equipment suitable for the varied array of product candidates in our pipeline. We intend to introduce a 13cm HAV line extension after commercial launch of the 42cm HAV. Using our existing LUNA manufacturing equipment, we can generate 400 13cm HAVs per batch. Our modular manufacturing platform can be scaled without impacting the operating parameters that support the HAV growth process. We have designed our manufacturing system to be functionally closed, to utilize single-use disposable materials with aseptic connections, and to be fully automated.

### *Modular Manufacturing Platform Allows for Production of Multiple Product Lengths Using the Same Equipment*



We currently have eight LUNA200 systems installed, commissioned and qualified in our manufacturing facility, creating an annual gross HAV capacity of approximately 7,200 HAVs. Our manufacturing facility contains space to increase capacity in future years to approximately 40 LUNA200 systems in total. As we continue to expand production, we believe that we will have the ability to take advantage of economies of scale and reduce production costs. The initiation and pace of the expansion of vessel capacity will be determined based on our assessment of market opportunity.



We initiate HAV production using primary human aortic vascular cells from a working cell stock (“WCS”) that is isolated from FDA-compliant donor tissues and cryopreserved. The WCS vials are stored at two separate qualified facilities to mitigate the risk of single site storage. We qualify all new WCSs for use in HAV manufacturing utilizing biochemical and gene expression assays. Each qualified primary isolation can produce approximately 500,000 to one million HAVs.

The WCS expanded using traditional cell culture techniques, and the cells are transferred onto a biocompatible, biodegradable polymer mesh within a flexible, single-use bioreactor bag. Cells inoculated onto this tubular mesh are cultured utilizing a proprietary culture medium and subjected to cyclic mechanical stretch for a period of approximately eight weeks. During this period, the cells proliferate and build extracellular matrix while the polymer mesh degrades. The resulting bioengineered vessel is comprised of the aortic vascular cells and their deposited extracellular matrix. After completion of the culture period, we decellularize the bioengineered vessel using a proprietary combination of salts, enzymes and detergents, followed by numerous washes in excipient grade neutral pH buffered saline. The resulting HAV retains the human extracellular matrix constituents and, therefore, the biomechanical properties of the bioengineered vessel, but cells and cellular components, which could induce a foreign body response or immune rejection following implantation, are removed. After decellularization, our HAVs are packaged for distribution inside the same flexible bioreactor bag in which they were produced, with sterile phosphate buffered saline as the excipient. Once the package is delivered to the operating room, the HAV is removed from the bioreactor bag by the surgical staff.

### ***Suppliers***

We source critical components and necessary raw materials from vendors that have been approved and qualified through our vendor management program. SeraCare, which was subsequently acquired by LGC Clinical Diagnostics, Inc. (“SeraCare”), is the current single source supplier of human plasma used in our manufacturing process and Confluent Medical Technologies, Inc. (“Confluent”) is the current single source supplier of the polymer mesh we use. We source custom, Humacyte-designed, pre-sterilized (gamma irradiated) assemblies and single-use tubing sets through multiple approved vendors. We source bioprocess solutions, including culture media and decellularization buffers, from a division of Thermo Fisher Scientific, which has a second production site to provide redundant media/buffer production capacity. We are in the process of developing redundant vendors for all critical materials and we manage all vendor changes through a robust change control process.

### ***Supply Agreement with SeraCare***

In January 2014, we entered into a supply agreement with SeraCare for the supply of human plasma, which was amended in October 2018. We refer to the supply agreement, as amended, as the SeraCare Agreement. Under the SeraCare Agreement, we agreed to purchase at least a substantial majority of our human plasma requirements from SeraCare. In the event SeraCare is unable to fulfill our requirements, and subject to certain conditions, we may engage another plasma supplier during the period in which SeraCare is unable to fulfill our requirements. The SeraCare Agreement is subject to annual price modifications in the case of significant changes in SeraCare’s cost of raw materials, with any modification to be determined at least three months prior to the end of the relevant year. The initial term of the SeraCare Agreement expires on October 12, 2023, but automatically extends for subsequent one-year periods unless terminated by either party at least 18 months prior to the end of the initial term. Either party may terminate the SeraCare Agreement for uncured material breach or for the insolvency of the other party at any time. In addition, either party may terminate the SeraCare Agreement without cause upon 12 months’ written notice. We may also terminate the agreement in the event of certain supply interruptions. Each party also agreed to indemnify the other against certain third-party claims up to a specified cap.

### *Supply Agreement with Confluent*

In August 2015, we entered into an agreement for the supply of polymer mesh, which we refer to as the mesh supply agreement, with Biomedical Structures LLC. Biomedical Structures' rights and obligations under the mesh supply agreement were subsequently assigned to Confluent in connection with Confluent's acquisition of Biomedical Structures in 2016. In 2020, the agreement was amended to align with the growth expected with the transition to commercial distribution following FDA approval. Pursuant to the mesh supply agreement, the price of polymer mesh we purchase from Confluent is subject to potential adjustment if Confluent's cost of raw materials increases above a specified threshold pursuant to good faith negotiations from both parties, which negotiation Confluent may not request more than once in a 12-month period. The 2020 amendment also provided volume driven discounts. Confluent is obligated to partner with Humacyte in order to establish redundant facilities for the manufacture of the polymer mesh at established contractual volume thresholds. The amended mesh supply agreement has a term of three years, which can be automatically extended for subsequent one-year periods and will continue to do so unless either party provides notice of non-renewal at least 120 days prior to the end of the then-current term or otherwise terminates in accordance with the agreement. We and Confluent are each also permitted to terminate the mesh supply agreement for convenience, however Confluent must provide us with at least 365 days written notice and we are obligated to provide 180 days' notice, prior to such a termination. In addition, each party is permitted to terminate the mesh supply agreement for an uncured material breach by the other party following failure to remedy the breach during a sixty-day cure period. Both parties have agreed to indemnify one another for certain third-party claims.

### **Distribution**

#### *Commercialization Strategy Within United States and for Earlier-Stage Pipeline Programs*

For our vascular repair and replacement applications of our technology, including renal replacement therapy for dialysis access, the treatment of PAD, and the treatment of vascular trauma, we have retained the right to commercialize our HAV within the United States, and expect to commercialize the HAV through a combination of our own direct sales and marketing team combined with our partnership with Fresenius Medical Care described below. We plan to own end-to-end commercialization while pursuing collaborations with appropriate strategic partners who have established distribution channels for supplying customer care centers.

Our first expected market launch, in the treatment of vascular trauma, is a highly concentrated market of approximately 190 Level I Trauma Centers that may be reached with a small field sales forces of no more than 20 representatives. Many of the major trauma centers already have familiarity with our HAV product candidate through their participation in our clinical trials. Our sales effort will include dual targeting of surgeons to create pull-through demand and hospital administration (trauma center Value Analysis Committees) to assure adoption and uptake of the HAV in vascular trauma.

We expect that the large market potential of earlier-stage applications of our technology platform such as CABG and biovascular pancreas for diabetes will provide additional collaboration opportunities, and we expect explore strategic partnerships for these product candidates as preclinical and clinical results providing additional proof of concept are generated.

#### *Distribution Agreement with Fresenius Medical Care*

We entered into a distribution agreement with Fresenius Medical Care in June 2018 which, as amended as of February 16, 2021, granted Fresenius Medical Care and its affiliates exclusive rights to develop outside the United States and European Union (the "EU") and commercialize outside of the United States our 6 millimeter x 42cm HAV and all improvements thereto, and modifications and derivatives thereof (including any changes to the length, diameter or configuration of the foregoing), for use in vascular creation, repair, replacement or construction, including renal replacement therapy for dialysis access, the treatment of peripheral arterial disease, and the treatment of vascular trauma, but excluding coronary artery bypass graft, pediatric heart surgery, or adhering pancreatic islet cells onto the outer surface of the distribution product for use in diabetic patients. Within the United States, Fresenius Medical Care will collaborate with Humacyte in its commercialization of the product in the field, including adoption of the distribution product as a standard of care in patients for which such use is supported by clinical results and health economic analyses.

We are responsible for developing and seeking regulatory approval for the distribution product in the field in the United States. For countries outside the United States, the parties agreed to use commercially reasonable efforts to satisfy certain agreed minimum market entry criteria for the distribution product in the field in such country. For the EU, once such criteria have been satisfied for the applicable country, or if the parties otherwise mutually agree to obtain regulatory

approval for the distribution product in the field in the applicable country, we agreed to use commercially reasonable efforts to obtain such regulatory approval (other than pricing approval), and Fresenius Medical Care agreed to use commercially reasonable efforts to obtain the corresponding pricing approval. For the rest of the world (i.e., outside the United States and the EU), once such criteria have been satisfied for the applicable country, or if the parties otherwise mutually agree to obtain regulatory and pricing approval for the distribution product in the field in the applicable country, Fresenius Medical Care agreed to use commercially reasonable efforts to obtain such approvals, and we agreed to use commercially reasonable efforts to support Fresenius Medical Care in its efforts.

Under the distribution agreement, we grant an exclusive, sublicensable license to Fresenius Medical Care under the patents, know-how and regulatory materials controlled by us during the term to commercialize the distribution product in the field outside the United States, subject to our retained rights to carry out our obligations under the distribution agreement. We also grant a non-exclusive, sublicensable license to Fresenius Medical Care under the patents, know-how and regulatory materials controlled by us during the term to develop the distribution product in accordance with the terms of the distribution agreement. In addition, we grant to Fresenius Medical Care, among other things, a perpetual, irrevocable, non-exclusive sublicensable license under the patents and know-how that primarily relate to the distribution product or its manufacture and that were created, conceived or developed solely or jointly by or on behalf of Fresenius Medical Care in the performance of its activities under the distribution agreement.

The distribution agreement provides that we will own all know-how and patents that primarily relate to the distribution product or its manufacture that are created, conceived or developed by or on behalf of either party in the performance of activities under the distribution agreement. Ownership of all other know-how, patents, materials and other intellectual property created, conceived or developed during the performance of activities under the distribution agreement will be determined in accordance with U.S. patent laws for determining inventorship.

We are obligated to make payments to Fresenius Medical Care based on a share of aggregate net sales by or on behalf of us of the distribution product in the United States in the field. Such revenue-share payments will be a percentage of net sales in the low double digits, without regard to the calendar year in which such net sales are attributable, until such time that we have paid to Fresenius Medical Care a certain total amount, at which time the revenue-share will decrease to a percentage of net sales in the mid-single digits. The amounts that Fresenius Medical Care will be obligated to pay us under the distribution agreement for sales of the distribution product in the field outside of the United States will vary. Fresenius Medical Care agreed to pay us initially, on a country-by-country basis for sales outside of the United States, the amount equal to the average cost of manufacturing our distribution product plus a fixed dollar amount per unit. Following a specified period, on a country-by-country basis outside of the United States, Fresenius Medical Care will pay us a fixed percentage of net sales for each unit sold in such country, such that the Company will receive more than half of such net sales.

The distribution agreement will generally continue on a country-by-country basis until the later of the tenth anniversary of the launch date of the distribution product in the relevant country or (b) the expiration of the last-to-expire valid claim of specified patents in such country. Each party is permitted to terminate the distribution agreement for insolvency of, or, under certain circumstances, including various cure periods, material breach by the other party. Subject to a cure period, Fresenius Medical Care may also terminate the distribution agreement in its entirety or on a country-by-country basis (i) for certain withdrawals of regulatory approval or (ii) for termination or expiration of any of our in-licenses that is necessary for the exercise of Fresenius Medical Care's rights, or the satisfaction of its obligations, under the distribution agreement. In addition, Fresenius Medical Care may terminate the distribution agreement for convenience on a country-by-country basis upon not less than 12 months' written notice to us, although Fresenius Medical Care is not permitted to give such notice prior to the end of the second year following launch of the distribution product in such country. Each party is required to indemnify one another for certain third-party claims.

### ***Third-Party Reimbursement***

We anticipate that coverage and reimbursement by the Centers for Medicare and Medicaid Services ("CMS") and private payors will be essential for most patients and health care providers to afford our treatments, particularly in the applications of renal replacement therapy for dialysis access and the treatment of PAD. Accordingly, sales of our products will depend substantially, both domestically and abroad, on reimbursement by government authorities, private health coverage insurers and other third-party payors. Our strategy around HAV reimbursement focuses on achieving alignment and agreement from CMS on coding and payment pathways; both are critical to influencing and achieving optimal reimbursement payment from private payor sources. Therefore, Humacyte continues to develop a comprehensive reimbursement strategy including CMS, private payors, and other key stakeholders to ensure a clear and sustainable reimbursement path for all HAV product opportunities.

We are pursuing a dual regulatory and legislative reimbursement strategy to ensure separate Medicare payment for the HAV at an appropriate price. The regulatory strategy includes (1) engaging CMS political and career staff directly on coverage, payment, and coding followed by (2) submission of formal applications in these areas once FDA approval is obtained. Currently, no RMTA tissue engineered product has established coverage and reimbursement by CMS, and it is difficult to predict what CMS will decide with respect to coverage and reimbursement for fundamentally novel products. See “Risk Factors — Risks Related to the Development and Commercialization of Our Product Candidates” for further information. Even if we receive marketing approval for our HAVs, there is uncertainty with respect to third-party coverage and reimbursement of our HAVs. They may also be subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, any of which could harm our business, prospects, operating results and financial condition.

### ***Intellectual Property***

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to the development of our business, including seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We also rely on trade secrets relating to our proprietary technology platform and on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain our proprietary position that may be important for the development of our business. We additionally may rely on regulatory protection afforded through data exclusivity, market exclusivity and patent term extensions where available.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets, and operate without infringing the valid and enforceable patents and proprietary rights of third parties.

As of December 31, 2021, our patent estate is comprised of 15 families of patents. Of these families, nine are solely owned by Humacyte, one is jointly owned by Humacyte and Global Life Sciences Solutions USA LLC, one is jointly owned by Humacyte and Yale University, two are exclusively licensed to Humacyte from Duke University and two are exclusively licensed to Humacyte from Yale University. For more information regarding these license agreements, see “— License Agreement with Duke University” and “— License Agreements with Yale University.”

Our 15 families of patents are comprised of:

- (i) eight issued U.S. patents, 64 foreign patents in Austria, Belgium, Canada, China, Cyprus, Denmark, France, Germany, Hong Kong, Hungary, Ireland, Italy, Japan, Liechtenstein, Netherlands, Spain, Sweden, Switzerland, Turkey, and the UK, five pending U.S. non-provisional patent applications, one pending PCT patent application and two pending foreign applications in Europe and Hong Kong, which are solely owned by us,
- (ii) three issued U.S. patents, 18 issued foreign patents in Australia, Austria, Belgium, Canada, Denmark, France, Germany, Ireland, Italy, Japan, Liechtenstein, Netherlands, Spain, Sweden, Switzerland, Turkey, and the UK, one pending U.S. non-provisional patent application, and three pending foreign patent applications in Europe and Canada, which we co-own, and
- (iii) two issued U.S. patents, 23 issued foreign patents in Australia, Austria, Belgium, Canada, Denmark, France, Germany, Ireland, Italy, Liechtenstein, Netherlands, Spain, Sweden, Switzerland, Turkey, and the UK, one pending U.S. non-provisional patent application, and seven pending foreign patent applications in Australia, Canada, Europe, Japan, China, and Hong Kong, which we exclusively license.

Many of these patents and patent applications generally relate to the scaffolds used to make our vessels, the composition of our vessels, and systems and methods of manufacturing our vessels. Excluding any patent term adjustment or patent term extension, the U.S. patent relating to the scaffold used to make our vessels expires in 2032, the U.S. patents relating to the composition of our vessels expire in 2032 and the U.S. patents relating to the systems and methods of manufacturing our vessels expires in 2032. The U.S. patent relating to the entangler machinery used to make tubular scaffolds expires in 2035. Included in our patent portfolio are three pending, Humacyte-owned non-provisional applications relating to the manufacturing of engineered tissues at commercial scale. If these three non-provisional applications are allowed, such additional patents issuing therefrom would be expected to expire around 2040.

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position for our product candidates will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, our owned and licensed pending patent applications, and any patent

applications that we may in the future file or license from third parties, may not result in the issuance of patents. For more information, see “Risk Factors — Risks Related to Our Intellectual Property.”

We have also registered trademarks for use in connection with our products. These include registrations for HUMACYL™ in the United States, Europe, Australia, Canada, China, and Israel; HUMAGRAFT™ in Australia, China, Europe, and Israel; HUMAPASS™ in Europe, Australia, and Israel; and HUMACYTE, in the United States, Europe, Australia, Canada, and Israel. We may pursue additional registrations for future products in markets of interest.

In addition to the above, we have established expertise and development capabilities focused in the areas of preclinical research and development, manufacturing process scale-up, cGMP manufacturing, quality control, quality assurance, compliance, regulatory affairs and clinical trial design and execution. We believe that our focus and expertise will help us develop and expand technology-based applications leveraging our proprietary intellectual property.

Finally, we rely, in some circumstances, on trade secrets to protect our technology. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

In addition to the intellectual property that we have developed internally, we license rights to certain intellectual property that is material to our business prospects. We have summarized our material license agreements below.

#### *License Agreement with Duke University*

In March 2006, we entered into a license agreement with Duke University (“Duke”), which was subsequently amended in 2011, 2014, 2015, 2018, 2019 and January 2022. We refer to the license agreement, as amended, as the Duke License Agreement. Under the Duke License Agreement, Duke granted us a worldwide, exclusive, sublicensable license to certain patents related to decellularized tissue engineering, which we refer to as the patent rights, as well as a non-exclusive license to use and practice certain know-how related to the patent rights. The relevant licensed patent on decellularization of tissue expired in 2021. We have agreed to use commercially reasonable efforts to develop, register, market and sell products utilizing the patent rights, which we refer to as the licensed products. Any services provided to a third party utilizing licensed products are referred to as licensed services. We have also agreed to meet certain benchmarks in our development efforts, including as to development events, clinical trials, regulatory submissions and marketing approval, within specified timeframes. Under the Duke License Agreement, Duke retains the right to use the patent rights for its own educational and research purposes, and to provide the patent rights to other non-profit, governmental or higher-learning institutions for non-commercial purposes without paying royalties or other fees.

In connection with our entry into the Duke License Agreement, we granted equity consideration to Duke in the form of 52,693 shares of our post-Merger common stock. Under the Duke License Agreement, we have also agreed to pay Duke: a low single-digit percentage royalty on eligible sales of licensed products and licensed services, plus a low double-digit percentage of any sublicensing revenue; an annual minimum royalty beginning in 2012, which increases in the calendar year immediately following the first commercial sale of licensed products or licensed services (whichever occurs first); and an additional amount in license fees, as certain scientific milestones are met.

The Duke License Agreement remains effective until the latter of (i) the last of the patent rights expires or (ii) four years after our first commercial sale, unless earlier terminated. Either party may terminate the agreement for fraud, willful misconduct or illegal conduct, or uncured material breach. Duke may terminate the agreement if we become insolvent. Duke may also terminate the license, convert the license into a non-exclusive license or seek assignment of any sublicense if we fail to reach diligence milestones within the applicable time period. If we abandon any claim, patent or patent application, our rights under the license with respect to such patent rights will be terminated in the territory in which we abandon such rights. We may terminate the Duke License Agreement unilaterally upon three months’ prior notice to Duke. We agree to indemnify Duke against certain third-party claims.

#### *License Agreements with Yale University*

##### *Large Diameter HAV*

In August 2019, we entered into a license agreement with Yale University (“Yale”) that granted us a worldwide license to the patents jointly owned with us related to tubular prostheses which are large diameter versions of our vessels, which may or may not contain a stent. The license granted under the agreement is exclusive in the field of engineered urinary conduits, engineered tracheae/airways and engineered esophagi, except that it is subject to Yale’s non-exclusive right, on

behalf of itself and all other non-profit academic institutions, to use the licensed products for research, teaching, and other non-commercial purposes. We have agreed to use reasonable commercial efforts to develop and commercialize the licensed patents and any licensed products and methods, and to use reasonable efforts to make the licensed products available to patients in low and low-middle income countries. We are also obligated to provide Yale periodically an updated and revised copy of our plan, which must indicate progress of our development and commercialization. We may also sublicense our rights without Yale's prior written consent, but such sublicense is subject to certain conditions.

In connection with our entry into the Yale License Agreement, we paid Yale an upfront cash fee of less than \$0.1 million. We have also agreed to pay to Yale: an annual maintenance fee, increasing between the first anniversary of the agreement until the fifth anniversary up to a maximum of less than \$0.1 million per year; milestone payments upon achievement of certain regulatory and commercial milestones of \$0.2 million and \$0.6 million for this license; a low single-digit percentage royalty on worldwide net sales, subject to reductions for third-party license fees; and a low double-digit percentage of sublicensing income.

If we or any of our future sublicensees bring a patent challenge against Yale or assist another party in bringing a patent challenge against Yale, the license fees described above will be subject to certain increases and penalties.

The agreement expires on a country-by-country basis on the date on which the last of the patents in such country expires, lapses or is declared invalid. Issued patents and additional patents issuing from this licensed portfolio will expire no earlier than 2032, and the term of each patent may be extended by patent term adjustment, patent term extension, or foreign equivalents thereof. Issued U.S. patent No. 10,172,707 will expire no earlier than 2035. Issued patents and additional patents issuing from this licensed portfolio will expire no earlier than 2032, and the term of each patent may be extended by patent term adjustment, patent term extension, or foreign equivalents thereof. Issued U.S. patent No. 10,172,707 will expire no earlier than 2035. Yale may terminate the agreement if we fail to (i) provide written diligence reports, (ii) provide a commercially reasonable diligence plan, (iii) implement the plan in accordance with the obligations under the agreement, or (iv) reach certain research and development milestones within the scheduled timeframe set forth in the agreement; however, any such termination right would be limited in scope to the country or countries to which such failure relates. Yale may also terminate for our non-payment, uncured material breach, failure to obtain adequate insurance, bringing or assisting in bringing of a patent challenge against Yale, abandonment of the research and development of our product or insolvency. We may terminate the license agreement (i) on 90 days' prior written notice to Yale, provided we are not in breach of the license agreement and have made all required payments to Yale thereunder and (ii) on written notice to Yale following an uncured material breach. Under certain circumstances, Yale may, at its option, convert the exclusive license to a non-exclusive license if we decline to initiate certain infringement or interference proceedings with respect to the licensed patents. We have agreed to indemnify Yale against certain third-party claims.

#### *Small Diameter HAV Coating*

In February 2014, we entered into a license agreement with Yale that granted us a worldwide license to the patents related to coatings for small-diameter vessels to inhibit clotting. The license granted under the agreement is exclusive in the field of engineered vascular tissues and tissues and extracellular matrix-based implants used for vascular repair, reconstruction and replacement (provided that all uses are vascular tissues within the range of 1-12mm in diameter), except that it is subject to Yale's non-exclusive right, on behalf of itself and all other non-profit academic institutions, to use the licensed products for research, teaching, and other non-commercial purposes. We have agreed to use reasonable commercial efforts to develop and commercialize the licensed patents and any licensed products and methods, and to use reasonable efforts to make the licensed products available to patients in low and low-middle income countries. We are also obligated to provide Yale periodically an updated and revised copy of our plan, which must indicate progress of our development and commercialization. We may also sublicense our rights without Yale's prior written consent, but such sublicense is subject to certain conditions.

In connection with our entry into the Yale License Agreement, we paid Yale an upfront cash fee of less than \$0.1 million. We have also agreed to pay to Yale: an annual maintenance fee, increasing between the first anniversary of the agreement until the fifth anniversary up to a maximum of less than \$0.1 million per year; milestone payments upon achievement of certain regulatory and commercial milestones of \$0.2 million and \$0.6 million for this license; a low single-digit percentage royalty on worldwide net sales, subject to reductions for third-party license fees; and a low double-digit percentage of sublicensing income.

If we or any of our future sublicensees bring a patent challenge against Yale or assist another party in bringing a patent challenge against Yale, the license fees described above will be subject to certain increases and penalties.



The agreement expires on a country-by-country basis on the date on which the last of the patents in such country expires, lapses or is declared invalid. Issued patents and additional patents issuing from this licensed portfolio will expire no earlier than 2034, and the term of each patent may be extended by patent term adjustment, patent term extension, or foreign equivalents thereof. Issued patents and additional patents issuing from this licensed portfolio will expire no earlier than 2034, and the term of each patent may be extended by patent term adjustment, patent term extension, or foreign equivalents thereof. Yale may terminate the agreement if we fail to (i) provide written diligence reports, (ii) provide a commercially reasonable diligence plan, (iii) implement the plan in accordance with the obligations under the agreement, or (iv) reach certain research and development milestones within the scheduled timeframe set forth in the agreement; however, any such termination right would be limited in scope to the country or countries to which such failure relates. Yale may also terminate for our non-payment, uncured material breach, failure to obtain adequate insurance, bringing or assisting in bringing of a patent challenge against Yale, abandonment of the research and development of our product or insolvency. We may terminate the license agreement (i) on 90 days' prior written notice to Yale, provided we are not in breach of the license agreement and have made all required payments to Yale thereunder and (ii) on written notice to Yale following an uncured material breach. Our rights under the license agreement will also terminate automatically with respect to a patent application or patent within the licensed patents in a specified country if, upon receipt of written notice from Yale, we do not agree to pay the patent filing, prosecution and maintenance fees incurred by Yale for such patent applications or patents in the specified country. Under certain circumstances, Yale may, at its option, convert the exclusive license to a non-exclusive license if we decline to initiate certain infringement or interference proceedings with respect to the licensed patents. We have agreed to indemnify Yale against certain third-party claims.

#### *Biovascular Pancreas*

In August 2019, we entered into a license agreement with Yale that granted us a worldwide license to its patents related to a biovascular pancreas. The license granted under the agreement is exclusive in the field of acellular vascular tissues that deliver pancreatic islet cells to patients, except that it is subject to Yale's non-exclusive right, on behalf of itself and all other non-profit academic institutions, to use the licensed products for research, teaching, and other non-commercial purposes. We have agreed to use reasonable commercial efforts to develop and commercialize the licensed patents and any licensed products and methods, and to use reasonable efforts to make the licensed products available to patients in low and low-middle income countries. We are also obligated to provide Yale periodically an updated and revised copy of our plan, which must indicate progress of our development and commercialization. We may also sublicense our rights without Yale's prior written consent, but such sublicense is subject to certain conditions.

In connection with our entry into the Yale License Agreement, we paid Yale an upfront cash fee of less than \$0.1 million. We have also agreed to pay to Yale: an annual maintenance fee, increasing between the first anniversary of the agreement until the fifth anniversary up to a maximum of less than \$0.1 million per year; milestone payments upon achievement of certain regulatory and commercial milestones of \$0.1 million and \$0.2 million for this license; a low single-digit percentage royalty on worldwide net sales, subject to reductions for third-party license fees; and a low double-digit percentage of sublicensing income.

If we or any future sublicensees bring a patent challenge against Yale or assist another party in bringing a patent challenge against Yale, the license fees described above will be subject to certain increases and penalties.

The agreement expires on a country-by-country basis on the date on which the last of the patents in such country expires, lapses or is declared invalid. Patents issuing from this licensed portfolio will expire no earlier than 2039, and the term of each patent may be extended by patent term adjustment, patent term extension, or foreign equivalents thereof. Patents issuing from this licensed portfolio will expire no earlier than 2039, and the term of each patent may be extended by patent term adjustment, patent term extension, or foreign equivalents thereof. Yale may terminate the agreement if we fail to (i) provide written diligence reports, (ii) provide a commercially reasonable diligence plan, (iii) implement the plan in accordance with the obligations under the agreement, or (iv) reach certain research and development milestones within the scheduled timeframe set forth in the agreement; however, any such termination right would be limited in scope to the country or countries to which such failure relates. Yale may also terminate for our non-payment, uncured material breach, failure to obtain adequate insurance, bringing or assisting in bringing of a patent challenge against Yale, abandonment of the research and development of our product or insolvency. We may terminate the license agreement (i) on 90 days' prior written notice to Yale, provided we are not in breach of the license agreement and have made all required payments to Yale thereunder and on written notice to Yale following an uncured material breach. Our rights under the license agreement will also terminate automatically with respect to a patent application or patent within the licensed patents in a specified country if, upon receipt of written notice from Yale, we do not agree to pay the patent filing, prosecution and maintenance fees incurred by Yale for such patent applications or patents in the specified country. Under certain circumstances, Yale may, at its option, convert the exclusive license to a non-exclusive license if we decline to initiate certain infringement or

interference proceedings with respect to the licensed patents. We have agreed to indemnify Yale against certain third-party claims.

### **Competition**

Despite the magnitude and critical nature of the diseases and conditions we are targeting, no significant advances in the open surgical market have been made in the last 35 years, and current treatment and products used in vascular repair, reconstruction and replacement suffer from various drawbacks. The large majority of vascular repair, reconstruction and replacement procedures rely on either harvesting autologous veins or using synthetic grafts. However, each method presents significant limitations as discussed below:

#### *Autologous Veins*

The harvest of autologous veins is a serious operation that can result in numerous complications, including infection, chronic pain, and limb swelling that severely impact the patient's quality of life. In addition, this procedure can often result in long recovery times, increased hospital stays, and increased risk of hospital readmission. In order to obtain an autologous vein, such as a saphenous vein, for use in a surgical procedure, a second operation must be performed on the patient to harvest the vein. The harvesting process must be completed before the bypass procedure occurs and can take significant time to complete, which increases costs related to the additional operative time and staff required to perform the operation. Even if successful, the patient's recovery time could increase as the patient must recover from two surgical procedures instead of one, further increasing morbidity and cost. Additionally, a significant percentage of patients are not suitable for vein harvesting either due to vein or limb damage, limited vein supply from prior harvest, venous disease or the surgeon's desire to preserve the vein for future coronary or other bypass procedures. In acute trauma, the time to restore blood flow to injured limbs is delayed when a vein must be harvested from the patient, which puts the limbs at greater risk of reduced function or amputation. For patients suffering from vascular trauma, some types of injury preclude the harvesting of autologous saphenous vein due to concomitant injuries of one or both legs. Furthermore, time is required to prepare the vein harvest site and to remove the vein from the leg, which adds to ischemia time and can increase the risk of tissue and limb loss. Rates of traumatic limb loss are strongly tied to ischemia time, and therefore rapid revascularization using an off-the-shelf HAV conduit may decrease ischemia time and lead to better outcomes.

The use of autologous vein for creating an AV fistula for use in hemodialysis is often limited by vein size and location. The vast majority of veins must go through a process of enlargement, known as maturation, prior to use for hemodialysis. For approximately 40% of patients receiving fistulae, the vein does not mature sufficiently to allow for hemodialysis even after six months. Even in patients having adequate veins for fistula creation, the fistula often becomes large, tortuous and disfiguring and can be at risk for sometimes fatal rupture.

#### *Synthetic Grafts*

Use of synthetic materials, such as ePTFE and Dacron, while widely available, have known complications, such as continuous chronic risk of infection and clotting inside the graft. Risk of infection is significantly increased in acute battlefield and civilian injuries, as well as in contaminated wounds. The body recognizes any synthetic materials as foreign and, therefore, can mount a host foreign body response following implantation. Synthetic materials also have been shown to be inferior to autologous vein in resisting infection, and generally only are used for vascular repair when autologous vein is not an option.

In hemodialysis access, persistent puncture presents an ongoing risk of graft infection. The annual risk of infection of ePTFE grafts in hemodialysis patients can be as high as 10% – 15% per patient-year. Furthermore, gradual degradation of the non-healing ePTFE graft material caused by persistent needle punctures can eventually lead to graft failure. In traumatic vascular injury, ePTFE grafts are generally contraindicated, due to the high rates of contamination of the wound that can lead to synthetic graft infection and failure.

Two lesser used products, cryopreserved human blood vessels, known as allografts, and animal-derived vessels, known as xenografts, also involve significant limitations.

#### *Cryopreserved Blood Vessels*

To eliminate the need for harvesting autologous vein, some surgeons use allogeneic vessels that have been previously harvested from cadavers and cryogenically preserved. These allogeneic vessels are stored at -80 degrees Celsius and must be thawed prior to use, which can take up to 60 minutes. The supply of cryopreserved vessels is limited by the number of cadaveric donors available, and the vessels are often non-uniform in size. In addition, because the vessels contain human

cells from a donor, they can generate an immune rejection response that can lead to aneurismal degradation or catastrophic failure. Furthermore, development of antibodies to the implanted cryopreserved human vessel frequently has a detrimental impact on the ability of the patient to receive a transplant in the future. Cryopreserved blood vessels are only rarely used in the treatment of vascular trauma, due to the time required for procurement and thawing, and the high rates of rejection response.

#### *Animal-Derived Vessels*

Xenogeneic tissues, including cow, pig or sheep-derived vessels, are used less frequently in vascular surgery, in part due to the risk of thrombosis and structural deterioration over time. The limited clinical data that are available for existing xenografts in vascular reconstruction indicates lower patency rates and higher incidence of complications when compared to autologous vein. Xenografts are all chemically treated in efforts to minimize rejection to animal components, and therefore do not respond like living tissue. Some of these products require rinsing to remove toxic chemicals used for storage.

#### *Our Solution*

We believe our HAVs combine the off-the-shelf availability of synthetic grafts with the regenerative capabilities of autologous vessels. We believe these and other attributes have the potential to address unmet clinical needs in a range of disease states, including atherosclerosis, end-stage kidney disease, coronary artery disease, vascular trauma, pediatric congenital heart disease, airway disease, and others. We believe that the HAV's multiple key characteristics will drive rapid clinical adoption amongst surgeons and the broader healthcare community:

- **Off-the-Shelf**: Our "cabinet" of HAVs of varying diameters and lengths is designed to be stored on-site at facilities such as hospitals, trauma centers and outpatient surgical centers.
- **Immediately Available**: When needed, our HAVs are available for immediate use by opening and removing the HAV from its original flexible bioreactor bag. Since our HAV does not need flushing, harvesting or thawing, as is common with other vascular substitute alternatives, we believe hospitals will be able to use our HAVs for vascular surgery more quickly with smaller surgical teams, reduced logistics and decreased overall cost.
- **No Surgical Harvesting**: The use of our HAVs does not subject patients to the serious operation of harvesting an autologous vein, which can result in greater procedure and recovery time, potential scarring and disfigurement, increased costs, and numerous potential health complications.
- **Non-Immunogenic and No Foreign Body Response**: Given their acellular nature, our HAVs have the potential to be universally implantable and durable across patients. Because our HAVs are derived from human tissue (but cleansed of all cells and cellular components), we believe (and have observed in clinical trials to date) that they do not generate the foreign body response associated with the use of synthetic grafts, or the immune response associated with cryopreserved vessels.
- **Low Infection Susceptibility**: In clinical trials to date, we have observed reduced rates of infection in our HAVs as compared to synthetic materials. As a result, we believe our HAVs may be used in complicated and potentially contaminated wounds with fewer patient complications following the initial procedure.
- **Uniform and Predictable Size, Structure and Quality**: Harvested veins vary in size, structure and quality by donor. We manufacture our HAVs to precise specifications under controlled quality standards, which will allow surgeons the flexibility to quickly and easily select an HAV in the appropriate size and shape for each indication.
- **Regenerative Potential**: Our HAVs repopulate with the patient's own vascular cells, creating a living vascular tissue with the associated long-term benefits of self-healing and infection resistance.

If approved, we expect our HAVs would compete with the use of a patient's own blood vessels, as well as a variety of marketed products, such as conventional synthetic grafts, xenografts, and allografts, as well as developing technologies. We expect the key competitive factors affecting the commercial success of our HAVs to likely be efficacy, safety, convenience, pricing and reimbursement.

### *Other Commercial Entities*

There are several conventional synthetic grafts made of ePTFE or Dacron presently on the market from companies such as Bard Peripheral Vascular, Inc., W.L. Gore & Associates, Inc., Terumo Medical Systems, and Atrium (Maquet Getinge Group) that are used for both AV access for hemodialysis and vascular repair. Xenograft and allograft products are also available, but not widely used. Xenografts, such as Artegraft<sup>®</sup> and Procol<sup>®</sup>, are processed animal-derived vessels, while allografts are processed allogeneic cellular vessels, such as CryoVein<sup>®</sup> and AngioGRAFT<sup>®</sup>.

There are also a number of companies of which we are aware that have preclinical and early clinical-stage research programs underway to develop products that could potentially compete with our HAVs, including NovaHep AB, Xeltis AG, Hancock Jaffe, and Vascudyne Inc. We may face competition from these and other emerging technologies such as bioabsorbable polymeric implants and electrospun or 3D printed tubular conduits.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, safer, have fewer or less severe side effects, are more convenient or are less expensive than the products that we develop. Our competitors also may obtain FDA or other marketing approval for their products more rapidly than we may obtain the same approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

### **Government Regulation**

#### *Overview*

The FDA and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements on the research, development, testing, manufacture, quality control, safety, effectiveness, packaging, labeling, storage, record keeping, marketing, advertising and promotion, import/export, and distribution of our vessels.

In the United States, the FDA regulates pharmaceutical drugs, medical devices and biologic products under the Federal Food, Drug, and Cosmetic Act (“FDCA”), the Public Health Service Act (“PHSA”), FDA implementing regulations, and other laws. Our vessels are subject to regulation by the FDA as biologics. Biologics require the submission of a BLA and approval by the FDA before being marketed in the United States. None of our vessels have been approved by the FDA for marketing in the United States, and we currently have no BLAs pending. If we fail to comply with applicable FDA or other requirements at any time during the product development process, clinical testing, and the approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA’s refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any FDA enforcement action could have a material adverse effect on us.

#### *Marketing Approval — Biological Products in the United States*

Before a biologic is approved in the United States, an applicant must submit a BLA that includes sufficient evidence to establish the safety, purity, and potency of the product candidate for its intended indications, including from the results of preclinical studies and clinical trials. A BLA must also contain extensive information about manufacturing and product quality control testing, and the applicant must pass an FDA preapproval inspection of the manufacturing facility or facilities at which the biologic product is produced and distributed from to assess compliance with current good manufacturing practices, or cGMPs.

The steps for obtaining FDA approval of a BLA to market a biologic product in the United States generally include:

- Completion of extensive preclinical laboratory tests and preclinical animal studies performed in accordance with the FDA’s current good laboratory practice (“GLP”) regulations;
- Submission to the FDA of an Investigational New Drug application (“IND”), which must become effective before human clinical trials in the United States may begin;
- Approval of the protocol and related documentation by an Institutional Review Board (“IRB”) or ethics committee representing each clinical site before each clinical trial may be initiated;

- Performance of adequate and well-controlled human clinical trials according to the FDA’s regulations commonly referred to as GCPs and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the product candidate for each proposed indication;
- Submission to the FDA of a BLA;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities and distribution site at which the product is produced: to assess compliance with cGMP regulations; to assure that the facilities, production methods, testing and controls are adequate; and, if applicable, to assure compliance with cGTP requirements for human cellular and tissue-derived products;
- Potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA;
- Review of the product candidate by an FDA advisory committee, if applicable;
- Payment of user fees for FDA review of the BLA (unless a fee waiver applies); and
- FDA review and approval, or licensure, of the BLA prior to any commercial marketing, sale or shipment of the product.

#### *U.S. Biological Products Development Process*

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our vessels will be granted on a timely basis, if at all.

Once a product candidate is identified for development, that biologic candidate enters the preclinical testing stage. Preclinical studies include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies to evaluate the product’s potential safety and activity. The results of the preclinical studies, together with manufacturing information, analytical data, and at least one protocol for clinical study, are submitted to the FDA as part of an IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. This is known as a “clinical hold.” In such a case, the IND sponsor must resolve all of the FDA’s concerns to the agency’s satisfaction before the clinical trial can begin. Submission of an IND may result in the FDA not allowing the clinical trials to commence or not allowing the clinical trials to commence on the terms originally specified in the IND. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development, and the FDA must grant permission, either explicitly or implicitly by not objecting, before each clinical trial can begin. Even after a clinical trial has begun, the FDA can issue a clinical hold at any time if it concludes that certain conditions exist, such as patients may be exposed to an unreasonable and significant risk of illness or injury.

Clinical trials involve the use of the product candidate in human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be used. Each protocol must be submitted to the FDA as part of the IND. An independent IRB for each medical center proposing to conduct a clinical trial must also review and approve a plan for any clinical trial before it can begin at that center and the IRB must monitor the clinical trial until it is completed. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. Some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. This group provides authorization as to whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study. Clinical testing also must satisfy extensive GCP requirements, including the requirements for informed consent. Information about clinical trials must be submitted within specific timeframes to the National Institutes of Health (“NIH”) for public dissemination on its ClinicalTrials.gov website.

For purposes of BLA submission and approval, clinical trials are typically conducted in three sequential phases, which may overlap or be combined. For Humacyte’s development of product candidates, Phase I and Phase II trials have heretofore been combined into a single trial design. For the V005 trauma trial, we are in discussions with FDA about converting a Phase II/III study into a Phase III pivotal study.

- *Phase I.* The biological product is initially introduced into human subjects and tested for safety. These initial trials to evaluate the potential toxicity and pharmacological activity of the investigational product (including pharmacokinetics, if applicable), and, if possible, gain early evidence on effectiveness.
- *Phase II.* The biological product is evaluated in a limited patient population to identify potential adverse events and safety risks, to evaluate preliminarily the efficacy of the product candidate for specific targeted indications in patients with the disease or condition under trial, and, when applicable, to evaluate dosage tolerance and appropriate dosage.
- *Phase III.* The biological product is administered to an expanded patient population, often large numbers of patients of several hundred to several thousand and generally at geographically dispersed clinical trial sites. These trials are designed to generate enough data to statistically evaluate clinical effectiveness and safety as well as to establish the overall benefit-risk relationship of the investigational new biological product, and to provide an adequate basis for product approval. FDA typically requires at least two Phase III trials to support approval, but in some cases may approve an application on the basis of one trial.

In some cases, the FDA may condition approval of a BLA on the sponsor's agreement to conduct additional clinical trials to further assess the biologic's safety and effectiveness after BLA approval. Such post-approval clinical trials are typically referred to as Phase IV clinical trials.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the progress of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators detailing serious and unexpected adverse events, any findings from other studies that suggest a significant risk to human patients, tests in laboratory animals or in vitro testing that suggest a significant risk for human patients, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information.

The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other trials on other products. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal trials and must also develop additional information about the characteristics of the biologic and finalize a process for manufacturing the biologic in commercial quantities in accordance with cGMP and, when applicable, GTP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

#### *BLA Review Process*

The results of preclinical studies and of the clinical trials, together with other detailed information, including extensive manufacturing information, information on the composition of the biologic, and proposed labeling, are submitted to the FDA in the form of a BLA requesting approval to market the biologic in the United States for one or more specified indications. The FDA reviews a BLA to determine, among other things, whether a biologic is safe and effective for its intended use.

The FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the FDA's threshold determination that the application is sufficiently complete to permit substantive review. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMPs (and, where applicable, GTPs) to assure and preserve the product's identity, safety, strength, quality, potency, and purity, and biological product standards. The FDA may refer applications for novel biological products or biological

products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes outside clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an application, the FDA will, among other things, inspect the facility or the facilities at which the biologic product is manufactured and distributed, and will not approve the product unless cGMP compliance is satisfactory. The FDA may also inspect the sites at which the clinical trials were conducted to assess their compliance, and may refuse to approve the biologic if compliance with GCP requirements is found to be unsatisfactory. For a human cellular or tissue product the FDA also may refuse to approve the product if the manufacturer is not in compliance with GTP requirements, in addition to cGMPs.

The FDA also has authority to require a Risk Evaluation and Mitigation Strategy (“REMS”) from manufacturers to ensure that the benefits of a biological product outweigh its risks. A sponsor may also voluntarily propose a REMS as part of the BLA submission. The need for a REMS is determined as part of the review of the BLA. Based on statutory standards, elements of a REMS may include “dear doctor letters,” a medication guide, more elaborate targeted educational programs, and in some cases restrictions on distribution and/or use. These elements are negotiated as part of the BLA approval, and in some cases may delay the approval date. Once adopted, REMS are subject to periodic assessment and modification.

The testing and approval processes require substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all. Even if we believe a clinical trial has demonstrated safety and efficacy of one of our vessels for the treatment of a disease, the results may not be satisfactory to the FDA. Preclinical and clinical data may be interpreted by the FDA in different ways, which could delay, limit or prevent regulatory approval. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our vessels. The FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of the products.

Biologics may be marketed only for the FDA approved indications and in accordance with the provisions of the approved labeling. Further, if there are any modifications to the biologic, including changes in indications, labeling, or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require developing additional data or conducting additional preclinical studies and clinical trials. As with new BLAs, the review process is often significantly extended by FDA requests for additional information or clarification.

The Biologics Price Competition and Innovation Act (“BPCIA”), amended the PHSA to authorize the FDA to approve similar versions of innovative biologics, commonly known as biosimilars. A competitor seeking approval of a biosimilar must file an application to establish its product as highly similar to an approved innovator biologic, among other requirements. The BPCIA, however, bars the FDA from approving biosimilar applications for 12 years after an innovator biological product receives initial marketing approval. This bar does not apply to submission or approval of full BLAs. Because FDA has determined that our HAVs are regulated as biologics and require a BLA for marketing, we believe that our lead product will be entitled to 12 years of exclusivity upon approval. Nevertheless, the BPCIA is complex and is only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning is subject to uncertainty.

#### *Expedited Development and Review Programs*

The FDA offers various programs, including Fast Track designation, Breakthrough Therapy Designation, accelerated approval, priority review and RMAT designation, that are intended to expedite the process for the development and FDA review of biological products that are intended for the treatment of serious or life-threatening diseases or conditions. To be eligible for Fast Track designation, biological product candidates must be intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a biological product candidate may request the FDA to designate the biologic as a Fast Track product at any time during the clinical development of the product. The sponsor of a Fast Track product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the product candidate may be eligible for priority review. A Fast Track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and

determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A biological product candidate may be eligible for Breakthrough Therapy Designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy Designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient development program beginning as early as Phase I, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any marketing application for a biological product submitted to the FDA for approval, including a product candidate with a Fast Track designation and/or Breakthrough Therapy Designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. Any product candidate is eligible for priority review if it is designed to treat a serious or life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness compared to available alternatives for such disease or condition. The FDA will attempt to direct additional resources to the evaluation of an application for a biological product candidate designated for priority review in an effort to facilitate the review. Under priority review, the FDA's goal is to review an application within six months of the 60-day filing date, compared to ten months for a standard review.

Additionally, FDA may grant accelerated approval to a product candidate intended to treat a serious or life-threatening disease or condition upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

In 2017, the FDA established a new RMAT designation as part of its implementation of the 21st Century Cures Act. The RMAT designation program is intended to fulfill the 21st Century Cures Act requirement that the FDA facilitate an efficient development program for, and expedite review of, any biological product that meets the following criteria: (i) the biological product qualifies as an RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (ii) the biological product is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and preliminary clinical evidence indicates that the biological product has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides all the benefits of Breakthrough Therapy Designation, including more frequent meetings with the FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Product candidates granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of clinical trial sites, including through expansion of trials to additional sites.

Fast Track designation, Breakthrough Therapy Designation, priority review, accelerated approval, and RMAT designation do not change the standards for approval but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Additionally, on December 12, 2017, Public Law No. 115-92 amended the FDCA to, among other things, allow the DoD to request, and FDA to provide assistance to expedite development and the FDA's review of products to diagnose, prevent, treat or mitigate a specific and life-threatening risk to the U.S. military. Similar to the designations described above that FDA may grant, a priority designation by the DoD does not change the standards for approval but may expedite the development or approval process.



### *Orphan Drug Designation*

Under the Orphan Drug Act, the FDA may grant orphan designation to a biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a biological product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting a BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity, or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if a second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

### *Other U.S. Regulatory Requirements*

For biologics that are human cells, tissues, and cellular and tissue-based products (“HCT/Ps”), manufacturers must also comply with the FDA’s HCT/P regulations at 21 C.F.R. Part 1271. These regulations impose a variety of specialized requirements as follows:

*HCT/P registration and listing.* Every establishment that manufactures an HCT/P must register with the FDA and provide a list of every HCT/P that the establishment manufactures. The definition of manufacture is broad and includes any and all steps in the recovery, processing, storage, labeling, packaging or distribution of any human cell or tissue and the screening or testing of the cell or tissue donor.

*Donor eligibility.* HCT/P manufacturers must maintain procedures for testing, screening and determining the eligibility of donors of cells and tissues used in HCT/Ps. An HCT/P may not be transferred or implanted into an individual until the donor has been determined to be eligible under these procedures. These procedures must involve, among other things, testing donors for certain communicable diseases and the use of quarantines for HCT/Ps that have not yet been shown to meet the eligibility requirements. Manufacturers must keep detailed records regarding donor eligibility determinations.

*Current Good Tissue Practices.* HCT/Ps must be recovered, processed, stored, labeled, packaged and distributed in a manner that is consistent with the FDA’s cGTP regulations. Cells and tissues must also be screened and tested according to these regulations. The goal of cGTPs is to prevent the introduction, transmission or spread of communicable diseases. The FDA’s cGTPs regulations require companies to establish a comprehensive quality program and to comply with rules related to personnel, facilities and equipment used to manufacture HCT/Ps, as well as rules on how these HCT/Ps are processed, labeled and stored. Companies must also keep detailed manufacturing records and product complaint files.

*Adverse Reaction Reports.* Manufacturers of nonreproductive HCT/Ps must investigate and report to the FDA certain adverse reactions.

*Inspections.* Establishments that manufacture HCT/Ps must allow the FDA to inspect the establishment and company records.

### *Post-Approval Requirements*

Any biologics manufactured or distributed by us or our collaborators pursuant to FDA approvals would be subject to continuing post-approval regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences associated with the product, as well as any post-marketing surveillance requested by the FDA as a condition to BLA approval. Manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall our product from distribution or withdraw approval of the BLA for that product.

The FDA closely regulates the post-approval marketing and promotion of biologics to healthcare professionals, including standards and regulations for direct-to-consumer advertising, false or misleading claims, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may prescribe legally available biologics for uses that are not described in the product's labelling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

### *U.S. Healthcare Reform*

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to significantly change the healthcare system. For example, the Patient Protection and Affordable Care Act (the "ACA") was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. In December 2017, portions of the ACA dealing with the individual mandate insurance requirement were effectively repealed by the Tax Cuts and Jobs Act of 2017.

### *U.S. Third-Party Payor Coverage and Reimbursement*

Although none of our vessels have been commercialized for any indication, if they are approved for marketing, commercial success of our vessels will depend, in part, upon the availability of coverage and reimbursement from third-party payors at the federal, state and private levels. Government payor programs, including Medicare and Medicaid, private health care insurance companies and managed-care plans have attempted to control costs by limiting coverage and the amount of reimbursement for particular procedures or treatments. The U.S. Congress and state legislatures from time to time propose and adopt initiatives aimed at cost-containment. Ongoing federal and state government initiatives directed at lowering the total cost of health care will likely continue to focus on health care reform and on the reform of the Medicare and Medicaid payment systems. Examples of how limits on coverage and reimbursement in the United States may cause reduced payments for products in the future include: changing Medicare reimbursement methodologies; fluctuating decisions on which drugs to include in formularies; allowing the federal government to negotiate drug prices for federal healthcare programs; revising drug rebate calculations under the Medicaid program; and reforming drug importation laws.

Some third-party payors also require pre-approval of coverage for new or innovative devices or therapies before they will reimburse health care providers who use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our vessels and operate profitably. Significant cost containment pressure and downward pricing pressures exist in the U.S. and around the world, which may negatively affect reimbursement at any time.

### *Other Healthcare Laws and Regulations*

We are also subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. The laws that may affect our ability to operate include but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively, “HIPAA”), which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the federal Physician Payments Sunshine Act, which requires drug and device companies to annually report to CMS all payments and transfers of value provided to physicians and teaching hospitals for posting on a public website; and
- state law equivalents of many of the above federal laws, including anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers.

If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and impact our financial results.

### *International Regulation*

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our future products. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

#### *EU Requirements Applicable to Medicinal Products*

In the EU, medicinal products are subject to extensive pre-and post-market regulation by regulatory authorities at both the EU and national levels.

#### *Clinical Trials*

Clinical trials of medicinal products in the EU must be conducted in accordance with EU (previously, Directive 2001/20/EC applied; as of January 31, 2022, Regulation EU No 536/2014 applies) and national regulations and the International Conference on Harmonization (“ICH”) guidelines on GCP.

Prior to commencing a clinical trial, the sponsor must obtain a clinical trial authorization from the competent authority, and a positive opinion from an independent ethics committee of the relevant EU Member State in which the clinical trial will be carried out. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be notified to or approved by the relevant competent authorities and ethics committees.

The sponsor of a clinical trial must register the clinical trial in advance, and certain information related to the clinical trial will be made public as part of the registration. The results of the clinical trial must be submitted to the competent authorities and, with the exception of non-pediatric Phase I trials, will be made public at the latest within 12 months after the end of the trial.

During the development of a medicinal product, the European Medicines Agency (“EMA”) and national medicines regulators within the EU provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Scientific Advice Working Party of the Committee for Medicinal Products for Human Use (“CHMP”). Advice is not legally binding with regard to any future marketing authorization application of the product concerned. To date, we have not initiated any scientific advice procedures with the EMA, but we have obtained confirmation from the EMA that our HAVs would be eligible for the EMA’s scientific advice procedures.

#### *Marketing Authorizations*

After completion of the required clinical testing, we must obtain a marketing authorization before we may place a medicinal product on the market in the EU. There are various application procedures available, depending on the type of product involved.

All application procedures require an application in the common technical document format, which includes the submission of detailed information about the manufacturing and quality of the product, and non-clinical and clinical trial information. There is an increasing trend in the EU towards greater transparency and, while the manufacturing or quality information is currently generally protected as confidential information, the EMA and national regulatory authorities are now liable to disclose much of the non-clinical and clinical information in marketing authorization dossiers, including the full clinical study reports, in response to freedom of information requests after the marketing authorization has been granted.

The centralized procedure gives rise to marketing authorizations that are valid throughout the EU. Applicants file marketing authorization applications with the EMA, where they are reviewed by a relevant scientific committee, in most cases the CHMP (although other specialist committees may also be involved; for example, the Committee for Advanced Therapies will also be involved in the review of advanced therapy medicinal products (“ATMP”), and HAVs could potentially be classified as an ATMP). The EMA forwards CHMP opinions to the European Commission, which uses them as the basis for deciding whether to grant a marketing authorization. The centralized procedure is compulsory for medicinal products that (1) are derived from biotechnology processes, (2) contain a new active substance (not yet approved on 20 November 2005) indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders, viral diseases or autoimmune diseases and other immune dysfunctions, (3) are orphan medicinal products or (4) are advanced therapy medicinal products. For medicines that do not fall within these categories, an applicant may voluntarily submit an application for a centralized marketing authorization to the EMA, as long as the CHMP agrees that (i) the medicine concerned contains a new active substance (not yet approved on November 20, 2005), (ii) the medicine is a significant therapeutic, scientific, or technical innovation, or if its authorization under the centralized procedure would be in the interest of public health.

For those medicinal products for which the centralized procedure is not available, the applicant must submit marketing authorization applications to the national medicines regulators through one of three procedures: (1) a national procedure, which results in a marketing authorization in a single EU member state; (2) the decentralized procedure, in which applications are submitted simultaneously in two or more EU member states; and (3) the mutual recognition procedure, in which the EU member states are required to grant an authorization recognizing an existing authorization in another EU member state, unless they identify a serious risk to public health.

#### *Data Exclusivity*

Marketing authorization applications for generic medicinal products do not need to include the results of preclinical and clinical trials, but instead can refer to the data included in the marketing authorization of a reference product for which regulatory data exclusivity has expired. If a marketing authorization is granted for a medicinal product containing a new active substance or to a different marketing authorization holder that has carried out a complete set of pre-clinical tests and clinical trials, that product benefits from eight years of data exclusivity, during which generic marketing authorization applications referring to the data of that product may not be accepted by the regulatory authorities, and a further two years of market exclusivity, during which such generic products may not be placed on the market. The two-year period may be extended to three years if during the first eight years a new therapeutic indication with significant clinical benefit over existing therapies is approved.

There is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, while a full set of pre-clinical tests and trials are not necessary, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

#### *Pediatric Development*

In the EU, companies developing a new medicinal product must agree to a Pediatric Investigation Plan (“PIP”) with the EMA and must conduct pediatric clinical trials in accordance with that PIP. The marketing authorization application for the product must ordinarily include the results of pediatric clinical trials conducted in accordance with the PIP. It is possible to obtain a deferral, in which case the pediatric clinical trials must be completed at a later date, or a complete waiver from the obligation to conduct pediatric clinical trials (e.g., because the relevant disease or condition occurs only in adults).

#### *Post-Approval Controls*

The holder of a marketing authorization is subject to various post-approval controls, such as obligations to maintain a pharmacovigilance system and report adverse reactions, and requirements relating to promotional activities, including a prohibition on the promotion of prescription medicines to the general public. Manufacturers/importers and distributors of medicinal products must obtain authorizations from the competent national authorities and are subject to periodic inspections for compliance with cGMPs and current good distribution practices (“cGDPs”), respectively. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization, such as additional safety monitoring or the conduct of additional clinical trials or post-authorization safety studies.

#### *EU Requirements Applicable to Medical Devices*

Under the previous medical devices directive, Directive 93/42/EEC, our HAVs were not classified as medical devices in the EU because, with limited exceptions, products incorporating or derived from tissues or cells of human origin are expressly excluded from the scope of the EU medical devices rules under Directive 93/42. However, as of May 26, 2021, Regulation (EU) 2017/745 applies, and this will bring us within the scope of the EU medical device rules products containing or derived from tissues or cells of human origin that are non-viable or are rendered non-viable.

Medical devices are generally governed by Regulation (EU) 2017/745 on Medical Devices that directly applies in all EU Member States and harmonizes the conditions for placing medical devices on the EU market. This Regulation, however, does not regulate certain important marketing aspects, such as pricing and reimbursement, which remain governed by national law. Additionally, certain areas, such as advertising, may be governed by additional national requirements.

A medical device may be placed on the market within the EU if it conforms to certain “general product safety requirements” or “GSPRs.” These are general in nature and broad in scope. A fundamental GSPR, for example, is that a device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users or other persons.

The manufacturer is obliged to demonstrate that the device conforms to the relevant GSPRs through a conformity assessment procedure. Once the appropriate conformity assessment procedure for a medical device has been completed, the manufacturer must draw up a written declaration of conformity and affix the CE mark to the device. The device can then be marketed throughout the EU.

The nature of the conformity assessment depends upon the classification of the device. The classification rules are mainly based on three criteria: the length of time the device is in contact with the body, the degree of invasiveness, and the extent to which the device affects the anatomy. As a general rule, Class I (low risk) devices are those that do not enter or interact with the body; Class IIa and IIb (medium risk) devices are invasive or implantable or interact with the body; and Class III (high risk) devices are those that affect the vital organs.

Conformity assessment procedures for all but the lowest risk classification of device involve a notified body, which are non-governmental, private entities licensed to provide independent certification of certain classes of medical device. EU regulatory bodies are not involved in the premarket approval of medical devices, with only very limited exceptions (such as medical devices that incorporate a medicinal product as an ancillary substance, in which case these regulatory bodies

review the medicinal product). The onus of ensuring a device is safe enough to be placed on the market is ultimately the responsibility of the manufacturer and the notified body.

As part of the conformity assessment procedure, the manufacture will need to conduct a clinical evaluation of the device. This clinical evaluation may consist of an analysis of the scientific literature relating to similar devices, new clinical investigations of the device, or a combination of the two. For Class III and implantable devices, the conduct of clinical investigations is mandatory (with limited exceptions). If a manufacturer wishes to conduct a clinical investigation in the EU, the manufacturer must notify the competent national regulatory authorities in advance and obtain ethics committee approval of the study.

#### *EU Requirements Applicable to Human Cells and Tissues*

EU rules, notably Directive 2004/23/EC and other implementing directives, govern the donation, procurement, testing and storage of human cells and tissues intended for human application, whether or not they are medicinal products. These rules also cover the donation, testing, processing, preservation, storage and distribution of human cell and tissues that are not medicinal products. Establishments that conduct such activities must be licensed and are subject to inspection by regulatory authorities. Such establishments must implement appropriate quality systems and maintain appropriate records to ensure that cells and tissues can be traced from the donor to the recipient and vice versa. There are also requirements to report SAEs and reactions linked to the quality and safety of cells and tissues. More detailed rules may exist at the national level.

In addition to regulations in Europe and the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial distribution of our future products.

#### **Facilities**

Our corporate headquarters, manufacturing, and research and development facilities are located in Durham, North Carolina where we lease approximately 83,000 square feet of space. This space includes approximately 55,000 square feet for production and distribution operations including manufacturing, bioprocessing, quality control, mechanical space and inventory. The remainder of the facility consists of offices, laboratories, and common spaces.

#### **Employees and Human Capital Management**

As of December 31, 2021, we had 146 employees, including 145 full-time employees. None of our employees are represented by a collective bargaining agreement, and we have never experienced any work stoppage. We believe we have good relations with our employees.

#### **Financing Arrangements**

In March 2021, Legacy Humacyte entered into a Loan Agreement with Silicon Valley Bank and SVB Innovation Credit Fund VIII, L.P., which provides a term loan facility of up to \$50.0 million with a maturity date of March 1, 2025. We became a co-borrower under the Loan Agreement in connection with the Merger. The obligations of Humacyte and Legacy Humacyte under the Loan Agreement are secured by substantially all of their assets, except for their intellectual property. In connection with the Loan Agreement, the lenders were each granted a warrant to purchase Legacy Humacyte common stock, with an exercise price of \$2.699 per share, subject to customary adjustments. In connection with the closing of the Merger, these warrants were exchanged for warrants to purchase 287,704 shares of our common stock at an exercise price of \$10.28 per share. On October 13, 2021, we borrowed an additional \$10.0 million under the Loan Agreement, and in connection with that borrowing, issued Silicon Valley Bank and SVB Innovation Credit Fund VIII, L.P. warrants to purchase an aggregate of 123,302 shares of our common stock at an exercise price of \$10.28 per share. The Loan Agreement contains certain customary covenants, including, but not limited to, those relating to additional indebtedness, liens, asset divestitures, and affiliate transactions. We may use the proceeds of borrowings under the Loan Agreement as working capital and to fund our general business requirements.

As of February 28, 2022, we had borrowed \$30.0 million of principal under the Loan Agreement.

#### **Additional Information**

We were incorporated in Delaware on July 1, 2020, under the name Alpha Healthcare Acquisition Corp. (“AHAC”), in order to effectuate a merger, capital stock exchange, asset acquisition, stock purchase, reorganization or similar business combination with one or more businesses or entities. AHAC completed its initial public offering on September 22, 2020.

On August 26, 2021, AHAC and Legacy Humacyte consummated the transactions contemplated by the Merger Agreement. In connection with the closing of the Merger, we changed our name to Humacyte, Inc.

Our principal executive office is located at 2525 East North Carolina Highway 54, Durham, North Carolina 27713, and our telephone number is (919) 313-9633.

Our website address is [www.humacyte.com](http://www.humacyte.com) and our investor relations website is located at <https://investors.humacyte.com>. The information posted on our website is not incorporated into this Annual Report on Form 10-K. The U.S. Securities and Exchange Commission (“SEC”) maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at <http://www.sec.gov>. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, (the “Exchange Act”) are also available free of charge on our investor relations website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

We provide notifications of news or announcements regarding our financial performance, including SEC filings, investor events, and press releases, as part of our investor relations website. The contents of these websites are not intended to be incorporated by reference into this report or in any other report or document we file.

## Item 1A. Risk Factors

*Our operations and financial results are subject to a high degree of risk. These risks include, but are not limited to, those described below, each of which may have a material and adverse effect on our business, prospects, operating results, financial condition and the trading price of our common stock. You should carefully consider the risks described below, together with all of the other information included in this Annual Report on Form 10-K. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business. In that event, the trading price of our common stock could decline and you could lose all or part of your investment.*

### Summary of Risk Factors

The following is a summary of the principal risks to which our business, operations and financial performance are subject. Each of these risks is more fully described in the individual risk factors immediately following this summary.

- We have never generated product revenue and have incurred significant losses to date. We expect to continue to incur losses for the foreseeable future and may never generate product revenue or be profitable. We will need to raise additional capital to finance our operations, which we may not be able to do on acceptable terms or at all.
- If our clinical trials fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce favorable results, we may incur significant additional costs or experience significant delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- Our near-term prospects are dependent on the success of our 6 millimeter HAV, and if we are unable to successfully develop and commercialize it, our business, operating results and financial condition will be materially harmed.
- We may experience delays or difficulties in the enrollment of patients in our clinical trials, which may delay or prevent additional clinical trials and our receipt of necessary marketing approvals.
- Lack of experience by investigators and surgeons with our HAVs can lead to incorrect implantation or follow-up procedures which could harm the results of our clinical trials and market acceptance of our HAVs, if approved.
- We may not be successful in our efforts to use our proprietary scientific technology platform to build a pipeline of additional product candidates.
- Even if our HAVs receive marketing approval in the future for one or more of our product candidates, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

- The sizes of the market opportunities for our product candidates have not been established with precision and are estimates that management believes to be reasonable. If these market opportunities are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the relevant patient population, our revenue and ability to achieve profitability might be materially and adversely affected.
- Our distribution agreement with Fresenius Medical Care imposes obligations on us that may restrict our ability to operate our business in ways we believe to be in our long-term best interest.
- If we receive approval for a product candidate that is not subject to our distribution agreement with Fresenius Medical Care, and we are unable to establish our own marketing, sales and distribution capabilities or are unable to enter into agreements with third parties do so, we may not be able to generate product revenue and will have to alter our development and commercialization plans.
- The outbreak of COVID-19 may continue to adversely impact our business, including our manufacturing efforts, and our preclinical studies and clinical trials.
- The manufacture of our product candidates is complex, we have not manufactured commercial product, and we may encounter difficulties in production. If we or any third-party manufacturer encounter such difficulties, our ability to supply our product candidates for clinical trials or, if approved, for commercial sale could be delayed or halted entirely.
- The terms of our existing indebtedness may limit our ability to incur future debt.
- We rely on third parties to conduct and support our clinical trials, and those third parties may not perform satisfactorily, including by failing to adhere to regulatory requirements or our stated protocols or to meet deadlines for the completion of such trials.
- We rely on third-party suppliers, including sole source suppliers, to provide certain components for our product candidates. Any failure by a third-party supplier to supply these components for manufacture may delay or impair our ability to complete our clinical trials and to commercialize our product candidates.
- We intend to rely on our strategic, global partnership with Fresenius Medical Care to undertake, or assist with, the marketing, sale and distribution of certain of our product candidates in certain markets if we receive marketing approval from relevant regulatory authorities. Disruption of this arrangement could materially adversely affect our business, prospects, operating results and financial condition.
- Our ability to successfully commercialize our products may be impaired if we are unable to obtain and maintain effective intellectual property rights for our proprietary scientific technology platform and product candidates.
- We may be required to take write-downs or write-offs, restructuring and impairment or other charges that could have a significant negative effect on our financial condition, results of operations and stock price, which could cause you to lose some or all of your investment.

#### **Risks Related to the Development and Commercialization of Our Product Candidates**

***If our clinical trials fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce favorable results, we may incur significant additional costs or experience significant delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. If we experience significant delays or significant additional costs, our business will be materially harmed.***

Before obtaining marketing approval for any of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive and time-consuming, and its outcomes are uncertain. We believe the novelty of our research and development efforts, which are focused on the development of bioengineered human, acellular, tissue-based vessels for use across a wide spectrum of applications in vascular surgery, augments this uncertainty. The scientific discoveries that form the basis for our efforts to develop our product candidates are relatively new, and the scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. At this time, no products based on HAVs have been approved in the United States or in Europe. The clinical trial requirements of the FDA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to



the type, complexity, novelty and intended use and market of the potential product, and we may not succeed in obtaining marketing approval even if we view our clinical trials as successful. Data obtained from preclinical and clinical activities, and manufacturing comparability studies, are also subject to varying interpretations, which may delay, limit or prevent marketing approval. In such circumstances, we could experience significant delays, or be prevented from, developing or commercializing our HAVs, and our business, prospects, operating results and financial condition could be materially harmed.

Our V006 trial did not meet its primary endpoint, and if we fail to achieve the primary endpoint of our other ongoing or future clinical trials, or if safety issues arise, our comparability demonstration between our former and new manufacturing process fails or is not accepted by the FDA, or the results from our clinical trials are otherwise inadequate to support regulatory approval of our product candidates, we may incur significant additional costs or experience significant delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Even if we receive FDA approval for our HAVs, we may face a number of difficulties if the results of our clinical trials are unfavorable, inconclusive, or only modestly favorable or if there are safety concerns, such as adverse events (“AEs”) or serious adverse events (“SAEs”), which could include clotting, mechanical failure, immunological rejection or infection, that could outweigh potential benefits associated with such product candidates. This could result in:

- obtaining approval for indications or patient populations that are not as broad as intended or desired;
- obtaining approval with, or later becoming subject to, labelling that includes significant use or distribution restrictions or significant safety warnings;
- being subject to a REMS or equivalent requirement from a comparable foreign regulatory agency, to ensure that the benefits of a biological product outweigh its risks or to change the way the product is used;
- being required to perform additional clinical trials to support approval or comparability or being subject to additional post-marketing testing requirements;
- having regulatory authorities withdraw their approval of the product;
- being sued; or
- suffering damage to our reputation.

Any of these events could cause us to incur significant additional costs, significant delays and prevent us from achieving or maintaining market acceptance of or commercializing one or more of our product candidates.

***If we experience failures or delays in our preclinical and clinical programs, we would be prevented from developing and commercializing our product candidates in a timely matter, if at all.***

A number of factors impact the timing of our preclinical and clinical programs and the development and commercialization of our product candidates. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. Events that prevent successful or timely completion of the development of our product candidates beyond unfavorable or inconclusive clinical trial results include, among others, the following:

- delays in the testing, validation, manufacturing or delivery of our product candidates to the clinical sites;
- delays in reaching — or inability to reach — agreement with the FDA or other regulatory agencies on trial design, including with respect to our ongoing discussions with the FDA as to whether trial size must be increased in our ongoing V005 trial;
- delays in reaching agreement on acceptable terms with prospective clinical research organizations (“CROs”) and clinical trial sites;
- delays in obtaining required IRB approval at each clinical trial site;
- delays in recruiting suitable patients in sufficient volume to participate in our clinical trials and in having those patients complete participation in our clinical trials or return for follow-up, including delays related to the ongoing COVID-19 pandemic;

- the occurrence of SAEs associated with any of our product candidates that are viewed to outweigh their potential benefits;
- imposition of a clinical hold by regulatory agencies, including after an inspection of our clinical trial sites;
- failure by CROs, other third parties or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA’s good clinical practices (“GCP”) or current good tissue practices (“cGTP”), or applicable regulatory guidelines in other countries;
- clinical trial sites dropping out of, or being removed from, a trial; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols or data.

Any inability to successfully complete development of our product candidates would likely result in significant additional costs to us, create delays in filing a BLA for regulatory approval of our product candidates and impair our ability to generate revenue. Clinical trial delays could also allow our competitors to bring products to market before we do, which could materially impair our ability to successfully commercialize our product candidates and may harm our business and prospects.

***Our progress in early stage clinical trials may not be indicative of long-term efficacy in late stage clinical trials, and our progress in trials for one product candidate may not be indicative of progress in trials for another product candidate.***

The product candidates in our pipeline are at various stages of development. Trial designs and results from previous studies are not necessarily predictive of our future clinical trial designs or results, and initial results of ongoing trials may not be confirmed upon full analysis of the complete trial data. A number of companies in the biotechnology industry have suffered significant setbacks in late-stage clinical trials even after achieving promising results in earlier stage clinical trials, and we may experience similar setbacks. Favorable results in clinical trials for one of our product candidates also do not necessarily indicate that we will obtain positive results in clinical trials related to other product candidates. The novelty of our proprietary scientific technology platform adds another layer of risk that early-stage clinical trials may not be indicative of long-term efficacy in our late-stage clinical trials. If we are unable to demonstrate favorable results in future clinical trials for our various product candidates, we expect that our business, prospects, operating results and financial condition will be materially adversely affected.

Additionally, several of our past, planned and ongoing clinical trials utilize an “open-label” trial design. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate. Some open-label clinical trials test only the investigational product candidate without a comparator. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates when studied in an environment with an active control.

***Interim, “topline,” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publicly disclose preliminary or topline data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, although we may not have received or had the opportunity to fully and carefully evaluate all data at the time such preliminary or topline results are released. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are

available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available, or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. In addition, the information we choose to publicly disclose regarding a particular clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

***If SAEs occur at an unacceptable rate or other unacceptable side effects are identified in our HAVs we may need to delay, abandon or limit development and marketing of our product candidates.***

Our HAVs may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining marketing approval. The reported SAEs related to the HAV for hemodialysis access, a patient population which typically has a high prevalence of existing medical conditions, are detailed in the table below which summarizes results from our V006 HUMANITY Phase III study in which subjects were randomized to receive either a HAV or a commercially available expanded polytetrafluoroethylene (“ePTFE”) graft.

#### SAEs Reported in V006 Phase III Clinical Study in AV Access

Description of SAE	Number of SAEs (% of total subjects)	
	HAV	ePTFE
Number of subjects in V006 study	177	178
General disorders and administration conditions:		
Implant site extravasation	0(0.0)%	1(0.6)%
Infections and infestations		
Vascular access site infection	0(0.0)%	5(2.8)%
Injury, poisoning and procedural complications:		
Anastomotic stenosis	1(0.6)%	(0.0)%

Description of SAE	Number of SAEs (% of total subjects)	
	HAV	ePTFE
Vascular access site hematomas	1(0.6)%	(0.0)%
Vascular access site hemorrhage	0(0.0)%	3(1.7)%
Vascular access site pain	1(0.6)%	0(0.0)%
Vascular access site pseudoaneurysm	10(5.6)%	0(0.0)%
Vascular access site rupture	2(1.1)%	0(0.0)%
Vascular access site thrombosis	41(23.2)%	28(15.7)%
Skin and subcutaneous tissue disorders:		
Skin necrosis	0(0.0)%	1(0.6)%
Vascular disorders:		
Steal syndrome	2(1.1)%	2(1.1)%
Subclavian vein occlusion	0(0.0)%	1(0.6)%
Vascular stenosis	34(19.2)%	27(15.2)%
Venous stenosis	3(1.7)%	9(0.0)%

In our V002 and V004 Phase II clinical studies in peripheral arterial disease (“PAD”) in 35 subjects, another patient population which typically has a high prevalence of existing medical conditions, the SAEs reported for the HAV are detailed in the table below.

#### SAEs Reported in V002 and V004 Phase II Clinical Studies in PAD

Description of SAE	Number of SAEs (% of total subjects)
Number of subjects in V002 and V004 studies	N=35
Arterial bypass thrombosis	3(8)%
Anastomotic stenosis	1(3)%
Graft thrombosis	2(6)%
Vascular graft complication	1(3)%

If our HAVs are associated with undesirable side effects in clinical trials or have negative characteristics that are unexpected, we may need to perform additional clinical trials, abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Even if one of our product candidates is approved, the FDA and other regulatory authorities may take action to withdraw it from the market if serious safety concerns emerge. Any of these events could cause us to delay, abandon or limit the development and, if approved, marketing of our product candidates.

*We may experience delays or difficulties in the enrollment of patients in our clinical trials, which may delay or prevent additional clinical trials and our receipt of necessary marketing approvals.*

We are currently enrolling patients in several clinical trials, including in our V005 trial, which is a Phase II/III clinical trial of our 6 millimeter HAV in traumatic vascular repair and our V007 trial, which is a Phase III clinical trial comparing the safety and efficacy of our 6 millimeter HAV to AV fistula for hemodialysis access. Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends in part on the rate at which we can recruit patients to participate in such trials. Additionally, the COVID-19 pandemic has had and may continue to have a sustained impact on our ability to recruit and follow up with patients. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA and other regulatory authorities, and as such our product candidates could be delayed or otherwise adversely affected. Patient enrollment and trial completion is affected by many factors including the:

- size of the patient population and process for identifying subjects;
- availability of clinical trial research resources at clinical sites in the era of the COVID-19 pandemic;
- availability of persons to provide or obtain patient consent for trial participation due to COVID-19 restrictions;
- design of the trial protocol;
- inclusion and exclusion criteria;
- safety profile to date of the product candidate under study;
- perceived risks and benefits of the product candidate under study;
- availability of competing therapies and clinical trials;
- severity of the disease under investigation;
- degree of progression of the subject’s disease at the time of enrollment;
- proximity and availability of clinical trial sites for prospective subjects;
- the impact of the COVID-19 pandemic or future pandemics or similar events on patients’ willingness and ability to participate in clinical trials or on study site policies;

- ability to obtain and maintain subject consent;
- risk that enrolled subjects will drop out before completion of the trial;
- patient referral practices of physicians; and
- ability to monitor subjects adequately during and after treatment.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business, financial condition, results of operations and prospects.

***Lack of experience by investigators and surgeons with our HAVs can lead to incorrect implantation or follow-up procedures which could harm the results of our clinical trials and market acceptance of our HAVs, if approved.***

Our HAVs are currently in various stages of preclinical and clinical testing and have not been widely used. We do not have the personnel capacity to directly conduct or manage all of the clinical trials that are necessary for the development of our HAVs. Therefore, we rely, and will continue to rely, on third parties to assist us in managing, monitoring and conducting our clinical trials. Some of the investigators in our clinical trials have not been, and, if our HAVs receive marketing approval, surgeons may not be, previously exposed to the implantation and follow-up procedures related to their use. As a result, our HAVs may be, and have been in the past, incorrectly implanted and follow-up procedures may be performed incorrectly, resulting in violations of our trial protocols, increased interventions or failure of the HAV. Our efforts to educate investigators, surgeons and interventionalists regarding the proper techniques for use of our HAVs both during clinical trials and following potential commercialization may be costly, prove unsuccessful and could materially harm our ability to continue the clinical trials or marketing of our HAVs. Regulatory authorities may also seek to impose restrictive labeling or proactive communication obligations on any marketing approval granted for use of our HAVs as a result, which could reduce market acceptance of any of our HAVs that receive marketing approval.

***Our near-term prospects are dependent on the success of our 6 millimeter HAV, and if we are unable to successfully develop and commercialize it, our business, operating results and financial condition will be materially harmed.***

We currently have no products approved for sale and, while we are developing a number of product candidates, we have invested and continue to invest a substantial portion of our efforts and financial resources in the development of our 6 millimeter HAV. None of our remaining product geometries and modifications have advanced beyond preclinical development. As a result, in the near term we are dependent on the success of our 6 millimeter HAV, and if we are unable to successfully develop, obtain marketing approval for, and commercialize it, our business, along with our operating results and financial condition, will be materially harmed. Even if we succeed with the development of our 6 millimeter HAV, our ability to generate product revenue and become profitable from our 6 millimeter HAV depends on our assumptions regarding the relevant market opportunity, for which our estimates may prove inaccurate, and market acceptance in any approved indication, which may never occur.

***We may not be successful in our efforts to use our proprietary scientific technology platform to build a pipeline of additional product candidates.***

A key element of our strategy is to use our proprietary scientific technology platform to expand our pipeline of HAVs and to progress other product candidates into and through clinical development. We may not be able to identify or develop future product candidates that are safe and effective. Even if we are successful in building our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including if they have harmful side effects or other characteristics that render them unlikely to receive marketing approval or achieve market acceptance. Research programs to identify new product candidates require substantial technical, financial and human resources, and we may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. If we do not successfully develop and commercialize additional product candidates based upon our technology, we may have difficulty generating product revenue in the future, which could result in significant harm to our business, prospects, operating results and financial condition and adversely affect our stock price.

***Even if our HAVs receive marketing approval in the future for one or more of our product candidates, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.***

Even with the requisite approvals from the FDA in the United States, the European Commission in the EU and other regulatory authorities internationally, the commercial success of our HAVs will depend, in part, on the acceptance of physicians, patients and health care payors, as medically necessary, cost-effective and safe. Any product that we commercialize may not gain acceptance by physicians, patients, health care payors and others in the medical community due to ethical, social, medical and legal concerns. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable.

The degree of market acceptance of any of our product candidates that receives marketing approval will depend on a number of factors, including:

- the efficacy and potential advantages of our product candidates compared with alternative products or methods, including convenience and ease of administration;
- the prices we charge for our products, if approved;
- the availability of third-party coverage and adequate reimbursement;
- the willingness of the target patient population to try new products and methods and of physicians to use these products and methods;
- the quality of our relationships with patient advocacy groups;
- the strength of marketing and distribution support;
- the availability of the product and our ability to meet market demand;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products, if approved.

***The sizes of the market opportunities for our product candidates have not been established with precision and are estimates that management believes to be reasonable. If these market opportunities are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the relevant patient population, our revenue and ability to achieve profitability might be materially and adversely affected.***

Our estimates of the market opportunity for certain of our product candidates are based on a number of internal and third-party estimates. While we believe our assumptions and the data underlying these estimates are reasonable, they may be inaccurate or based on imprecise data. In addition, the assumptions and conditions underlying the estimates may change at any time. For example, the number of patients who ultimately use our product candidates, if approved by regulatory authorities, and our total market opportunities for such product candidates, will depend on, among other things, pricing and reimbursement, market acceptance of those product candidates and patient access, and may be lower than we estimate. Additionally, any approval we receive for our product candidates may be based on a narrower definition of the relevant patient population than we have estimated. Either of these circumstances could materially harm our business, financial condition, results of operations and prospects.

***We face and will continue to face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do, which may adversely affect our ability to successfully market or commercialize our HAVs.***

The development and commercialization of new biological products is highly competitive and subject to rapid change and technological advancements. If approved, we expect our HAVs would compete with the use of a patient's own blood vessels, as well as a variety of marketed products, such as conventional synthetic grafts, xenografts, and allografts, as well as developing technologies.

We expect to face competition with respect to any additional product candidates that we may seek to develop or commercialize in the future from a variety of sources, including major pharmaceutical companies, specialty pharmaceutical

companies and biotechnology companies, hospital product-focused companies, as well as public and private universities and research organizations.

Many of our existing or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining marketing approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than the products that we develop. Our competitors also may obtain FDA or other marketing approval for their products more rapidly than we may obtain the same approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

We plan to seek marketing approval for our HAVs in the United States as a biologic and in the EU as a medicinal product. In both the United States and the EU, our competitors may try to market vascular conduits similar to our product candidates as medical devices. Such competitive products could have comparable characteristics and could function similarly in the body (and could even be protein-based like our product candidates). Companies may be able to obtain marketing approval for such products on the basis of less data than the data required for a BLA and marketing similar products as devices could permit our competitors to circumvent regulatory exclusivity for biologics in the United States and medicinal products in the EU.

***Our distribution agreement with Fresenius Medical Care imposes obligations on us that may restrict our ability to operate our business in ways we believe to be in our long-term best interest.***

We expect to rely on our strategic, global relationship with Fresenius Medical Care for the development and commercialization of certain of our product candidates. As discussed in more detail in the section of this Annual Report on Form 10-K titled “Business — Distribution — Distribution Agreement with Fresenius Medical Care,” Fresenius Medical Care will have the exclusive right to develop outside of the United States and EU and commercialize outside of the United States, among other things, our 6 millimeter x 42 centimeter HAV and all improvements thereto, and modifications and derivatives thereof (including any changes to the length, diameter, or configuration of the foregoing), which we refer to as the distribution product, for use in vascular creation, repair, replacement or construction (including renal replacement therapy for dialysis access, the treatment of vascular trauma, and the treatment of PAD, but excluding coronary artery bypass graft, pediatric heart surgery, or adhering pancreatic islet cells onto the outer surface of the distribution product for use in diabetic patients). We refer to these indications wherein Fresenius Medical Care has rights to develop and commercialize Humacyte’s products as the field. The distribution agreement also imposes a number of restrictions on our business. For instance, outside the United States, the distribution agreement restricts our ability to engage a distributor for the distribution product outside the field or for HAV products other than the distribution product: we have granted Fresenius Medical Care (i) an exclusive right of first negotiation for exclusive distribution rights outside the United States for the distribution product for use outside the field, and (ii) an exclusive right of first negotiation for exclusive distribution rights outside the United States for our other HAV products, if any, subject, in each case, to certain conditions. These and other obligations may restrict our ability to operate our business in ways we believe are in our long-term best interest, which could harm our business and our prospects.

***If we receive approval for a product candidate that is not subject to our distribution agreement with Fresenius Medical Care, and we are unable to establish our own marketing, sales and distribution capabilities or are unable to enter into agreements with third parties to do so, we may not be able to generate product revenue and will have to alter our development and commercialization plans.***

We currently have limited internal marketing, sales or distribution capabilities, and our management team has limited experience commercializing products following marketing approval. If one of our product candidates that is not subject to the distribution agreement with Fresenius Medical Care receives marketing approval, we will be required either to develop these capabilities internally or to make arrangements with third parties for the marketing, sales and distribution of the relevant product candidate. The establishment and development of our own marketing, sales and distribution functions will be expensive and time-consuming and may delay any product launch, and we may ultimately be unable to successfully develop the product candidate. In addition, or in the alternative, we could seek one or more partners to handle some or all

of the marketing, sales and distribution activities associated with any such product candidate. However, we may face significant competition in seeking appropriate strategic partners, and the negotiation process is time consuming and complex. Therefore, we may not be able to enter into arrangements with third parties to do so on favorable terms or at all. In the event we are unable to develop our own marketing, sales and distribution functions or collaborate with a third-party organization for this purpose, we may not be able to successfully commercialize a product candidate that is not subject to the distribution agreement with Fresenius Medical Care, which would adversely affect our ability to generate revenue. Further, whether we commercialize any such product candidate on our own or rely on a third party to do so, our ability to generate revenue will be dependent on the effectiveness of the organization performing these functions.

***Even if we receive marketing approval for our HAVs, there is uncertainty with respect to third-party coverage and reimbursement of our HAVs. They may also be subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, any of which could harm our business, prospects, operating results and financial condition.***

There is uncertainty around third-party coverage and reimbursement of newly approved regenerative medicine type products, even those with the RMAT designation from FDA, such as our 6 millimeter HAV for AV access for performing hemodialysis, which received the RMAT designation in 2017. In the United States, third-party payors, including government payors such as the Medicare and Medicaid programs, play an important role in determining the extent to which medical products and biologics will be covered and reimbursed. The Medicare and Medicaid programs increasingly are used as models for how private payors and government payors develop their coverage and reimbursement policies. Currently, no RMAT tissue engineered product has established coverage and reimbursement by the CMS. Even if our HAVs receive approval from regulatory authorities, it is difficult to predict what CMS or any comparable foreign regulatory agency will decide with respect to coverage and reimbursement for novel products such as ours, as there is no body of established practices and precedents for these types of products.

The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement. These payors may not view our products, if any, as cost-effective, and coverage and reimbursement may not be available to our customers or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost-control initiatives could also cause us to decrease any price we might establish for products, which could result in lower than anticipated product revenue. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including our costs related to research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. If the prices for our products, if any, decrease or if governmental and other third-party payors do not provide adequate coverage or reimbursement, our business, prospects, operating results and financial condition will suffer, perhaps materially.

In some countries, particularly in Europe, the pricing of our product may be subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products, if approved, is unavailable or more limited in scope or amount than we anticipate, or if pricing is set at even lower levels than we anticipate, our business could be harmed, possibly materially.

***Product liability lawsuits against us could cause us to incur substantial liabilities that may not be covered by our limited product liability insurance and may limit development, approval and commercialization of our HAVs and any other product candidates that we develop in the future.***

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk, if and when we commercially sell our HAVs and any other product candidates that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for any product candidates or products that we develop or sell, leading to loss of revenue;
- injury to our reputation and significant negative media attention;
- withdrawal, or slower enrollment, of clinical trial participants;



- significant costs to defend the related litigation and reduced resources of our management to pursue our business strategy;
- substantial monetary awards to trial participants or patients; and
- inability to further develop or commercialize our product candidates.

We currently hold limited product liability insurance coverage, and it may not be adequate to cover all liabilities that we may incur. We also may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

***The outbreak of COVID-19 may continue to adversely impact our business, including our manufacturing efforts, and our preclinical studies and clinical trials.***

The ongoing COVID-19 pandemic has impacted our business and we expect it to continue to do so. In response to the spread of COVID-19, we limited entry into our facilities for non-essential personnel, and instituted daily health checks and weekly COVID-19 screenings for employees who entered the facility. In addition, we have experienced delays in the ongoing enrollment of our clinical trials as a result of COVID-19. If COVID-19 continues to spread in the United States and elsewhere, we may experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- further delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in hospital or research institution policies or local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals and clinics serving as our clinical trial sites and hospital and clinic staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, or the closing of clinical trial sites due to the virus, the occurrence of which could affect the integrity of clinical trial data;
- interruption in global shipping affecting the transport of clinical trial materials, such as our HAVs and other supplies used in our clinical trials;
- interruption in supply of raw materials required to manufacture our product candidates, or increased costs due to supply chain disruptions or inflation in the cost of goods, services or other operating inputs;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, or will withdraw from the clinical trial due to concerns over COVID-19, which could impact the results of the clinical trial, including by increasing the number of observed adverse events, or reducing the statistical power of the clinical trials;
- interruptions or delays in preclinical studies, including delays in obtaining and housing experimental animals and in performing surgical interventions on animals to test our products;
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- delays in receiving feedback or responses from the FDA regarding regulatory submissions;
- delays in obtaining meetings with FDA reviewers regarding manufacturing and clinical trials;

- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials or the manufacture of our product candidates, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- changes to the clinical endpoints, statistical analysis plan, or enrollment plans for ongoing clinical trials due to limitations in patients, resources, or sites, including due to COVID-19;
- unanticipated deaths of clinical trial patients due to COVID-19 or due to lack of healthcare resources and follow-up as a consequence of COVID-19;
- interruption or delays to our sourced discovery and clinical activities; and
- impacts from prolonged remote work arrangements, such as increased cybersecurity risks and strains on our business continuity plans.

The demand for COVID-19 vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials for the products needed for our clinical trials, which could lead to delays in these trials. In addition, the competition for bioprocessing, quality control, manufacturing and logistics personnel due to COVID-19 vaccine production in the North Carolina region may make it difficult to recruit and retain necessary employees. The extent to which the COVID-19 pandemic impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

### **Risks Related to Manufacturing Our Product Candidates**

***The manufacture of our product candidates is complex, we have not manufactured commercial product, and we may encounter difficulties in production. If we or any third-party manufacturer encounter such difficulties, our ability to supply our product candidates for clinical trials or, if approved, for commercial sale could be delayed or halted entirely.***

The process of manufacturing our HAVs is complex, highly regulated and subject to multiple risks. The manufacture of biologics such as our HAVs is susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which would harm our business, operating results and financial condition as well as our reputation.

We currently manufacturing the 6 millimeter HAVs for our clinical trials at our manufacturing facility in Durham, North Carolina, where we have created a scalable modular manufacturing process, which we refer to as the LUNA200 system, that we believe will enable us to manufacture our HAVs, if approved, in commercial quantities in compliance with current good manufacturing practices (“cGMPs”). Our efforts to scale out our manufacturing operations may not succeed. Scaling out a biologic manufacturing process is a difficult task, as there are risks including, among others, cost overruns, process reproducibility, stability issues, lot consistency and timely availability of raw materials. Prior to the establishment of our internal manufacturing facility, we employed a contract manufacturer who produced our HAVs using a smaller-production system known as the AURA system. We have limited experience manufacturing our HAVs in-house with the LUNA200 system, and no experience manufacturing the volume that we anticipate will be required to supply all of our clinical trials or to achieve planned levels of commercial sales following marketing approval, if received. Additionally, our manufacturing process has evolved over time and we may not have the experience, resources, or facility capacity to handle adoption of future changes or expansion of capacity. The forecasts of demand we plan to use to determine order quantities and lead times for components from outside suppliers may be incorrect, and we may be unable to obtain such components when needed and at a reasonable cost. In addition, we may not be able to develop and implement efficient manufacturing capabilities and processes to manufacture our HAVs in sufficient volumes that also satisfy the legal, regulatory, quality, price, durability, engineering, design and production standards required to commercialize our HAVs successfully.

If we are unable to produce sufficient quantities of our HAVs for our clinical trial needs or commercialization due to production system limitations, we may need to make additional changes to our manufacturing processes and procedures. Such changes to our manufacturing platform could trigger the need to conduct additional bridging studies between our prior clinical supply and that of any new manufacturing processes and procedures. Should we experience delays or be unable to produce sufficient quantities of our HAVs utilizing our current or a modified version of our manufacturing

system, we expect that our development and commercialization efforts would be impaired as a result, which would likely materially adversely affect our business, prospects, operating results and financial condition.

***Manufacturing facilities are subject to significant government regulations and approvals, which are often costly and could result in adverse consequences to our business if we fail to comply with the regulations or maintain the approvals.***

Our manufacturing facility is subject to ongoing regulation and periodic inspection by the FDA and other regulatory authorities to ensure compliance with cGMPs. Failure to follow and document adherence to such regulations or other regulatory requirements may (i) lead to significant delays in the availability of product for our clinical trials, (ii) result in the termination of or a hold being placed on one or more of our clinical trials, or (iii) delay or prevent filing or approval of marketing applications for our HAVs.

To monitor compliance with applicable regulations, the FDA routinely conducts inspections of facilities and may identify potential deficiencies. For example, the FDA issues what are referred to as “Form 483s” that set forth observations and concerns that are identified during its inspections. Failure to satisfactorily address the concerns or potential deficiencies identified in a Form 483 could result in the issuance of a warning letter, which is a notice of the issues that the FDA believes to be significant regulatory violations requiring prompt corrective actions. Failure to respond adequately to a warning letter, or to otherwise fail to comply with applicable regulatory requirements could result in enforcement, remedial or punitive actions by the FDA or other regulatory authorities.

### **Risks Related to Our Reliance on Third Parties**

***We rely on third parties to conduct and support our clinical trials, and those third parties may not perform satisfactorily, including by failing to adhere to regulatory requirements or our stated protocols or to meet deadlines for the completion of such trials.***

We do not independently conduct clinical trials for our product candidates and instead rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to perform various functions, including implanting our HAVs and monitoring patients. The FDA and other regulatory authorities require us and these third parties to comply with GCP and, where applicable, cGTPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of patients in clinical trials are protected; ultimately, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and trial protocol. Failure by us or these third parties to do so could require us to enroll additional trial subjects beyond those we anticipate, could require us to modify our protocol, which may cause us to lose previously established Special Protocol Assessment (“SPA”) agreements with the FDA or similar agreements with other regulatory authorities concerning whether the design and size of our clinical trial adequately addresses scientific and regulatory requirements to support marketing approval, or could materially harm our ability to complete our clinical trials, including as a result of the need to remove trial sites and participants from the trial. We have in the past and may in the future need to terminate trial sites due to failure to conduct a trial in accordance with its protocol, applicable regulations, and generally accepted research standards.

The performance of the sites for our clinical trials may also be adversely affected by various other issues, including familiarity with the properties of our HAVs, intervention rates, insufficient training of personnel, variances in medical infrastructure, lack of familiarity with conducting clinical trials in accordance with international regulatory standards, communication difficulties or changes in local regulations. If these third parties do not successfully conduct our clinical trials in accordance with regulatory requirements or our stated protocols, carry out their contractual duties, or meet expected deadlines, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and may not be able to, or may be delayed in our efforts to, successfully commercialize our products if approved by regulatory authorities.

***We rely on third-party suppliers, including sole source suppliers, to provide certain components for our product candidates. Any failure by a third-party supplier to supply these components for manufacture may delay or impair our ability to complete our clinical trials and to commercialize our product candidates.***

We currently rely, and expect to continue to rely, on third parties for the supply of certain components necessary for our product candidates, such as donor tissue, other biologically derived substances, the PGA polymer mesh and the bioreactor bags in which our HAVs are grown. Our suppliers for certain of these materials, including SeraCare for the supply of human plasma and Confluent for the supply of polymer mesh, are sole source suppliers. Failure of one or more of our suppliers, including these sole source suppliers, to deliver components necessary for the production of our HAVs in a timely and sufficient manner, whether due to shortages of such materials, difficulties in scaling up supply to satisfy our

clinical trial and commercial needs, contamination, recall, the COVID-19 pandemic or otherwise, or to source or manufacture such components in accordance with cGMPs and cGTPs, as applicable, could delay our ability to complete our clinical trials, obtain marketing approval and commercialize our product candidates. Establishing additional or replacement suppliers for these components could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. In addition, as part of the FDA's approval of our product candidates, the FDA must review and approve the individual components of our production process, which includes raw materials, the manufacturing processes and facilities of our suppliers. Some of our current suppliers have not undergone this process nor have they had any components included in any product approved by the FDA. If our suppliers fail to comply with applicable regulations, and if we do not qualify alternate suppliers, the clinical development, marketing approval or commercialization of our product candidates could be delayed, thereby increasing our costs to complete clinical development and to obtain marketing approval and depriving us of potential product revenue.

***We intend to rely on our strategic, global relationship with Fresenius Medical Care to undertake, or assist with, the development and commercialization of certain of our product candidates if we receive marketing approval from relevant regulatory authorities. Disruption of this arrangement could materially adversely affect our business, prospects, operating results and financial condition.***

Under the distribution agreement, Fresenius Medical Care has the exclusive right to sell and distribute the distribution product in the field outside of the United States. In addition, under the terms of the distribution agreement, Fresenius Medical Care will collaborate with Humacyte in its commercialization of the distribution product in the field in the United States, including adoption of the distribution product as a standard of care in patients for which such use is supported by clinical results and health economic analyses. As a result of our arrangement with Fresenius Medical Care, we expect to be reliant on Fresenius Medical Care to undertake or assist with the development and commercialization, as well as, in some cases, obtaining and maintaining regulatory approval, of the distribution product in the field and for Fresenius Medical Care to do so in a manner consistent with applicable law and regulatory requirements outside of the United States. If Fresenius Medical Care otherwise fails to undertake or assist with the development or commercialization, or obtaining or maintaining regulatory approvals, of the distribution product in accordance with the terms of the distribution agreement, our business, prospects, operating results and financial condition would be adversely affected, perhaps materially.

Fresenius Medical Care also maintains certain discretionary termination rights on a country-by-country basis with respect to any country outside of the United States under the distribution agreement, as discussed in more detail in the section of this Annual Report on Form 10-K titled "Business — Distribution — Distribution Agreement with Fresenius Medical Care." If the distribution agreement is terminated, we may not be able to secure an alternative distributor in the applicable country on a timely basis or at all, in which case our ability to generate revenues from the distribution product in such country would be harmed.

In addition, if Fresenius Medical Care fails to undertake or assist with the development or commercialization, or obtaining or maintaining regulatory approval, as applicable, of the distribution product in a manner consistent with applicable law and regulatory requirements, patient access to, and demand for, the distribution product could be reduced, our reputation could be damaged, and, under certain circumstances, we could be exposed to potential liability. Furthermore, while Fresenius Medical Care has certain commercialization diligence obligations, Fresenius Medical Care is not restricted from offering its own products and services or the products and services of other companies that compete with the distribution product, and may not undertake or assist with the development or commercialization of the distribution product effectively.

#### **Risks Related to Our Financial Position and Need for Additional Funding**

***We have never generated product revenue and have incurred significant losses to date. We expect to continue to incur losses for the foreseeable future and may never generate product revenue or be profitable.***

Since inception, we have generated no product revenue, and prior to receipt of marketing approval from regulatory authorities, we will be unable to do so. We incurred net losses of \$26.5 million and \$66.5 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021 and 2020, we had an accumulated deficit of \$414.6 million and \$388.1 million, respectively. Up to the date of the consummation of the Merger, we financed our operations primarily through the sale of equity securities and convertible debt and, to a lesser extent, through grants from governmental agencies. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials and development of manufacturing technology, and we anticipate that our expenses will continue to increase over the next several years as we continue these activities. Our V005 and V007 trials are currently enrolling, and we currently intend to submit a BLA to the FDA relating to vascular trauma in

2022 or 2023 and submit a BLA for AV access for hemodialysis in 2023. We also intend to continue scaling out our manufacturing facility to satisfy potential demand if the FDA approves our BLA, advancing preclinical and clinical development of additional clinical applications for our HAVs and funding our operations. Accordingly, we expect to continue to incur substantial operating losses for the foreseeable future, which may fluctuate significantly from quarter-to-quarter and year-to-year.

To become and remain profitable, we must succeed in obtaining marketing approval for our HAVs in the United States, in commercializing our HAVs, and in developing and commercializing additional product candidates that generate significant revenue. We may never succeed in these activities and, even if we do, may never generate revenue that is sufficient to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability. Our failure to become and remain profitable would depress the value of our company and could impair our ability to maintain our research and development efforts, expand our business, diversify our product offerings or even continue our operations. A decline in the value of Humacyte could also cause you to lose all or part of your investment in our securities.

***Our ability to use our net operating loss and tax credit carryforwards to offset future taxable income may be subject to certain limitations.***

As of December 31, 2021, we had net operating loss carryforwards for federal and state tax purposes of approximately \$278.5 million and \$278.9 million, respectively, which begin to expire in 2025. In addition, we had tax credit carryforwards for federal and state tax purposes of approximately \$17.0 million, as of December 31, 2021, which begin to expire in 2025 and will expire completely in 2041. The future utilization of net operating loss and tax credit carryforwards may be limited due to changes in ownership. In general, if we experience a greater than 50% aggregate change in ownership of certain significant stockholders or groups over a three-year period (which constitutes an ownership change under Section 382 of the Internal Revenue Code of 1986, as amended (the “Code”)), utilization of our pre-change net operating loss carryforwards is subject to an annual limitation under Section 382 of the Code (and similar state laws). The annual limitation generally is determined by multiplying the value of our stock at the time of such ownership change (subject to certain adjustments) by the applicable long-term tax-exempt rate. Such limitations may result in expiration of a portion of the pre-change net operating loss carryforwards before utilization and may be substantial. In the past we may have experienced, and in the future may experience, ownership changes as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

***We expect to need to raise additional funding, which may not be available on acceptable terms, or at all, and any failure to obtain capital when needed may force us to delay, limit or terminate our product development or commercialization efforts.***

We expect to incur significant expenses in connection with our ongoing activities as we seek to (i) scale out our manufacturing facility to satisfy potential demand if our HAVs receive marketing approval in the United States, (ii) continue our preclinical and clinical development efforts, including the ongoing clinical trials, and (iii) obtain marketing approval for our 6 millimeter HAV, and, if marketing approval is obtained, to commercialize our HAVs for one or more approved indications. We will need additional funding in connection with these activities. Our future capital requirements will depend on many factors, including:

- the progress and results of our clinical trials and interpretation of those results by the FDA and other regulatory authorities;
- the cost, timing and outcome of regulatory review of our product candidates, particularly for approval of our HAVs in the United States;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our additional product candidates;
- the cost and timing of our future commercialization activities, including product manufacturing, marketing and distribution for our HAVs if approved by the FDA, and any other product candidate for which we receive marketing approval in the future;

- the amount and timing of revenues, if any, that we receive from commercial sales of any product candidates for which we receive marketing approval; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims.

Adequate capital may not be available to us when needed or on acceptable terms. If we are unable to raise capital, we could be forced to delay, reduce, suspend or cease our research and development programs or any future commercialization efforts, which would have a negative impact on our business, prospects, operating results and financial condition. As of December 31, 2021 and 2020, we had \$225.5 million and \$39.9 million, respectively, in cash and cash equivalents and short-term investments. Based upon our current operating plan, we believe that our cash and cash equivalents and short-term investments will be sufficient to fund our operations, including clinical trial expenses and capital expenditure requirements, for at least 12 months from the date of this Annual Report on Form 10-K.

***Pursuant to the terms of our outstanding indebtedness, we may be limited in our ability to incur future debt.***

In March 2021, Humacyte Global, Inc., or Legacy Humacyte, entered into a Loan and Security Agreement (as amended, the “Loan Agreement”) with Silicon Valley Bank and SVB Innovation Credit Fund VIII, L.P., which provides a term loan facility of up to \$50.0 million with a maturity date of March 1, 2025. We became a co-borrower under the Loan Agreement in connection with the Merger. The obligations of Humacyte and Legacy Humacyte under the Loan Agreement are secured by substantially all of their assets, except for their intellectual property.

Pursuant to the terms of the Loan Agreement, we are limited in our ability to incur additional indebtedness. In addition, a failure to comply with the covenants under the Loan Agreement could result in an event of default and an acceleration of amounts due. If an event of default occurs that is not waived by the lenders, and the lenders accelerate any amounts due, we may not be able to make accelerated payments, and the lenders could seek to enforce their security interests in the collateral securing such indebtedness, which could have a material adverse effect on our business and results of operations. Our payment obligations under the Loan Agreement reduce cash available to fund working capital, capital expenditures, research and development and other corporate purposes, and limit our ability to obtain additional financing for working capital, capital expenditures, expansion plans and other investments, which may in turn limit our ability to implement our business strategy, heighten our vulnerability to downturns in our business, the industry, or in the general economy, limit our flexibility in planning for, or reacting to, changes in our business and the industry and prevent us from taking advantage of business opportunities as they arise. If market rates increase, we will have to pay additional interest on this indebtedness, which would further reduce cash available for our other business needs.

We cannot assure you that our business will generate sufficient cash flow from operations or that future financing will be available to us in amounts sufficient to enable us to make required and timely payments on our indebtedness, or to fund our operations.

***To date, we have not requested or obtained marketing approval for, or commercialized, any of our product candidates, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

We are a development-stage company. Our operations to date, with respect to the development of our product candidates, have been limited to organizing and staffing our company, business planning, raising capital, identifying markets for our product candidates, undertaking preclinical studies and clinical trials of our product candidates for various potential indications and establishing research and development, manufacturing and distributing collaborations. We have not yet demonstrated the ability to obtain marketing approval for a product, to manufacture an approved product at commercial scale or to successfully commercialize an approved product. Consequently, any predictions you make about our financial prospects may not be as accurate as they could be if we had received marketing approval and begun commercializing a product.

**Risks Related to Government Regulation**

***We may not obtain marketing approval from the FDA for any of our product candidates even if we successfully complete our clinical trials, which failure would materially harm our business, prospects, operating results and financial condition.***

Prior to commercialization, biologics, like our HAVs, require the submission of a BLA to, and approval of the BLA by, the FDA. A BLA must be supported by extensive preclinical and clinical data, as well as extensive information regarding chemistry, manufacturing and controls (“CMC”), sufficient to demonstrate the safety, purity, potency and

effectiveness of the applicable product candidate to the satisfaction of the FDA. We have never submitted a BLA for approval or otherwise obtained FDA approval for any of our product candidates.

The BLA approval process is expensive and uncertain, it may take several years to complete, and we may not be successful in obtaining such approval. The FDA has substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for BLA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. The FDA could delay, limit or deny approval of our product candidates for many reasons, including because it:

- may not deem the product candidate to be adequately safe or effective;
- may not find the data from preclinical studies, clinical trials or CMC data sufficient to support approval;
- may not approve the manufacturing processes or facilities associated with the product candidate;
- may conclude that the long-term integrity of the product candidate for which approval is being sought has not been sufficiently demonstrated;
- may change approval policies or adopt new regulations; or
- may not accept a submission due to, among other reasons, the content or formatting of the submission.

In some cases, the FDA may agree to an SPA for a clinical trial, when it determines that the trial is adequately designed to provide necessary data to support a license application. Even in such cases, however, the FDA may subsequently abandon the SPA if a substantial scientific issue essential to determining the safety or effectiveness of the product candidate has been identified after the testing has begun. In addition, if a company alters the protocol for a trial, the SPA may no longer apply. Further, the results of pivotal clinical trials are always subject to thorough FDA review. Even highly significant clinical trial results are no guarantee of approval.

We currently intend to submit a BLA to the FDA relating to vascular trauma in 2022 or 2023, and submit a BLA for AV access in hemodialysis in 2023, based on the results and trial design of our V005 and V007 trials. The FDA may decline to approve our 6 millimeter HAV on the basis of these or other trial results, or for other reasons.

***Even if we obtain and maintain approval for our HAVs from the FDA, we may never obtain approval for our HAVs outside of the United States, where the regulatory process is also complex and subject to significant uncertainty. Failure to do so would limit our market opportunities and adversely affect our business.***

Even if we receive FDA approval to market any biologic in the United States, we must comply with the numerous and varying regulatory and compliance related requirements of other countries, including the submission of extensive preclinical and clinical data, manufacturing and quality information regarding the process and facility, scientific data characterizing the relevant product candidate and other supporting data in order to establish safety and effectiveness. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods, including obtaining reimbursement and pricing approval in select markets. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The marketing approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may negatively impact the regulatory process in others, including the risk that our product candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the product candidate may be marketed.

***Even if we seek “rolling review” or priority review, the review time for BLAs for our product candidates may be longer and more expensive than for other products because of the novelty and complexity of our product candidates, which would delay our ability to begin commercialization and earn product revenues.***

The marketing approval process for novel product candidates such as ours may take longer to complete and be more expensive than the process for other, better known or extensively studied pharmaceutical or other product candidates. We may be eligible for a “rolling review” of a BLA, which means we may submit completed modules of a BLA rather than waiting until every module of the BLA is completed before submitting the full BLA for FDA review. Such “rolling review” is common for indications that are part of one of FDA’s expedited programs, such as our 6 millimeter HAV, which

has received Fast Track and RMAT designations for AV access in hemodialysis. The FDA may also designate one or more of our product candidates for priority review after we submit a BLA. Under priority review, the FDA's goal is to review an application within six months of the 60-day filing date, compared to ten months for a standard review. Even if we are able to utilize a "rolling review" and/or the FDA designates one or more of our product candidates for priority review, it may not lead to a shorter review period. The FDA could also decide to consult an advisory committee as part of our BLA review process, which often leads to a longer review time. We are not permitted to commercialize our product candidates in the United States until they have been approved by the FDA, and if we experience a lengthier review period than expected, our ability to generate product revenues would be materially harmed.

***We may in the future seek orphan drug designation for the use of our HAVs to treat congenital pediatric heart defects. We may be unable to obtain such designation or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our revenue, if any, to be reduced.***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population of 200,000 or more in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease, as well as the same drug or biologic for a different indication or disease. The FDA can also approve the same drug or biologic for the same indication or disease if the subsequent drug or biologic demonstrates clinical superiority. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

***Inadequate funding for the FDA and other government agencies, including from government shut downs, global health concerns or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, policy changes, and the risk of slowdowns and shutdowns due to the COVID-19 pandemic. Average review times at the FDA have fluctuated in recent years as a result.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

We may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process. In addition, disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

On March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities as a result of the COVID-19 pandemic. In July 2021, the FDA resumed standard inspectional operations of domestic facilities. However, the FDA may not be able to maintain this pace and delays or setbacks are possible in the future, including where a pre-approval inspection or an inspection of clinical sites is required, and due to the COVID-19



pandemic and travel restrictions, the FDA is unable to complete such required inspections during the review period. The FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic.

Additionally, regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

***Even if we receive marketing approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to significant penalties if we fail to comply with applicable regulatory requirements.***

If we obtain marketing approval for any of our product candidates, the approved product will be subject to ongoing regulatory requirements from the FDA and, if applicable, non-U.S. regulatory authorities. Any marketing approval that we receive for our product candidates may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up trials to monitor the safety and efficacy of the product. The FDA could also approve our product candidates with a REMS, which could include significant restrictions on distribution and/or use of our products. In addition, if the FDA and non-U.S. regulatory authorities approve any of our product candidates, we will be subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to the manufacturing, labelling, packaging, AE reporting, storage, advertising, distribution, promotion and recordkeeping for our products. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with regulatory requirements of the FDA and, if relevant, other non-U.S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including the following:

- issuance of warning letters or untitled letters by regulatory authorities asserting that we are in violation of the law;
- imposition of injunctions or significant civil monetary penalties or pursuit by regulatory authorities of civil or criminal prosecutions and fines against us or our responsible officers;
- suspension or withdrawal of marketing approval;
- suspension of any ongoing clinical trials or refusal by regulatory authorities to approve pending marketing applications or supplements to approved applications;
- seizure of products or refusal to allow us to enter into supply contracts, including government contracts, or to import or export products;
- voluntary or mandatory product recalls and publicity requirements; and
- restrictions on operations, including marketing efforts, or restrictions that mandate costly new manufacturing requirements.

Any of these events could reduce market acceptance of any of our product candidates that had received marketing approval, substantially reduce our revenue, increase the costs of operating our business, and cause us significant reputational damage, among other consequences. If we ultimately receive approval for any product candidates in jurisdictions outside the U.S., we expect to be subject to similar ongoing regulatory oversight by the relevant foreign regulatory authorities.

Our products may be subject to product recalls that could harm our reputation and could materially and adversely affect our business, financial condition, operating results, cash flows and prospects. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, if approved. In particular, while the FDA permits the dissemination of truthful and non-misleading information about an approved product, the FDA restricts our ability to promote a product for uses that are not approved by the FDA. The misuse or off-label use of our product may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory authorities if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business. We may also face risks in other non-U.S. jurisdictions from product recalls and advertising/promotion rules.

We could also face product liability suits or regulatory delays due to defects in our products, which could be expensive and time-consuming and result in substantial damages payable by us and increases in our insurance rates.

***Designation of our product candidates for expedited programs, such as Fast Track designation, Breakthrough Therapy Designation, or RMAT designation, or accelerated approval by the FDA, or priority designation by the Department of Defense, may not lead to a faster development or regulatory review or approval process, and even if granted, will not increase the likelihood that our product candidates will receive marketing approval.***

In 2014, the FDA granted Fast Track designation for our 6 millimeter HAV for use in the creation of AV access for hemodialysis, and, in 2017, the FDA granted RMAT designation for our 6 millimeter HAV for the creation of vascular access for performing hemodialysis. We have not received designations pursuant to any of the FDA's expedited programs for vascular trauma, peripheral arterial disease or our other indications, although we may in the future seek such designations if such product candidates meet the criteria for that designation. As a result, even if we submit a BLA for vascular repair, reconstruction and replacement, including in AV access in hemodialysis, our Fast Track and RMAT designations, and their attendant benefits, may not apply to this broader requested indication. In addition, even with one or more of these designations, we may not experience a faster development process, or faster review or approval, for our product candidates compared to product candidates that are not part of the expedited programs. Further, the FDA may withdraw a designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, a product candidate may no longer demonstrate a potential to address unmet medical need if, for example, a new product is approved that addresses the same need, which could lead to loss of a designation. The loss of a designation under an expedited program, including a Fast Track designation, Breakthrough Therapy Designation, or RMAT designation, could significantly increase the costs of development and length of time required before we could seek marketing approval of such a product candidate.

We may seek accelerated approval for our HAV relating to vascular trauma. A product candidate may be eligible for accelerated approval if it treats a serious or life-threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. As a condition of accelerated approval, the FDA may require that a sponsor of a product receiving accelerated approval perform adequate and well-controlled confirmatory clinical trials post-approval. These confirmatory trials must be completed with due diligence. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate full FDA approval. Accelerated approval may also be withdrawn if, among other things, a confirmatory trial required to verify the predicted clinical benefit of the product fails to verify such benefit or if such trial is not conducted with due diligence.

In addition, in 2018, our HAV product candidate was assigned a priority designation by the Secretary of Defense under Public Law 115-92. Similar to the designations described above that FDA may grant, a priority designation by the Department of Defense does not change the standards for approval but may expedite the development or approval process.

***Healthcare reform measures could hinder or prevent our product candidates' commercial success.***

Our industry is highly regulated, and changes in or revisions to laws and regulations that make gaining coverage of and adequate reimbursement for our product candidates more difficult or subject to different criteria and standards may adversely impact our business, prospects, operating results and financial condition. In the United States, there have been and we expect there will continue to be a number of legislative, regulatory and other changes to the healthcare system to contain or reduce healthcare costs that may adversely affect our ability to set a price we believe is fair for our product candidates, our ability to generate revenues and achieve or maintain profitability, and the availability of capital.

Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, ACA, enacted in 2010 and amended by the Health Care and Education Reconciliation Act, contains a number of provisions that were intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies for fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms. The Bipartisan Budget Act of 2018, among other things, amended the ACA to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole," in part by requiring greater discounts from manufacturers. Various members of Congress have expressed a desire to repeal all or portions of the ACA, and in December 2017, portions of the ACA dealing with the individual mandate insurance requirement were effectively repealed by the Tax Cuts and Jobs Act of 2017. On February

10, 2021, the Biden administration withdrew the federal government's support for overturning the ACA. Further, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which ran until August 15, 2021. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In June 2021, the United States Supreme Court held that the individual plaintiffs and states lacked standing to challenge the constitutionality of the ACA.

Additionally, in December 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Since then, the ACA risk adjustment program payment parameters have been updated annually. In addition, CMS published a final rule that gave states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

At this time, it remains unclear whether there will be further changes made to the ACA. The ACA, as currently enacted or as amended in the future, may adversely affect our business and operating results, and we do not know how future federal or state legislative or administrative changes relating to healthcare reform will affect our business. Other legislative changes that have been adopted since enactment of the ACA could also affect potential pricing and utilization of our product candidates.

In addition, the Secretary of Health and Human Services, various members of Congress and CMS have made statements and issued proposals regarding containment of drug prices through various means, including enabling CMS to negotiate U.S. drug pricing to align with foreign drug pricing, pricing transparency measures, reform of drug rebate programs, and conditioning coverage and reimbursement of certain drugs upon the prior failure or inadequacy of less expensive therapies, sometimes referred to as "step therapy." Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies. At the federal level, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In addition, at the state level, individual states have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Beginning in fiscal year 2018, CMS altered the reimbursement formula on specified covered outpatient drugs ("SCODs"). A SCOD drug product may also be a covered outpatient drug under the 340B program, which allows 340B-participating hospitals to purchase the drug product at the 340B discounted rate and, when prescribing it to a Medicare patient, be reimbursed at the Medicare rate. Under the prior Medicare reimbursement rate, this created a significant, positive gap for 340B-participating health care facilities. CMS's change in the Medicare reimbursement rate for SCODs significantly impacted, or eliminated, the positive gap for 340B-participating health care facilities. The District Court for the District of Columbia invalidated the formula change, but the U.S. Court of Appeals for the District of Columbia Circuit reversed the district court's decision and found that the changes were within the Secretary's authority. The case is currently under review by the U.S. Supreme Court, and a decision is expected by summer of 2022. It is unlikely the Medicare rate litigation will impact 340B pricing for our approved products in the future, but it possible it could affect covered hospitals who might purchase our products.

The FDA also released a final rule on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Additionally, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The 2020 rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to a court order, HHS subsequently delayed the effective date for aspects of the rule, including those relating to pharmacy benefit managers, until

2023. The rule was then effectively delayed until January 1, 2026, as part of the Infrastructure Investment and Jobs Act, which was signed into law on November 15, 2021. In addition, on November 19, 2021, the House of Representatives passed a version of the Build Back Better Act that includes a provision prohibiting the implementation, administration, or enforcement of the rule. Although a number of these, and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, Congress has indicated that it will continue to seek new legislative measures to control drug costs.

The ultimate content, timing, or effect of any healthcare reform legislation or executive order or the impact that the resulting changes may have on us is uncertain, but we expect there will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care.

***If we fail to comply with healthcare regulations, we could face substantial penalties and our business, prospects, operating results and financial condition could be adversely affected.***

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business even though we do not and will not control referrals of healthcare services. We could also be subject to patient privacy regulation by both the U.S. Government and the states in which we conduct our business. Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements. The regulations that may affect our ability to operate include, without limitation:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs, even if the person does not have actual knowledge of the statute or specific intent to violate it;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the U.S. Government;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the anti-inducement law, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of items or services reimbursable by a federal or state governmental program;
- the federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act and its implementing regulations, which require applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the State Children's Health Insurance Program to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Effective January 1, 2022, these reporting obligations were extended to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- HIPAA, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participating in federal health care programs and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment, exclusion, or restructuring of our operations could adversely affect our ability to operate our business, prospects, operating results and financial condition. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy and fraud and abuse laws may prove costly.

***Our business and operations, including our development programs, could be materially disrupted in the event of system failures, security breaches, violations of data protection laws or data loss or damage by us or third parties on which we rely, including our CROs or other contractors or consultants.***

Our internal computer systems (including our LUNA200 manufacturing system) and those of third parties on which we rely, including our CROs and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could have a material adverse effect on our business operations, including a material disruption of our development program. Unauthorized disclosure of sensitive or confidential patient or employee data, including personally identifiable information, whether through breach of computer systems, systems failure, employee negligence, fraud or misappropriation, or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third parties, could result in negative publicity, legal liability and damage to our reputation. Unauthorized disclosure of personally identifiable information could also expose us to sanctions for violations of data privacy laws and regulations around the world. To the extent that any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed. For example, the loss of or damage to clinical trial data, such as from completed or ongoing clinical trials, for any of our product candidates would likely result in delays in our marketing approval efforts and significantly increased costs in an effort to recover or reproduce the data.

We have previously been, and expect to remain, the target of cyber-attacks. As we become more dependent on information technologies to conduct our operations, cyber incidents, including deliberate attacks, such as ransomware attacks, and attempts to gain unauthorized access to computer systems (including our LUNA200 manufacturing system) and networks, may increase in frequency and sophistication. These incidents pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data and these risks apply both to us, and to third parties on whose systems we rely for the conduct of our business. While the effect of these incidents has not historically been material to our results of operations, financial condition or prospects, cyber threats are persistent and constantly evolving. Such threats have increased in frequency, scope and potential impact in recent years, which increase the difficulty of detecting and successfully defending against them. As cyber threats continue to evolve, we may be required to incur additional expenses in order to enhance our protective measures or to remediate any information security vulnerability. There can be no assurance that we or our third-party providers will be successful in preventing cyber-attacks or successfully mitigating their effects. Similarly, there can be no assurance that our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. Any cyber-attack or destruction or loss of data could have a material adverse effect on our business and prospects. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or destruction or loss of data and may incur significant additional expense to implement further data protection measures. It is also possible that unauthorized access to data may be obtained through inadequate use of security controls by our suppliers or other vendors. In 2021, a remote code execution vulnerability in Apache Log4j was identified as affecting large amounts of systems worldwide. We were not impacted by the Log4j vulnerability, however we cannot provide assurance that these and other attacks will not have an impact in the future.

Although we have general liability insurance coverage, our insurance may not cover all claims, continue to be available on reasonable terms or be sufficient in amount to cover one or more large claims. Additionally, the insurer may disclaim coverage as to any claim. The successful assertion of one or more large claims against us that exceed or are not covered by our insurance coverage or changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, prospects, operating results and financial condition.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines and penalties or incur costs that could harm our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. In the event of contamination or injury resulting from our use or production of hazardous materials, we could be held liable for any resulting damages even if we contract with a third party for their disposal, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties resulting from contamination or injury from our use or production of hazardous materials. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use or production of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous materials.

In addition, we may be required to incur substantial costs to comply with future environmental, health and safety laws and regulations. Compliance with such laws and regulations may divert resources away from our research, development and manufacturing efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

***Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and adverse publicity and could negatively affect our operating results and business.***

We and any potential collaborators may be subject to federal, state and foreign data protection laws and regulations (*i.e.*, laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state privacy and health information privacy laws and federal and state consumer protection laws (*e.g.*, Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to civil or criminal penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

International data protection laws, including Regulation 2016/679, known as the General Data Protection Regulation ("GDPR"), may also apply to health-related and other personal information obtained outside of the United States. The GDPR will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU (which also includes the European Economic Area, or "EEA") data protection rules. Further, the United Kingdom's vote in favor of exiting the EU, often referred to as Brexit, has created more uncertainty with regard to data protection regulation in the United Kingdom (the "UK"). The UK retained the GDPR in UK law, which sits alongside the amended version of the Data Protection Act 2018. The EU adopted an adequacy decision so data can be transferred from the EU to the UK. Additionally, there are no new requirements for transfer from the UK to the EU. However, going forward, the EU and UK's data protection rules could diverge and data transfers may not be possible and/or new arrangements may need to be put in place. In particular, it is unclear to what extent the UK regime will begin diverging from the GDPR and how data transfers to and from the UK will be regulated.

In addition, California recently enacted the California Consumer Privacy Act ("CCPA"), which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA became effective on January 1, 2020, but the California Consumer Rights Act ("CPR") was recently enacted to strengthen elements of the CCPA effective January 1, 2023. In addition, there are a number of other states that have considered similar privacy proposals, with states like Virginia and Colorado enacting their own privacy laws (also scheduled to come into effect in January 1, 2023 and July 1, 2023, respectively). These privacy laws may impact our business activities and exemplify the vulnerability of our business to the evolving regulatory environment related to personal data.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to

operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

***We or the third parties upon which we depend may be adversely affected by natural disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Natural disasters such as hurricanes could severely disrupt our operations and have a material adverse effect on our business, prospects, operating results and financial condition. In addition, flooding, lightning strikes, meteor strikes, and polar vortices could affect our building operations. If a natural disaster, power outage or other unforeseen event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our in-house manufacturing facility, or that otherwise significantly disrupted our operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently may prove inadequate in the event of a natural disaster or similar event. We may incur substantial expenses as a result of any natural disaster, which could have a material adverse effect on our business.

***We are subject to anti-corruption and a variety of other laws governing our international operations. If we fail to comply with these laws, we could be subject to, among other things, civil or criminal penalties, other sanctions and remedial measures, and reputational damage, which could adversely affect our business, prospects, operating results and financial condition.***

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act ("FCPA"), the U.K. Bribery Act and other anti-corruption laws. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We are conducting certain of our trials at a number of trial sites around the world. Certain of these jurisdictions pose a risk of potential FCPA violations, and we have relationships with third parties, including government-affiliated hospitals and universities, whose actions could potentially subject us to liability under the FCPA or local anti-corruption laws.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the U.S. Department of Commerce's Bureau of Industry and Security, the U.S. Department of the Treasury's Office of Foreign Assets Control, and various non-U.S. government entities, including applicable economic sanctions on countries and persons, customs requirements, currency exchange regulations and transfer pricing regulations.

If we fail to comply with applicable anti-corruption laws and other legal requirements, we may become subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, including the loss of export or import privileges and debarment, and face substantial legal expenses. Likewise, even an investigation by U.S. or foreign authorities of potential violations of such laws could damage our reputation. In either case, our business, prospects, operating results and financial condition could be adversely affected. Under certain circumstances, we could also be held liable for the activities of our employees, contractors, and partners that violate anti-corruption laws, even if we do not explicitly authorize or have actual knowledge of such activities. Even allegations of such violations could potentially damage our reputation and harm our business.

## **Risks Related to Our Intellectual Property**

***Our ability to successfully commercialize our products may be impaired if we are unable to obtain and maintain effective intellectual property rights for our proprietary scientific technology platform and product candidates.***

Our success depends in large part on our and our licensors' ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary scientific technology platform and products. We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates that we and/or our licensors view as important to our business. This process is expensive and time-consuming, and we and our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we and/or our licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent

protection. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents or enforce the patents, covering technology or products that we license from third parties. Our existing patents and any future patents and the existing and any future licenses to third-party patents we obtain may not be sufficiently broad to prevent others from using our technologies or from developing competing products and technologies.

The patent position of biotechnology companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unresolved. In recent years, patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors' patent rights are highly uncertain. Additionally, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our owned or licensed patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. We, or our licensors, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of future product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage.

***The patent protection we obtain for our product candidates may not be sufficient enough to provide us with any competitive advantage or our owned or licensed patents may be challenged.***

In some instances, agreements through which we license patent rights may not give us control over patent prosecution or maintenance, so that we may not be able to control which claims or arguments are presented, how claims are amended, and may not be able to secure, maintain, or successfully enforce necessary or desirable patent protection from those patent rights. We have not had and do not have primary control over patent prosecution and maintenance for certain of the patents and patent applications we license and therefore cannot guarantee that these patents and applications will be prosecuted or maintained in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. Moreover, some of our in-licensed patents and patent applications are, and our future owned and licensed patents may be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in any future patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

It is possible that defects of form in the preparation or filing of our owned or licensed patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments or extensions. If we or our partners, collaborators, licensees, or licensors, whether current or future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees, or licensors, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our owned or licensed patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent.



However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, we cannot be certain that parties from whom we do or may license or purchase patent rights were the first to make relevant claimed inventions, or were the first to file for patent protection for them. If third parties have filed prior patent applications on inventions claimed in our owned or licensed patents or applications that were filed on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of such owned or licensed patent applications. If third parties have filed such prior applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our owned or licensed invention was derived from theirs.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our owned and licensed patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. There is no assurance that all of the potentially relevant prior art relating to our owned or licensed patents and patent applications has been found. If such prior art exists, it may be used to invalidate a patent, or may prevent a patent from issuing from a pending patent application. For example, such patent filings may be subject to a third-party submission of prior art to the U.S. Patent and Trademark Office (“USPTO”), or to other patent offices around the world. Alternately or additionally, we may become involved in post-grant review procedures, oppositions, derivation proceedings, *ex parte* reexaminations, *inter partes* review, supplemental examinations, or interference proceedings or challenges in district court, in the United States or in various foreign patent offices, including both national and regional, challenging patents or patent applications in which we have rights, including patents on which we rely to protect our business. An adverse determination in any such challenges may result in loss of the patent or in patent or patent application claims being narrowed, invalidated or held unenforceable, in whole or in part, or in denial of the patent application or loss or reduction in the scope of one or more claims of the patent or patent application, any of which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

Pending and future patent applications may not result in patents being issued that protect our business, in whole or in part, or which effectively prevent others from commercializing competitive products.

Competitors may also be able to design around our owned or licensed patents. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our owned or licensed patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than United States law does. If these developments were to occur, they could have a material adverse effect on our ability to generate revenue.

Issued patents that we have or may obtain or license may not provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend or assert our owned or licensed patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our owned or licensed patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

***We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and unsuccessful.***

Competitors may infringe, misappropriate or violate our owned or licensed patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or

unenforceable, in whole or in part. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly and refuse to stop the other party from using the technology at issue on the grounds that our owned or licensed patents do not cover such technology. The standards that courts use to interpret patents are not always applied predictably or uniformly and can change, particularly as new technologies develop. As a result, we do not know how much protection, if any, will be given to our owned or licensed patents if we attempt to enforce them and they are challenged in court. An adverse result in any litigation proceeding could put one or more of our owned or licensed patents at risk of being invalidated or interpreted narrowly.

Inequitable conduct is frequently raised as a defense during intellectual property litigation. It is believed that all parties involved in the prosecution of our patent applications have complied with their duties of disclosure in the course of prosecuting our patent applications; however, it is possible that legal claims to the contrary could be asserted if we were engaged in intellectual property litigation, and the results of any such legal claims are uncertain due to the inherent uncertainty of litigation. If a court determines that any party involved in the prosecution of our owned or licensed patents failed to comply with its duty of candor, the subject patent could be held to be unenforceable.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Intellectual property litigation or other legal proceedings may cause us to incur significant expenses and may also absorb significant management time. Uncertainties resulting from our participation in patent litigation or other proceedings could have a material adverse effect on our business.

***Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could harm our business, prospects, operating results and financial condition.***

Third parties may assert infringement, misappropriation or other claims against us, or other parties we have agreed to indemnify, based on existing third-party patents or patents that may be granted in the future as well as other intellectual property rights. There may be existing third-party patents or patent applications covering aspects of our technology. Furthermore, because patent applications are published sometime after filing, and because applications can take several years to issue, there may be additional currently pending third-party patent applications that are unknown to us, which may later result in issued patents. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We may not have sufficient resources to bring these actions to a successful conclusion. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

Because of the inevitable uncertainty in intellectual property litigation, we could lose a patent infringement or other action asserted against us regardless of our perception of the merits of the case. If we are found to infringe upon, misappropriate or otherwise violate a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the implicated technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, which could be significant, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement, misappropriation or that we otherwise violated intellectual property rights could prevent us from commercializing our product candidates or force us to cease some or all of our business operations.

***If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.***

We are a party to intellectual property license agreements with third parties. For example, we have licenses with each of Duke University and Yale University for patents associated with our proprietary technology, and may enter into additional license agreements in the future. Our existing license agreements impose, and we expect that our future license agreements will impose, various diligence, royalty payment, milestone payment, insurance and other obligations on us. If we fail to comply with these obligations or other obligations in our license agreements, our licensors may have the right to terminate these agreements, in which event we may not be able to develop and market any product or use any platform technology that is covered by these agreements. If our license agreements terminate, or we experience a reduction or elimination of licensed rights under these agreements, we may have to negotiate new or reinstated licenses with less

favorable terms or we may not have sufficient intellectual property rights to operate our business. The occurrence of such events could materially harm our business.

Further, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. Accordingly, disputes may arise between us and our licensor, our licensor and its licensors, regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights, if any, granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- whether our licensor or its licensor had the right to grant the license agreement;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the intellectual property without their authorization;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- whether we are complying with our obligations with respect to the use of the licensed technology in relation to our development and commercialization of product candidates;
- our involvement in the prosecution of the licensed patents and our licensors' overall patent enforcement strategy;
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us and our partners; and
- the amounts of royalties, milestones or other payments due under the license agreement.

The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, or are insufficient to provide us the necessary rights to use the intellectual property, we may be unable to successfully develop and commercialize the affected product candidates. If we or any such licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer. Any disputes with our licensors or any termination of the licenses on which we depend could have a material adverse effect on our business, financial condition, results of operations and prospects.

***We may not be successful in obtaining necessary intellectual property rights to product candidates for our development pipeline through acquisitions and in-licenses.***

Although we intend to develop product candidates through our own internal research, we may need to obtain additional licenses from others to advance our research or allow commercialization of our product candidates. However, we may be unable to acquire or in-license intellectual property rights relating to, or necessary for, any such product candidates from third parties on commercially reasonable terms or at all. In that event, we may be unable to develop or commercialize such product candidates. We may also be unable to identify additional, future product candidates that we believe are an appropriate strategic fit for our company and intellectual property relating to, or necessary for, such product candidates.

The in-licensing and acquisition of third-party intellectual property is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for product candidates that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may be unable to in-license or acquire the third-party intellectual property rights for product candidates on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to suitable product candidates, our business, financial condition, results of operations and prospects for growth could suffer.

***We may be unable to protect the confidentiality of our trade secrets, particularly in light of our reliance on third parties, which increases the possibility that such trade secrets will be disclosed or misappropriated, thus harming our business and competitive position.***

In addition to our patented technology and products, we rely upon trade secrets, including unpatented know-how, technology and other proprietary information to develop and maintain our competitive position, particularly with respect to our manufacturing process. We seek to protect our trade secrets, in part, through confidentiality agreements with our employees, collaborators and consultants. We seek to have agreements with our employees and selected consultants that obligate them to assign any inventions created during their tenure with us. However, we may not obtain these agreements in all circumstances and the assignment of intellectual property under such agreements may not be self-executing. If the employees, collaborators or consultants that are parties to these agreements breach or violate their respective terms, we may not have adequate remedies for any such breach or violation. Our trade secrets could also be misappropriated by our competitors. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, time-consuming and potentially distracting, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent such a party from using that technology or information to compete with us. If our trade secrets are disclosed to or misappropriated or independently developed by a third party, it would harm our ability to protect our rights and could materially harm our business and competitive position.

***Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.***

We may employ individuals or engage consultants that previously worked with other organizations, including our competitors or potential competitors. Although we seek to ensure that such persons do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or they, or both, have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third party. Litigation may be necessary to defend against these claims. If we fail in defending any such claims or settling those claims, we may lose valuable intellectual property rights or personnel in addition to paying monetary damages or a settlement. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

***Patent terms may be inadequate to protect our competitive position on our HAVs or our other product candidates for an adequate amount of time.***

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our HAVs are obtained, once the patent life has expired, we may face competition, including from other competing technologies. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting, maintaining, defending and enforcing patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in countries outside the United States, or from selling or importing products made using our inventions in and into other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our products, to the extent approved, and our owned or licensed patents or other intellectual property rights may not be effective or sufficient to prevent them from doing so.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our owned or licensed patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign

jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our owned or licensed patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded to us, if any, may not be commercially meaningful.

Many countries have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license, which could adversely affect our business, financial condition, results of operations, and prospects.

***Some of our internal intellectual property and most of our in-licensed intellectual property has been generated under U.S. Government grants and contracts that trigger certain obligations and U.S. Government rights and thus is subject to federal regulations such as “march-in” rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.***

Some of our internal intellectual property and most of our in-licensed intellectual property has been generated under U.S. Government grants and contracts that trigger certain obligations and U.S. Government rights under federal statutes and regulations, including the Bayh-Dole Act of 1980 and the Federal Technology Transfer Act of 1986. For example, the U.S. Government has a non-exclusive, non-transferable, irrevocable worldwide license to inventions conceived or first actually reduced to practice in the performance of a U.S. Government agreement. In addition, the U.S. Government has certain “march-in” rights to require us to grant exclusive, partially exclusive, or non-exclusive licenses to such inventions for the benefit of a third party if the U.S. Government determines that: (i) action is necessary to alleviate health or safety needs not reasonably met by us, our assignees, our licensees, or, in some cases, our licensors, (ii) action is necessary due to noncompliance with a U.S.-based manufacturing requirement applicable to exclusive licenses, (iii) action is necessary to meet requirements for public use specified by federal regulations and such requirements are not reasonably satisfied by us, our assignees, our licensees, and, in some cases, our licensors, and (iv) with respect to inventions made under funding agreements, adequate steps have not been taken to achieve practical application of the invention. The U.S. Government also has the right to take title to these inventions if we, or the applicable licensor, fails to disclose, elect title to, file or prosecute a patent application for, or defend or obtain a patent covering such inventions within time limits specified in particular funding agreements. The U.S. Government also has varying rights to use and disclose information, including copyrighted works, generated or delivered under a U.S. Government agreement depending on the terms of the agreement and the nature of the information. Intellectual property generated under a U.S. Government agreement is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, when inventions that are conceived or first actually reduced to practice under a U.S. Government funding agreement are exclusively licensed, products embodying or produced through the use of such inventions must be manufactured substantially in the United States. This U.S.-based manufacturing requirement may limit our ability to contract with non-U.S. companies to produce a covered product, although this requirement can be waived in certain circumstances. To the extent that any of our licensors’ current or future intellectual property is generated in the performance of U.S. Government grants or contracts, these requirements may apply to such intellectual property.

***If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our marks of interest and our business may be adversely affected.***

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

***Intellectual property rights do not necessarily address all potential threats.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we own or license or may own or license in the future;
- we, or our current or future licensors might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or license or may own or license in the future;
- we, or our current or future licensors might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our and our licensors' pending owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could harm our business, financial condition, results of operations, and prospects.

**Risks Related to Business Matters and Our Ability to Manage Growth**

***Our future success depends on our ability to retain our key employees, consultants and advisors and to attract, retain and motivate qualified personnel.***

We are highly dependent on the research and development, clinical, regulatory, financial, commercial, and manufacturing expertise of the principal members of our management, scientific and clinical teams. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, losing or replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain marketing approval of and commercialize our product candidates. Competition to hire from this limited pool is intense. We also experience competition for the hiring of scientific and clinical personnel from public and private universities and research institutions. In addition, we rely on consultants and advisors, including scientific, commercial and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under employment, consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

***We expect to increase the size of our workforce in the future, and we may encounter difficulties in managing this growth, which could harm our operations.***

As of December 31, 2021, we had 146 employees. As we move forward in our efforts to commercialize our HAVs, if approved, we expect to continue to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of development, regulatory affairs, manufacturing and quality and compliance and support functions. Due to our limited financial resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage this growth effectively could delay the execution of our business plans or harm our operations.

### **Risks Related to Ownership of Our Securities**

***The price of our common stock may be volatile.***

The price of our common stock may fluctuate due to a variety of factors, including:

- actual or anticipated fluctuations in our quarterly and annual results and those of other public companies in our industry;
- mergers and strategic alliances in the industry in which we operate;
- market prices and conditions in the industry in which we operate;
- changes in government regulation;
- the impact of the COVID-19 pandemic on our business and operations;
- potential or actual military conflicts or acts of terrorism;
- announcements concerning Humacyte or our competitors; and
- the general state of the securities markets.

These market and industry factors may materially reduce the market price of our common stock, regardless of our operating performance.

***Reports published by analysts, including projections in those reports that differ from our actual results, could adversely affect the price and trading volume of our common stock.***

We expect that securities research analysts will establish and publish their own periodic projections for the business of Humacyte. These projections may vary widely and may not accurately predict the results we actually achieve. Our stock price may decline if our actual results do not match the projections of these securities research analysts. Similarly, if one or more of the analysts who write reports on Humacyte downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price could decline. If one or more of these analysts ceases coverage of Humacyte or fails to publish reports on Humacyte regularly, our stock price or trading volume could decline.

***We may issue additional shares of common stock or other equity securities without your approval, which would dilute your ownership interests and may depress the market price of our common stock.***

As of December 31, 2021, we had Warrants outstanding to purchase up to an aggregate of 5,177,500 shares of our common stock and options and warrants outstanding to purchase up to an aggregate of 7,122,198 shares of our common stock. Under the Humacyte, Inc. 2021 Long-Term Incentive Plan (the “2021 Plan”) and the Humacyte, Inc. 2021 Employee Stock Purchase Plan (the “ESPP”), we also have the ability to issue 7,725,253 shares and 1,030,033 shares, respectively. In addition, such aggregate number of shares under the 2021 Plan and the ESPP will automatically increase on January 1 of each year commencing January 1, 2022, in an amount equal to 5% and 1%, respectively, of the number of shares of our capital stock outstanding on December 31 of the preceding year, unless our board of directors (the “Board”) acts prior to January 1 of a given year to provide that the increase for such year will be a lesser number. At the end of 2021, our Board elected not to increase the number of shares under the 2021 Plan and the ESPP. We may also issue additional shares of common stock or other equity securities of equal or senior rank in the future in connection with, among other things, future acquisitions or repayment of outstanding indebtedness, without stockholder approval, in a number of circumstances.

Our issuance of additional shares of common stock or other equity securities of equal or senior rank would have the following effects:

- our existing stockholders' proportionate ownership interest in Humacyte will decrease;
- the amount of cash available per share, including for payment of dividends in the future, may decrease;
- the relative voting strength of each previously outstanding share of common stock may be diminished; and
- the market price of shares of our common stock may decline.

***Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.***

We may retain future earnings, if any, for future operations, expansion and debt repayment and have no current plans to pay any cash dividends for the foreseeable future. Any decision to declare and pay dividends as a public company in the future will be made at the discretion of the Board and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that the Board may deem relevant. In addition, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur. As a result, you may not receive any return on an investment in our securities unless you sell your securities for a price greater than that which you paid for it.

***The Public Warrants may not be in the money in the future, and they may expire worthless, and the terms of the Public Warrants may be amended in a manner adverse to a holder if holders of at least 50% of the then outstanding Public Warrants approve of such amendment.***

In connection with the Merger, the Company assumed 5,000,000 publicly-traded warrants ("Public Warrants") and 177,500 private placement warrants issued to AHAC Sponsor LLC (the "Sponsor"), Oppenheimer & Co. Inc. and Northland Securities, Inc. in connection with AHAC's initial public offering ("Private Placement Warrants" and, together with the Public Warrants, the "Warrants"). The Warrants were issued in registered form under a warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and AHAC. The warrant agreement provides that the terms of the Warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision or correct any mistake, but requires the approval by the holders of at least 50% of the then-outstanding Public Warrants to make any change that adversely affects the interests of the registered holders of Public Warrants. Accordingly, we may amend the terms of the Public Warrants in a manner adverse to a holder if holders of at least 50% of the then-outstanding Public Warrants approve of such amendment and, solely with respect to any amendment to the terms of the Private Placement Warrants or any provision of the warrant agreement with respect to the Private Placement Warrants, holders of at least 50% of the number of the then outstanding Private Placement Warrants. Although our ability to amend the terms of the Public Warrants with the consent of at least 50% of the then-outstanding Public Warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the Warrants, convert the Warrants into cash, shorten the exercise period or decrease the number of shares of common stock purchasable upon exercise of a Warrant.

***We may redeem your unexpired Public Warrants prior to their exercise at a time that is disadvantageous to you, thereby making your Public Warrants worth less than they would be if you held and exercised them at a later time.***

We have the ability to redeem outstanding Public Warrants prior to their expiration, at a price of \$0.01 per Warrant, provided that the last reported sales price of our common stock equals or exceeds \$18.00 per share (as adjusted for share subdivisions, share dividends, rights issuances, subdivisions, reorganizations, recapitalizations and the like) for any 20 trading days within a 30 trading-day period ending on the third trading day prior to the date we send the notice of redemption to the holders thereof. If and when the Public Warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding Public Warrants could force you to: (i) exercise your Public Warrants and pay the exercise price therefor at a time when it may be disadvantageous for you to do so; (ii) sell your Public Warrants at the then-current market price when you might otherwise wish to hold your Public Warrants; or (iii) accept the nominal



redemption price which, at the time the outstanding Public Warrants are called for redemption, is likely to be substantially less than the market value of your Public Warrants.

The value received upon exercise of the Public Warrants (i) may be less than the value the holders would have received if they had exercised their Public Warrants at a later time where the underlying share price is higher and (ii) may not compensate the holders for the value of the Public Warrants.

The Private Placement Warrants are not subject to the same risk of redemption as the Public Warrants as the Private Placement Warrants are not redeemable so long as they are held by the Sponsor, the underwriters of AHAC's initial public offering or their permitted transferees. If the Private Placement Warrants are held by holders other than the Sponsor, the underwriters or their permitted transferees, the Private Placement Warrants will be redeemable by us.

***We have derivative securities that are accounted for as liabilities and the changes in value of such derivative securities could have a material effect on our financial results.***

Included on the Company's consolidated balance sheets as of December 31, 2021 are derivative liabilities related to the Contingent Consideration and the Private Placement Warrants. Accounting Standards Codification 815, Derivatives and Hedging ("ASC 815"), provides for the remeasurement of the fair value of such derivatives at each balance sheet date, with a resulting non-cash gain or loss related to the change in the fair value being recognized in earnings in the statement of operations. As a result of the recurring fair value measurement, our financial statements and results of operations may fluctuate quarterly, based on factors which are outside of our control. Due to the recurring fair value measurement, we expect that we will recognize non-cash gains or losses on the Contingent Consideration and the Private Placement Warrants each reporting period and that the amount of such gains or losses could be material.

Prior to the Merger, on April 12, 2021, the Acting Director of the Division of Corporation Finance and Acting Chief Accountant of the SEC together issued a statement regarding the accounting and reporting considerations for warrants issued by special purpose acquisition companies entitled "Staff Statement on Accounting and Reporting Considerations for Warrants Issued by Special Purpose Acquisition Companies ("SPACs")" (the "SEC Statement"). Specifically, the SEC Statement focused on certain settlement terms and provisions related to certain tender offers following a business combination, which terms are similar to those contained in the Public Warrants. As a result of the SEC Statement, prior to the Merger, AHAC reevaluated the accounting treatment of the Public Warrants and determined to classify the Public Warrants as derivative liabilities measured at fair value, with changes in fair value each period reported in earnings. As a result, included on AHAC's balance sheet as of December 31, 2020 are derivative liabilities related to embedded features contained within the Public Warrants.

In connection with its Amended Annual Report on Form 10-K/A for the year ended December 31, 2020, AHAC reached a determination to restate certain previously issued financial statements and related disclosures for the periods disclosed in order to correct the accounting treatment for the Warrants following the publication of the SEC Statement. As a result, prior to the Merger, AHAC incurred unanticipated costs for accounting and legal fees in connection with or related to the restatement, and we may become subject to additional risks and uncertainties related to the restatement.

AHAC restated certain previously issued financial statements and related disclosures for the periods disclosed, and as of September 30, 2021, our management concluded that the conditions causing the material weakness that led to these restatements did not exist. However, in the future, we may determine that we have additional material weaknesses. Our failure to remediate any material weaknesses or failure to identify and address any material weaknesses or control deficiencies could result in inaccuracies in our financial statements and could also impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis, which could cause investors to lose confidence in our reported financial information, which may result in volatility in and a decline in the market price of our common stock.

***Our business could be adversely impacted by inflation.***

Increases in inflation may have an adverse effect on our business. Current and future inflationary effects may be driven by, among other things, supply chain disruptions and governmental stimulus or fiscal policies. Continuing increases in inflation could impact the overall demand for our products, our costs for labor, material and services, and the margins we are able to realize on our products, all of which could have an adverse impact on our business, financial position, results of operations and cash flows. Inflation may also result in higher interest rates, which in turn would result in higher interest

expense related to our variable rate indebtedness and any borrowings we undertake to refinance existing fixed rate indebtedness.

***We may be required to take write-downs or write-offs, restructuring and impairment or other charges that could have a significant negative effect on our financial condition, results of operations and stock price, which could cause you to lose some or all of your investment.***

We may be forced to write-down or write-off assets, restructure our operations, or incur impairment or other charges that could result in losses. Even though these charges may be non-cash items and may not have an immediate impact on our liquidity, the fact that we may report charges of this nature could contribute to negative market perceptions about our securities. In addition, charges of this nature may cause us to be unable to obtain future financing on favorable terms or at all. Accordingly, a stockholder could suffer a reduction in the value of their shares.

***The obligations associated with being a public company involve significant expenses and will require significant resources and management attention, which may divert from our business operations.***

As a public company, we are subject to the reporting requirements of the Exchange Act and the Sarbanes-Oxley Act. The Exchange Act requires the filing of annual, quarterly and current reports with respect to a public company's business and financial condition. The Sarbanes-Oxley Act requires, among other things, that a public company establish and maintain effective internal control over financial reporting. As a result, we will incur significant legal, accounting and other expenses that we did not incur as a private company. Our entire management team and many of its other employees will need to devote substantial time to compliance, and may not effectively or efficiently manage our transition into a public company.

These rules and regulations will result in our incurring substantial legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations have made it more difficult and more expensive for Humacyte to obtain director and officer liability insurance, and it has accepted reduced coverage. As a result, it may be difficult for us to attract and retain qualified people to serve on the Board or committees of the Board or as executive officers.

***We are an "emerging growth company" and a "smaller reporting company" within the meaning of the rules adopted by the SEC, and if we take advantage of certain exemptions from disclosure requirements available to emerging growth companies and smaller reporting companies, this could make our securities less attractive to investors and may make it more difficult to compare our performance with other public companies.***

We are an emerging growth company as defined in the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, our stockholders may not have access to certain information they may deem important. We could be an emerging growth company for up to five years from the closing of AHAC's initial public offering, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds \$700 million as of any June 30 before that time, in which case we would no longer be an emerging growth company as of the following December 31. We cannot predict whether investors will find our securities less attractive because we will rely on these exemptions. If some investors find our securities less attractive as a result of our reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be, there may be a less active trading market for our securities and the trading prices of our securities may be more volatile.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that an emerging growth company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies, but any such an election to opt out is irrevocable. We have elected not to opt out of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our financial statements with another public

company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Additionally, we are a “smaller reporting company” as defined under the Exchange Act. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company for so long as (1) the market value of our common stock held by non-affiliates is less than \$250 million as of the last business day of the second fiscal quarter, or (2) our annual revenues in our most recent fiscal year completed before the last business day of our second fiscal quarter are less than \$100 million and the market value of our common stock held by non-affiliates is less than \$700 million as of the last business day of the second fiscal quarter. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.***

Effective internal control over financial reporting is necessary for us to provide reliable financial reports. Any failure to implement new or improved controls necessary to maintain effective internal control over financial reporting, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations.

In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or our independent registered public accounting firm, may identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company’s annual or interim financial statements will not be prevented or detected on a timely basis.

Ineffective internal control over financial reporting could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. In connection with its Amended Annual Report on Form 10-K/A for the year ended December 31, 2020, AHAC reached a determination to restate certain previously issued financial statements and related disclosures for the periods disclosed in order to correct the accounting treatment for the Warrants following the publication of the SEC Statement.

Our assessment is that, after the Merger, we have a sufficiently staffed and technically experienced finance and accounting team to address the financial reporting requirements of a public company. Because the conditions causing the material weakness no longer existed, and are not expected to exist in the foreseeable future, we determined the material weakness did not exist in internal control over financial reporting as of September 30, 2021. Prior to the Merger, AHAC’s management concluded that its disclosure controls and procedures were not effective as of December 31, 2020, and that its internal control over financial reporting was not effective as of December 31, 2020, as a result of a material weakness in controls related to the accounting for the Warrants. As a result, AHAC incurred unanticipated costs for accounting and legal fees in connection with or related to the restatement, and we may become subject to additional risks and uncertainties related to the restatement, such as a negative impact on investor confidence in the accuracy of our financial disclosures, and may face reputational risks for our business. Effective as of the closing of the Merger, our management is responsible for internal control over financial reporting and the former management of AHAC no longer participates in financial reporting.

As long as we are an emerging growth company under the JOBS Act or a non-accelerated filer and a “smaller reporting company” as defined in Rule 12b-2 of the Exchange Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. An independent assessment of the effectiveness of our internal control over financial reporting could detect deficiencies that our management’s assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

***Anti-takeover provisions in our Second Amended and Restated Certificate of Incorporation and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult, and may prevent attempts by our stockholders to replace or remove our current management.***

Our Second Amended and Restated Certificate of Incorporation (the “Charter”) contains provisions that may delay or prevent an acquisition of the company or change in our management. These provisions may make it more difficult for stockholders to replace or remove members of the Board. Because the Board is responsible for appointing the members of the management team, these provisions could in turn frustrate or prevent any attempt by our stockholders to replace or

remove our current management. In addition, these provisions could limit the price that investors might be willing to pay in the future for shares of our common stock. Among other things, these provisions include:

- the limitation of the liability of, and the indemnification of, our directors and officers;
- provisions that permit only (i) the chairperson of the Board, (ii) our chief executive officer or (iii) a majority of our Board to call special meetings of stockholders and therefore do not permit our stockholders to call stockholder meetings;
- a prohibition on actions by our stockholders by written consent; and
- the ability of the Board to issue preferred stock without stockholder approval.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the “DGCL”), which prohibits a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15% or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This could discourage, delay or prevent a third party from acquiring or merging with us, whether or not it is desired by, or beneficial to, our stockholders. This could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in our stockholders’ best interests. Finally, these provisions establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings. These provisions would apply even if the offer may be considered beneficial by some stockholders.

*Our Charter provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware and the federal district courts of the United States of America are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.*

Our Charter provides that the Court of Chancery of the State of Delaware will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our Charter or our amended and restated bylaws (the “Bylaws”);
- any action or proceeding asserting a claim as to which the DGCL confers jurisdiction upon the Court of Chancery of the State of Delaware; and
- any action asserting a claim against us that is governed by the internal affairs doctrine or otherwise related to our internal affairs.

This exclusive forum provision may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims. We cannot be certain that a court will decide that this provision is either applicable or enforceable, and if a court were to find the choice of forum provision contained in our Charter to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

This exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. In addition, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act or the rules and regulations promulgated thereunder.

**Item 1B. Unresolved Staff Comments.**

None.

**Item 2. Properties.**

Our corporate headquarters, manufacturing, and research and development facilities are located in Durham, North Carolina where we lease approximately 83,000 square feet of space. This space includes approximately 55,000 square feet for production and distribution operations including manufacturing, bioprocessing, quality control, mechanical space and inventory. The remainder of the facility consists of offices, laboratories, and common spaces.

**Item 3. Legal Proceedings**

The Company currently is not aware of any legal proceedings or claims that management believes will have, individually or in the aggregate, a material adverse effect on the Company's business, financial condition, results of operations, or cash flows.

**Item 4. Mine Safety Disclosures.**

None.

## Part II

### Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

#### Market Information

Our common stock is currently listed on The Nasdaq Global Select Market under the symbol “HUMA.” Prior to the consummation of the Merger, our common stock was listed on The Nasdaq Global Select Market under the symbol “AHAC.” As of February 28, 2022, there were 188 holders of record of our common stock.

#### Dividend Policy

We have never declared or paid any dividends on shares of our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. We are currently not permitted to pay cash dividends under the Loan Agreement with Silicon Valley Bank and SVB Innovation Credit Fund VIII, L.P. Any decision to declare and pay dividends in the future will be made at the sole discretion of our Board will depend on, among other things, our results of operations, cash requirements, financial condition, contractual restrictions and other factors that our board of directors may deem relevant.

#### Item 6. [Reserved]

### Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations

*You should read the following discussion and analysis of our financial condition and results of operations together with our accompanying consolidated financial statements and the related notes contained in Part II, Item 8 of this Annual Report on Form 10-K. Unless the context indicates otherwise, references in this Annual Report on Form 10-K to the “Company,” “Humacyte,” “we,” “us,” “our” and similar terms refer to Humacyte, Inc. (formerly known as Alpha Healthcare Acquisition Corp.) and its consolidated subsidiaries (including Humacyte Global, Inc.) following the Company’s merger with Alpha Healthcare Acquisition Corp (the “Merger”); references to “Legacy Humacyte” refer to Humacyte, Inc. prior to the Merger; and references to “AHAC” refer to Alpha Healthcare Acquisition Corp. prior to the Merger.*

#### Cautionary Statement Regarding Forward-Looking Statements

In addition to historical information, some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, future financial performance, expense levels and liquidity sources, includes forward-looking statements that involve risks and uncertainties. You should read the sections of this Annual Report on Form 10-K entitled “Forward-Looking Statements” and “Risk Factors” for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

#### Overview

We are pioneering the development and manufacture of off-the-shelf, universally implantable, bioengineered human tissues with the goal of improving the lives of patients and transforming the practice of medicine. We believe our technology has the potential to overcome limitations in existing standards of care and address the lack of significant innovation in products that support tissue repair, reconstruction and replacement. We are leveraging our novel, scalable technology platform to develop proprietary, bioengineered, acellular human tissues for use in the treatment of diseases and conditions across a range of anatomic locations in multiple therapeutic areas.

We are initially using our proprietary, scientific technology platform to engineer and manufacture Human Acellular Vessels (“HAVs”). Our investigational HAVs are designed to be easily implanted into any patient without inducing a foreign body response or leading to immune rejection. We are developing a portfolio, or “cabinet”, of HAVs with varying diameters and lengths. The HAV cabinet would initially target the vascular repair, reconstruction and replacement market, including vascular trauma; AV access for hemodialysis; PAD; and CABG. In addition, we are developing our HAVs for pediatric heart surgery and the delivery of cellular therapies, including pancreatic islet cell transplantation to treat Type 1 diabetes. We will continue to explore the application of our technology across a broad range of markets and indications, including the development of urinary conduit, trachea, esophagus and other novel cell delivery systems.

We believe there is substantial clinical demand for safe and effective vascular conduits to replace and repair blood vessels throughout the body. Vascular injuries resulting from trauma are common in civilian and military populations, frequently resulting in the loss of either life or limb. Existing treatment options in the vascular repair, reconstruction and replacement market include the use of autologous vessels and synthetic grafts, which we believe suffer from significant limitations. For example, the use of autologous veins to repair traumatic vascular injuries can lead to significant morbidity associated with the surgical wounds created for vein harvest and prolonged times to restore blood flow to injured limbs leading to an increased risk of amputation and infection. Synthetic grafts are often contraindicated in the setting of vascular trauma due to higher infection risk that can lead to prolonged hospitalization and limb loss. Given the competitive advantages our HAVs are designed to have over existing vascular substitutes, we believe that HAVs have the potential to become the standard of care and lead to improved patient outcomes and lower healthcare costs.

We have generated no product revenue and incurred net losses and negative cash flows from operations in each year since our inception in 2004. As of December 31, 2021 and 2020, we had an accumulated deficit of \$414.6 million and \$388.1 million, respectively, and working capital of \$218.3 million and \$30.2 million, respectively. Our net losses were approximately \$26.5 million and \$66.5 million for the years ended December 31, 2021 and 2020, respectively. Net cash flows used in operating activities were \$81.2 million and \$55.6 million during the years ended December 31, 2021 and 2020, respectively. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to incur substantial operating losses and negative cash flows from operations for the foreseeable future as we advance our product candidates.

As of December 31, 2021, we had cash and cash equivalents and short-term investments of \$225.5 million. We believe our cash and cash equivalents and short-term investments on hand will be sufficient to fund operations, including clinical trial expenses and capital expenditure requirements for at least the next 12 months from the date of this Annual Report on Form 10-K. See Note 1 — Organization and Description of Business in the notes to our accompanying consolidated financial statements contained in Part II, Item 8 of this Annual Report on Form 10-K for additional information regarding this assessment.

Our need for additional capital will depend in part on the scope and costs of our development and commercial manufacturing activities. To date, we have not generated any revenue from the sale of commercialized products. Our ability to generate product revenue will depend on the successful development and eventual commercialization of one or more of our product candidates. Until such time, if ever, we expect to finance our operations through the use of existing cash and cash equivalents and short-term investments, sale of equity or debt, borrowings under credit facilities, or through potential collaborations, other strategic transactions or government and other grants. Adequate capital may not be available to us when needed or on acceptable terms. If we are unable to raise capital, we could be forced to delay, reduce, suspend or cease our research and development programs or any future commercialization efforts, which would have a negative impact on our business, prospects, operating results and financial condition. See “Risk Factors” for additional information.

We expect to continue to incur significant expenses and to increase operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we seek to:

- obtain marketing approval for our 6 millimeter HAV for vascular repair, reconstruction and replacement, including for vascular trauma and AV access for hemodialysis;
- commercialize the HAV via U.S. market launches in vascular trauma and hemodialysis AV access;
- scale out our manufacturing facility to the extent required to satisfy potential demand following any receipt of marketing approval;
- continue our preclinical and clinical development efforts;
- maintain, expand and protect our intellectual property portfolio;
- add operational, financial and management information systems and personnel to support, among other things, our product development and commercialization efforts and operations; and
- operate as a public company, which includes higher costs associated with hiring additional personnel, director and officer insurance premiums, audit and legal fees, investor relations fees and expenses for compliance with public company reporting requirements under the Exchange Act and rules implemented by the SEC and The Nasdaq Stock Market LLC (“Nasdaq”).

## Recent Developments

### *Closing of Merger*

On August 26, 2021 (the “Closing Date”), Legacy Humacyte and AHAC consummated a merger pursuant to that certain Business Combination Agreement, dated as of February 17, 2021 (the “Merger Agreement”), by and among Legacy Humacyte, AHAC and Hunter Merger Sub, Inc. (“Merger Sub”). As contemplated by the Merger Agreement, Merger Sub merged with and into Legacy Humacyte, with Legacy Humacyte continuing as the surviving corporation and as a wholly owned subsidiary of AHAC (the “Merger”). As a result of the Merger, AHAC was renamed Humacyte, Inc. and Legacy Humacyte was renamed Humacyte Global, Inc. Operations prior to the Merger included in this Annual Report on Form 10-K are those of Legacy Humacyte.

Pursuant to the terms of the Merger Agreement, at the effective time of the Merger (the “Effective Time”), (1) each outstanding share of common stock of Legacy Humacyte (“Legacy Humacyte common stock”) was cancelled and converted into the right to receive approximately 0.26260 shares of the Company’s common stock, par value \$0.0001 per share (“Common Stock”), and (2) each outstanding share of preferred stock of Legacy Humacyte (“Legacy Humacyte preferred stock”) was cancelled and converted into the aggregate number of shares of Common Stock that would be issued upon conversion of the shares of Legacy Humacyte preferred stock based on the applicable conversion ratio immediately prior to the Effective Time, multiplied by approximately 0.26260, resulting in the issuance of a total of 75,656,935 shares of Common Stock. Prior holders of shares of Legacy Humacyte common stock and Legacy Humacyte preferred stock also received the contingent right to receive certain Contingent Earnout Shares (as defined below), for each share owned by each such Legacy Humacyte stockholder that was outstanding immediately prior to the closing of the Merger (the “Closing”). In addition, certain investors purchased an aggregate of 17,500,000 shares of Common Stock (such investors, the “PIPE Investors”) in a private placement that closed concurrently with the Closing for an aggregate purchase price of \$175 million (the “PIPE Financing”). Additionally, at the Closing, 2,500,000 shares of AHAC’s Class B common stock (“Founder Shares”) automatically converted into shares of Common Stock on a one-for-one basis.

Pursuant to the terms of the Merger Agreement, at the Effective Time of the Merger, (1) warrants to purchase shares of Legacy Humacyte common stock were converted into warrants to purchase an aggregate of 287,704 shares of Common Stock, and (2) options to purchase shares of Legacy Humacyte common stock were converted into options to purchase an aggregate of 6,405,138 shares of Common Stock.

Following the Closing Date, former holders of Legacy Humacyte common stock and Legacy Humacyte preferred stock may receive up to 15,000,000 additional shares of Common Stock (“Contingent Earnout Shares”) in the aggregate in two equal tranches if the volume-weighted average closing sale price of our Common Stock is greater than or equal to \$15.00 and \$20.00, respectively, for any 20 trading days within any 30 consecutive trading day period.

Unless otherwise noted, the Company has retroactively adjusted all common and preferred share and related price information to give effect to the Exchange Ratio established in the Merger Agreement.

### *Impact of COVID-19*

The COVID-19 pandemic, which began in December 2019 and has spread worldwide, has caused many governments to implement measures to slow the spread of the outbreak, including shelter-in-place orders and the mandatory shutdown of certain businesses. The outbreak and government measures taken in response have had a significant impact, both direct and indirect, on our business, as supply chains have been disrupted, and facilities and production have been suspended. The future progression of the COVID-19 pandemic, including any existing or potential variants of the virus which causes COVID-19, and its effects on our business and operations are uncertain. The COVID-19 pandemic may affect our ability to initiate and complete preclinical studies, delay our clinical trials or future clinical trials, disrupt regulatory activities, or have other adverse effects on our business and operations. The pandemic has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, which could impact our ability to raise additional funds to support our operations. Moreover, the pandemic has significantly impacted economies worldwide and could result in adverse effects on our business and operations.

To date, the COVID-19 pandemic has not resulted in material financial impacts or impairment losses in the carrying values of our assets and we are not aware of any specific related event or circumstance that would require us to revise the estimates reflected in our financial statements. The extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, including current and future clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new



information that may emerge concerning COVID-19, the actions taken to contain or treat it, and the duration and intensity of the related economic impact of the COVID-19 pandemic.

## **Components of Results of Operations**

### *Revenue*

To date, we have not generated revenue from the sale of any products. All of our revenue has been derived from government and other grants. Since inception we have been awarded grants from the California Institute of Regenerative Medicine (“CIRM”), NIH, and the DoD, to support our development, production scaling and clinical trials of our product candidates. We may generate revenue in the future from government and other grants, payments from future license or collaboration agreements and, if any of our product candidates receive marketing approval, from product sales. We expect that any revenue we generate will fluctuate from quarter to quarter. If we fail to complete the development of, or obtain marketing approval for, our product candidates in a timely manner, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

### *Research and Development Expenses*

Since our inception, we have focused our resources on our research and development activities, including conducting preclinical studies and clinical trials, developing our manufacturing process and activities related to regulatory filings for our product candidates. We recognize research and development expenses as they are incurred. Our research and development expenses consist primarily of:

- salaries and related overhead expenses for personnel in research and development functions, including stock-based compensation and benefits;
- fees paid to consultants and CROs, including in connection with our clinical trials, and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work and statistical compilation and analysis;
- allocation of facility lease and maintenance costs;
- depreciation of leasehold improvements, laboratory equipment and computers;
- costs related to purchasing raw materials for and producing our product candidates for clinical trials;
- costs related to compliance with regulatory requirements;
- costs related to our manufacturing development and expanded-capabilities initiatives; and
- license fees related to in-licensed technologies.

The majority of our research and development resources are currently focused on our Phase III clinical trials for our 6 millimeter HAV and other work needed to obtain marketing approval for our 6 millimeter HAV for use for vascular repair, reconstruction and replacement, including vascular trauma and AV access in hemodialysis in the United States and Europe. We have incurred and expect to continue to incur significant expenses in connection with these and our other clinical development efforts, including expenses related to regulatory filings, trial enrollment and conduct, data analysis, patient follow up and study report generation for our Phase II and Phase III clinical trials. We do not allocate all of our costs by each research and development program for which we are developing our cabinet of HAVs, as a significant amount of our development activities broadly support multiple programs that use our technology platform. We plan to further increase our research and development expenses for the foreseeable future as we continue the development of our proprietary scientific technology platform and our novel manufacturing paradigm.

The successful development of our preclinical and clinical product candidates is highly uncertain. At this time, we cannot estimate with any reasonable certainty the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of any of our preclinical or clinical product candidates or the period, if any, in which material net cash inflows from these product candidates may commence. This is due to the numerous risks and uncertainties associated with the development of our product candidates, including:

- the scope, rate of progress, expense and results of our preclinical development activities, our ongoing clinical trials and any additional clinical trials that we may conduct, and other research and development activities;

- successful patient enrollment in and the initiation and completion of clinical trials;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities including the FDA and non-U.S. regulators;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- development of clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that it or its third-party manufacturers are able to successfully manufacture our product;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulations;
- launching commercial sales of our product candidates, if approved, whether alone or in collaboration with others;
- the degree of market acceptance of any product candidates that obtain marketing approval; and
- maintaining a continued acceptable safety profile following approval, if any, of our product candidates.

A change in the outcome of any of these variables could lead to significant changes in the costs and timing associated with the development of our product candidates. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate being required to conduct in order to complete the clinical development of any of our product candidates, or if we experience significant delays in the enrollment or the conduct of any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

#### *General and Administrative Expenses*

General and administrative expenses consist primarily of salaries and related costs for employees in executive, finance, human resources, commercialization, and administrative support functions, which also include stock-based compensation expenses and benefits for such employees. Other significant general and administrative expenses include facilities costs, professional fees for accounting and legal services and expenses associated with obtaining and maintaining patents.

We expect our general and administrative expenses will increase for the foreseeable future to support our expanded infrastructure and increased costs of operating as a public company. These increases are expected to include increased employee-related expenses and increased director and officer insurance premiums, audit and legal fees, investor relations fees and expenses for compliance with public company reporting requirements under the Exchange Act and rules implemented by the SEC, as well as Nasdaq rules.

#### *Other Income (Expenses), Net*

Total other income (expenses), net consists of (i) the change in fair value of the contingent earnout liability that was accounted for as a liability as of the date of the Merger, and is remeasured to fair value at each reporting period, resulting in a non-cash gain or loss, (ii) a gain on Paycheck Protection Program (“PPP”) loan forgiveness, (iii) a change in fair value of private placement common stock warrant liabilities related to the Private Placement Warrants, which we assumed in connection with the Merger, and which are subject to remeasurement to fair value at each balance sheet date resulting in a non-cash gain or loss, (iv) interest income earned on our cash and cash equivalents and short-term investments, (v) interest expense incurred on the Loan Agreement, finance leases, and our PPP loan during the periods each were outstanding, and (vi) legal, accounting, and investment banking fees and other costs directly related to the consummation of the Merger that were associated with the aforementioned warrant liabilities. See Note 8 to our accompanying consolidated financial statements contained in Part II, Item 8 of this Annual Report on Form 10-K for a description of the leases.

## Results of Operations

Comparison of the Years Ended December 31, 2021 and 2020

(\$ in thousands)	Year Ended December 31,		Change	
	2021	2020	\$	%
<b>Revenue</b>	\$ 1,263	\$ 1,491	\$ (228)	(15)%
<b>Operating expenses:</b>				
Research and development	61,341	54,078	7,263	13 %
General and administrative	21,130	12,013	9,117	76 %
Total operating expenses	82,471	66,091	16,380	25 %
<b>Loss from operations</b>	<b>(81,208)</b>	<b>(64,600)</b>	<b>(16,608)</b>	26 %
Other income (expenses), net:				
Change in fair value of contingent earnout liability	55,772	—	55,772	100 %
Gain on PPP loan forgiveness	3,284	—	3,284	100 %
Interest expense	(4,348)	(2,202)	(2,146)	97 %
Other income, net	23	278	(255)	(92)%
Total other income (expenses), net	54,731	(1,924)	56,655	*
<b>Net loss</b>	<b>\$ (26,477)</b>	<b>\$ (66,524)</b>	<b>\$ 40,047</b>	(60)%

\* Not meaningful

### Grant Revenue

For the years ended December 31, 2021 and 2020, we generated \$1.3 million and \$1.5 million of revenue, respectively, related to the reimbursement of qualifying expenses incurred in connection with our grants from DoD and NIH. The decrease in revenue of \$0.2 million, or 15%, was primarily driven by \$0.3 million of revenue recognized during 2020 related to our grant from NIH before the program ended in 2020, partially offset by \$0.1 million related to the timing of reimbursement of certain allowable costs related to our grant from DoD in 2021 as compared to 2020.

### Research and Development Expenses

The following table discloses the breakdown of research and development expenses:

(\$ in thousands)	Year Ended December 31,		Change	
	2021	2020	\$	%
External services	\$ 15,786	\$ 14,675	\$ 1,111	8 %
Lab supplies	10,901	9,769	1,132	12 %
Payroll and personnel expenses	23,227	17,885	5,342	30 %
Other research and development expenses	11,427	11,749	(322)	(3) %
	<b>\$ 61,341</b>	<b>\$ 54,078</b>	<b>\$ 7,263</b>	<b>13 %</b>

Research and development expenses increased from \$54.1 million for the year ended December 31, 2020 to \$61.3 million for the year ended December 31, 2021. The increase of \$7.3 million, or 13%, was primarily driven by a \$5.3 million increase in payroll and personnel expenses to support our expanding research and development initiatives, including a \$3.2 million increase in salaries and benefits and a \$2.1 million increase in non-cash stock compensation expense. Other components of the current-year increase included a \$1.1 million increase in external services and a \$1.1 million increase in the purchase of lab supplies to be used in the development of our commercial-scale manufacturing process and other research and development initiatives, including the support of clinical studies.

### General and Administrative Expenses

General and administrative expenses were \$21.1 million and \$12.0 million for the years ended December 31, 2021 and 2020, respectively. The increase in general and administrative expenses during this period of \$9.1 million, or 76%, was driven by (i) increases in non-cash stock compensation expense of \$3.4 million primarily related to stock option grants associated with the appointment of our Chief Executive Officer in November 2020 and our Chief Financial Officer in May

2021, (ii) professional fees of \$2.2 million related to the completion of the PIPE Financing and the Merger, (iii) \$1.3 million in salaries and benefits and \$0.7 million in recruiting costs primarily due to headcount added during 2021 and (iv) \$0.6 million in insurance costs driven by the purchase of directors and officers insurance in 2021 related to the transition to being a public company.

*Total Other Income (Expenses)*

Total other income (expenses) was \$54.7 million and \$(1.9) million for the years ended December 31, 2021 and 2020, respectively. The increase of \$56.7 million in income resulted from a \$55.8 million non-cash gain related to the remeasurement of the contingent earnout liability as of December 31, 2021 and a \$3.3 million gain on PPP loan forgiveness, partially offset by a \$2.1 million increase in interest expense related to our loan facility with Silicon Valley Bank which commenced in March 2021.

**Liquidity and Capital Resources**

*Sources of Liquidity*

To date, we have financed our operations primarily through the sale of equity securities and convertible debt, proceeds from the Merger and related PIPE Financing, borrowings under loan facilities and, to a lesser extent, through grants from governmental and other agencies. Since our inception, we have incurred significant operating losses and negative cash flows. As of December 31, 2021 and 2020, we had an accumulated deficit of \$414.6 million and \$388.1 million, respectively.

As of December 31, 2021 and 2020, we had cash and cash equivalents and short-term investments of \$225.5 million and \$39.9 million, respectively. We believe our cash and cash equivalents and short-term investments will be sufficient to fund operations, including clinical trial expenses and capital expenditure requirements for at least 12 months from the date of this Annual Report on Form 10-K. See Note 1 to our accompanying consolidated financial statements contained in Part II, Item 8 of this Annual Report on Form 10-K for additional information on our assessment. We believe that our longer-term working capital, planned research and development, capital expenditures and other general corporate funding requirements will be satisfied through the sale of equity, debt, borrowings under credit facilities or through potential collaborations with other companies, other strategic transactions or government or other grants. Our liquidity plans are subject to a number of risks and uncertainties, including those described in the sections entitled “Forward-Looking Statements” and “Risk Factors.”

As of December 31, 2021 and 2020, we had working capital of \$218.3 million and \$30.2 million, respectively. As of December 31, 2021, we have \$30.0 million outstanding principal and \$20.0 million of contingent borrowing capacity under our Loan Agreement as defined below. We do not currently have any committed external source of funds beyond the Loan Agreement.

*Material Cash Requirements*

Our known material cash requirements include: (1) the purchase of supplies and services that are primarily for research and development; (2) debt repayments (for additional information, see below and Note 7 to our accompanying consolidated financial statements contained in Part II, Item 8 of this Annual Report on Form 10-K); (3) employee wages, benefits, and incentives; and (4) financing and operating lease payments (for additional information see below and Note 8 to our accompanying consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K). We have also entered into contracts with CROs primarily for clinical trials. These contracts generally provide for termination upon limited notice, and therefore we believe that our non-cancellable obligations under these agreements are not material. Moreover, we may be subject to additional material cash requirements that are contingent upon the occurrence of certain events, e.g., legal contingencies, uncertain tax positions, and other matters.

As of December 31, 2021, we had non-cancellable purchase commitments of \$12.8 million for supplies and services that are primarily for research and development. We have entered into license agreements with Duke University and Yale University and have a distribution agreement with Fresenius Medical Care Holdings, Inc. The amount and timing of any potential milestone payments, license fee payments, royalties and other payments that we may be required to make under these agreements are unknown or uncertain at December 31, 2021. For additional information regarding these agreements and the nature of payments that could become due thereunder, see “Business — Distribution” and “Business — Intellectual Property,” included elsewhere in this Annual Report on Form 10-K.

## Debt

In April 2020, we received loan proceeds in the amount of approximately \$3.3 million under the PPP established under the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”). The loan and accrued interest were forgivable after a 24-week period as long as we used the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities, and maintained its payroll levels. On May 25, 2021, the Small Business Administration approved the forgiveness of the outstanding amount of the PPP loan and we recognized a gain from loan extinguishment in the amount of \$3.3 million during the year ended December 31, 2021.

In March 2021, we entered into the Loan Agreement with Silicon Valley Bank and SVB Innovation Credit Fund VIII, L.P., as amended in June and September 2021, which provides a term loan facility of up to \$50.0 million, with a maturity date of March 1, 2025. The initial term loan tranche of \$20.0 million was funded upon the closing of the Loan Agreement, and on October 13, 2021, we borrowed an additional \$10.0 million under the Loan Agreement. The additional \$20.0 million becomes accessible in two tranches of \$10.0 million each contingent on the achievement of certain business and clinical development milestones. As a result of the additional borrowing in October 2021, the commencement of repayment of principal was deferred until no earlier than July 2023 and potentially later if the remaining tranches are drawn. As of December 31, 2021, principal of \$30.0 million was outstanding under the Loan Agreement and we were in compliance with all covenants in all material respects. Assuming no additional borrowings under the Loan Agreement, we expect to make interest payments of approximately \$5.5 million under the Loan Agreement from January 1, 2022 through March 1, 2025, approximately \$2.3 million of which we expect to pay during the year ended December 31, 2022.

Our obligations under the Loan Agreement are secured by substantially all of our assets, except for our intellectual property. The Loan Agreement contains certain customary covenants, including, but not limited to, those relating to additional indebtedness, liens, asset divestitures, and affiliate transactions. We may use the proceeds of borrowings under the Loan Agreement as working capital and to fund our general business requirements.

Borrowings under the Loan Agreement bear interest at a rate of 7.5% or the sum of the Wall Street Journal Prime Rate plus 4.25%, whichever is greater. In addition, the lenders were granted warrants to purchase common stock. Interest-only payments on the principal amount outstanding are due monthly beginning in the first month after the loan is dispersed. We are required to repay principal beginning on July 1, 2023, unless we draw the remaining two loan tranches, in which case repayment of the outstanding principal amount will begin no later than April 1, 2024. Additionally, we are obligated to pay to the lenders a final payment fee of \$1.5 million upon the maturity of the loan.

Our contractual obligations under the Loan Agreement as of December 31, 2021, include no cash payments related to principal within one year, \$27.1 million within one to three years, and \$2.9 million within three to five years.

## Leases

Our finance lease relates to our headquarters facility containing our manufacturing, research and development and general and administrative functions, which was substantially completed in June 2018 and leased through May 2033, and our operating lease relates to the land lease associated with our headquarters. See Note 8 to our accompanying consolidated financial statements contained in Part II, Item 8 of this Annual Report on Form 10-K for further information regarding our leases. Our future contractual obligations under our lease agreements as of December 31, 2021 are as follows:

(\$ in thousands)	Total	Less than 1 year	1 – 3 years	3 – 5 years	More than 5 years
Finance leases	\$ 33,001	\$ 3,868	\$ 8,030	\$ 8,404	\$ 12,699
Operating leases	1,099	105	210	210	574

## Future Funding Requirements

We expect to incur significant expenses in connection with our ongoing activities as we seek to (i) continue clinical development of our 6 millimeter HAV for use in vascular trauma and dialysis AV access and submit biologics license applications for FDA approval, (ii) if marketing approval is obtained, to launch and commercialize our HAVs for dialysis AV access and vascular repair in the U.S. market, including subsequent launches in key international markets, (iii) advance our pipeline in major markets, including PAD Phase III trials and continue preclinical development and advance to planned clinical studies in CABG and biovascular pancreas for diabetes, and (iv) scale out our manufacturing facility as required to satisfy potential demand if our HAVs receive marketing approval. We will need additional funding in connection with these activities.

Our future funding requirements, both short-term and long-term, will depend on many factors, including:

- the progress and results of our clinical trials and interpretation of those results by the FDA and other regulatory authorities;
- the cost, timing and outcome of regulatory review of our product candidates, particularly for marketing approval of our HAVs in the United States;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our additional product candidates;
- the cost and timing of our future commercialization activities, including product manufacturing, marketing and distribution for our HAVs if approved by the FDA, and any other product candidate for which we receive marketing approval in the future;
- the amount and timing of revenues, if any, that we receive from commercial sales of any product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the costs of operating as a public company, including hiring additional personnel as well as increased director and officer insurance premiums, audit and legal fees, investor relations fees and expenses for compliance with public company reporting requirements under the Exchange Act and rules implemented by the SEC and Nasdaq.

Until such time, if ever, as we are able to successfully develop and commercialize one or more of our product candidates, we expect to continue financing our operations through the sale of equity, debt, borrowings under credit facilities or through potential collaborations with other companies, other strategic transactions or government or other grants. Adequate capital may not be available to us when needed or on acceptable terms. We do not currently have any committed external source of funds beyond the Loan Agreement. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures. Debt financing would also result in fixed payment obligations. If we are unable to raise capital, we could be forced to delay, reduce, suspend or cease our research and development programs or any future commercialization efforts, which would have a negative impact on our business, prospects, operating results and financial condition.

Humacyte's principal use of cash in recent periods has been primarily to fund its operations, including the clinical and preclinical development of its product candidates. Humacyte's future capital requirements, both short-term and long-term, will depend on many factors, including the progress and results of our clinical trials and preclinical development, timing and extent of spending to support development efforts, cost and timing of future commercialization activities, and the amount and timing of revenues, if any, that we receive from commercial sales. See "Risk Factors" for additional risks associated with our substantial capital requirements.

*Cash Flows*

The following table shows a summary of our cash flows for each of the periods shown below:

(\$ in thousands)	Year Ended December 31,	
	2021	2020
Net loss	\$ (26,477)	\$ (66,524)
Non-cash adjustments to reconcile net loss to net cash used in operating activities <sup>(1)</sup> :	(39,695)	13,325
Payment of liabilities assumed in Merger	(14,461)	—
Changes in operating assets and liabilities:	(557)	(2,369)
Net cash used in operating activities	(81,190)	(55,568)
Net cash used in investing activities	(8,220)	(268)
Net cash provided by financing activities	266,983	2,052
Net increase (decrease) in cash and cash equivalents	\$ 177,573	\$ (53,784)
Cash and cash equivalents at the beginning of the period	\$ 39,929	\$ 93,713
Cash and cash equivalents at the end of the period	\$ 217,502	\$ 39,929

<sup>(1)</sup> Includes depreciation, amortization related to our leases and our debt discount, stock-based compensation expense, and in 2021 includes the change in fair value of our contingent earnout liability and our common stock warrant liabilities and a gain on PPP loan forgiveness.

*Cash Flow from Operating Activities*

The increase in net cash used in operating activities from 2020 to 2021 was primarily due to \$14.5 million in payments of liabilities acquired in the Merger as well as increased payroll and personnel expenses and spending on pre-clinical, clinical and pre-commercial activities.

*Cash Flow from Investing Activities*

The increase in net cash used in investing activities from 2020 to 2021 was primarily due to our \$8.0 million investment in certificates of deposit classified as short-term investments on our consolidated balance sheet.

*Cash Flow from Financing Activities*

The increase in net cash provided by financing activities was primarily due to \$242.4 million of proceeds in connection with the Merger, including proceeds from the trust account that we obtained in connection with the closing of the Merger, as well as from the PIPE Financing. We also received \$29.7 million of net proceeds in connection with draws under our loan facility with Silicon Valley Bank.

*Off-Balance Sheet Arrangements*

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in SEC rules and regulations.

*Critical Accounting Estimates*

Our consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of our consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses, and disclosure of contingent liabilities. We base our estimates and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Although we believe that our estimates, assumptions, and judgments are reasonable, they are based upon information presently available. Actual results may differ significantly from these estimates under different assumptions, judgments, or conditions.

An accounting estimate or assumption is considered critical if both (a) the nature of the estimate or assumption involves a significant level of estimation uncertainty, and (b) the impact within a reasonable range of outcomes of the estimate and assumption is material to our financial condition. Our critical accounting policies are summarized below.

### *Common Stock Warrants*

Under the Merger, we assumed 5,000,000 publicly-traded warrants (“Public Warrants”) and 177,500 private placement warrants issued to AHAC in connection with AHAC’s initial public offering (“Private Placement Warrants” and, together with the Public Warrants, the “Common Stock Warrants”). We account for the Common Stock Warrants in accordance with the guidance contained in ASC Topic 480, *Distinguishing Liabilities from Equity* and ASC Topic 815, *Derivatives and Hedging* (“ASC 815”).

We account for the Private Placement Warrants in accordance with the guidance contained in ASC 815, under which the warrants do not meet the criteria for equity treatment and must be recorded as liabilities. As the Private Placement Warrants meet the definition of a derivative under ASC 815, we recorded these warrants as liabilities on the consolidated balance sheet at fair value, with subsequent changes in their respective fair values recognized in the consolidated statements of operations and comprehensive loss at each reporting date. The fair value of the warrants was estimated using a Monte Carlo simulation value model utilizing assumptions including our current common stock price, expected volatility, risk-free rate, expected term and expected dividend yield. The fair value of the Private Placement Warrants is based on significant unobservable inputs, which represent Level 3 fair value measurements within the fair value hierarchy (see “Fair Value of Financial Instruments” accounting policy described in Note 2 to our accompanying consolidated financial statements contained in Part II, Item 8 of this Annual Report on Form 10-K). Determining the fair value of the Private Placement Warrants involves certain assumptions requiring significant judgment and actual results can differ from assumed and estimated amounts.

The Public Warrants are considered to be “indexed to the Company’s own stock” and as we have a single class of common stock, a qualifying cash tender offer of more than 50% of the Company’s common stock will always result in a change-in-control and would not preclude permanent equity classification of the Public Warrants. Based on this evaluation, we concluded that the Public Warrants meet the criteria to be classified within stockholders’ equity.

### *Contingent Earnout Liability*

In connection with the Reverse Recapitalization, Legacy Humacyte equity holders are entitled to receive as additional merger consideration of up to 15,000,000 shares of our common stock in the aggregate, in two equal tranches of 7,500,000 shares of common stock per tranche, for no consideration upon the occurrence of certain triggering events, including a change of control event that is not solely indexed to the common stock. In accordance with ASC 815-40, as the Contingent Earnout Shares were not indexed to the common stock, they were accounted for as a liability at the Reverse Recapitalization date and subsequently remeasured at each reporting date with changes in fair value recorded as a component of other (expense) income, net in the consolidated statements of operations and comprehensive loss.

The estimated fair value of the Contingent Earnout Shares was determined using a Monte Carlo simulation valuation model using a distribution of potential outcomes on a monthly basis over a 10-year period prioritizing the most reliable information available. The assumptions utilized in the calculation were based on the achievement of certain stock price milestones, including our current common stock price, expected volatility, risk-free rate, expected term and expected dividend yield. See Note 9 to our accompanying consolidated financial statements contained in Part II, Item 8 of this Annual Report on Form 10-K for further information regarding the assumptions used in the valuation at the Closing Date and December 31, 2021.

The Contingent Earnout Shares are categorized as a Level 3 fair value measurement (see “Fair Value of Financial Instruments” accounting policy described in Note 2 to our financial statements contained elsewhere in this Annual Report on Form 10-K) because we estimated projections over a ten-year period utilizing unobservable inputs. Contingent earnout payments involve certain assumptions requiring significant judgment and actual results can differ from assumed and estimated amounts.

### *Stock-Based Compensation*

We measure and recognize compensation expense for all options based on the estimated fair value of the award on the grant date. We use the Black-Scholes option-pricing model to estimate the fair value of option awards. The fair value is recognized as expense on a straight-line basis over the requisite service period. We account for forfeitures as they occur.

The determination of the grant date fair value of options using an option pricing model is affected principally by our estimated fair value of shares of our common stock and requires management to make a number of other assumptions, including the expected term of the option, the volatility of the underlying shares, the risk-free interest rate and expected dividends. The assumptions used in our Black-Scholes option-pricing model represent management’s good faith estimates



at the time of measurement. These estimates are complex, involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective. If any assumptions change, our stock-based compensation expense could be materially different in the future.

These assumptions are estimated as follows:

- *Fair Value of Common Stock.* As our common stock was not publicly traded prior to the Merger, the fair value of the shares of our common stock underlying the options has historically been determined by our board of directors with input from management, after considering independent third-party valuation reports. See “—Fair Value of Common Stock” and “—Common Stock Valuation Methodology.”
- *Expected Term.* The expected term represents the period that stock options are expected to be outstanding. We calculated the expected term using the simplified method for options, which is available where there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this method. For awards with multiple vesting-tranches, the times from grant until the mid-points for each of the tranches may be averaged to provide an overall expected term.
- *Expected Volatility.* The expected volatility was based on the historical share volatility of several publicly traded peer companies over a period of time equal to the expected term of the options, as we have limited trading history to use to determine the volatility of our common stock. For purposes of identifying these peer companies, we considered the industry, stage of development, size and financial leverage of potential comparable companies.
- *Risk-Free Interest Rate.* The risk-free interest rate was based on the yields of U.S. Treasury zero-coupon securities with maturities similar in duration to the expected term of the options.
- *Expected Dividend Yield.* We have not paid dividends on our common stock nor do we expect to pay dividends in the foreseeable future. Accordingly, we have estimated the dividend yield to be zero.

#### *Fair Value of Common Stock*

Historically, for all periods prior to the Merger, the fair values of the shares of common stock underlying our options were determined on each grant date by our board of directors with input from management. In order to determine the fair value, our board of directors considered, among other things, contemporaneous valuations of our common stock and preferred stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation (the “Practice Aid”). Given the absence of a public trading market of our capital stock, the assumptions used to determine the estimated fair value of our common stock are based on a number of objective and subjective factors, including:

- our stage of development and business strategy;
- the prices, rights, preferences and privileges of our redeemable convertible preferred stock relative to our common stock;
- our business, financial condition and results of operations, including related industry trends affecting our operations;
- the likelihood of achieving a liquidity event, such as an initial public offering or sale of our company, given prevailing market conditions;
- the lack of marketability of our common stock;
- the market performance of comparable publicly traded companies; and
- U.S. and global economic and capital market conditions and outlook.

### *Common Stock Valuation Methodology*

The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date. In accordance with the Practice Aid, we considered the following methods:

- **Option Pricing Method.** Under the option pricing method (“OPM”), shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the preferred and common stock are inferred by analyzing these options.
- **Probability-Weighted Expected Return Method.** The probability-weighted expected return method (“PWERM”) is a scenario-based analysis that estimates value per share based on the probability-weighted present value of expected future investment returns, assuming various outcomes, as well as the economic and control rights of each share class.

Based on our early stage of development, we determined that the PWERM method, incorporating the OPM as one of several scenarios, was the most appropriate method for allocating our enterprise value to determine the estimated fair value of our common stock for valuations performed as of November 13, 2020 and October 23, 2019, which resulted in common stock valuations of \$10.28 and \$8.48 per share, respectively. In January, February, March and June 2021, stock options were granted at fair market value with an exercise price of \$10.28, consistent with the fair market value determined two months earlier in November 2020. The \$10.28 exercise price is greater than the public trading price of the AHAC Class A common stock as of the date of grant and also greater than the share price reflected in the \$800 million equity value agreed upon in connection with the Merger. We also utilized the PWERM method for our valuation as of June 25, 2018, which resulted in a common stock valuation of \$8.48 per share. In determining the estimated fair value of our common stock, our board of directors also considered the fact that our stockholders could not freely trade our common stock in the public markets. Accordingly, we applied discounts to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity. The estimated fair value of our common stock at each grant date reflected a non-marketability discount partially based on the anticipated likelihood and timing of a future liquidity event.

Following the closing of the Merger, the fair value of our common stock is determined based on the closing price of our common stock on the primary stock exchange on which our common stock is traded on the date stock options or other awards are granted under the 2021 Plan.

### *Income Taxes*

Income taxes are computed using the asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in our financial statements. In estimating future tax consequences, we consider all expected future events other than enactment of changes in tax laws or rates. A valuation allowance is recorded to reduce net deferred tax assets to their realizable values if management does not believe it is more likely than not that the net deferred tax assets will be realized. As of December 31, 2021 and 2020, we have recorded a full valuation allowance against our net deferred tax assets.

We recognize the benefit of an income tax position only if it is more likely than not (greater than 50%) that the tax position will be sustained upon tax examination, based solely on the technical merits of the tax position. Otherwise, no benefit can be recognized. Assessing an uncertain tax position begins with the initial determination of the sustainability of the position and is measured at the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed. Additionally, we must accrue interest and related penalties, if applicable, on all tax exposures for which reserves have been established consistent with jurisdictional tax laws. We have not identified any uncertain tax positions for the years ended December 31, 2021 and 2020.

We have analyzed our filing positions in all significant Federal and state jurisdictions where we are required to file income tax returns, as well as open tax years in these jurisdictions. As of December 31, 2021 and 2020, we have determined that no uncertain tax positions would have a material impact on our financial statements. We are no longer subject to U.S. Federal, state, and local tax examinations by tax authorities for years before 2018 although carry-forward attributes that were generated prior to 2018 may still be adjusted upon examination by the taxing authorities if they either have been or will be used in a future period. No income tax returns are currently under examination by taxing authorities.

As of December 31, 2021 and 2020, we had not recorded any amounts for unrecognized tax benefits. Our policy is to recognize interest and penalties related to uncertain tax positions in the provision for income taxes, if any. As of December

31, 2021 and 2020, we had no accrued interest or penalties related to uncertain tax positions, and no amounts had been recognized in our statements of operations and comprehensive loss.

*Emerging Growth Company and Smaller Reporting Company Status*

The Company is an “emerging growth company” as defined in the Jumpstart our Business Startups Act of 2012 (the “JOBS Act”), and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies until it is no longer an emerging growth company. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We expect to use the extended transition period and, therefore, while the Company is an emerging growth company it will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies, unless it chooses to early adopt a new or revised accounting standard. This may make it difficult or impossible to compare the Company’s financial results with the financial results of another public company because of the potential differences in accounting standards used.

Additionally, the Company is a “smaller reporting company” as defined in Item 10(f)(1) of Regulation S-K under the Exchange Act (“Regulation S-K”). Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. The Company will remain a smaller reporting company if (1) the market value of Common Stock held by non-affiliates is less than \$250 million as of the last business day of the second fiscal quarter, or (2) the Company’s annual revenues in its most recent fiscal year completed before the last business day of its second fiscal quarter are less than \$100 million and the market value of Common Stock held by non-affiliates is less than \$700 million as of the last business day of the second fiscal quarter.

**Item 7A. Quantitative and Qualitative Disclosure about Market Risk**

We qualify as a smaller reporting company, as defined by Item 10 of Regulation S-K and, thus, are not required to provide the information required by this Item.

**Item 8. Financial Statements and Supplementary Data.**

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HUMACYTE, INC.**

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## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Humacyte, Inc.

### *Opinion on the Financial Statements*

We have audited the accompanying consolidated balance sheets of Humacyte, Inc. and its subsidiary (the “Company”) as of December 31, 2021 and 2020, and the related consolidated statements of operations and comprehensive loss, of changes in redeemable convertible preferred stock and stockholders’ equity (deficit) and of cash flows for the years then ended, including the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

### *Basis for Opinion*

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP  
Raleigh, North Carolina  
March 29, 2022

We have served as the Company’s auditor since 2013.

**HUMACYTE, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
(in thousands except for share and per share amounts)

	As of December 31,	
	2021	2020
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 217,502	\$ 39,929
Short-term investments	8,000	—
Accounts receivable	176	113
Prepaid expenses	3,662	1,407
<b>Total current assets</b>	<b>229,340</b>	<b>41,449</b>
Finance lease right-of-use assets, net	21,432	23,492
Operating lease right-of-use assets, net	727	769
Property and equipment, net	35,034	40,978
<b>Total assets</b>	<b>\$ 286,533</b>	<b>\$ 106,688</b>
<b>LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities		
Accounts payable	\$ 2,094	\$ 2,274
Accrued expenses	6,757	4,592
Finance lease obligation, current portion	1,981	1,729
Deferred payroll tax, current portion	173	145
Operating lease obligation, current portion	45	42
PPP loan payable, current portion	—	2,451
<b>Total current liabilities</b>	<b>11,050</b>	<b>11,233</b>
Contingent earnout liability	103,660	—
Finance lease obligation, net of current portion	21,109	23,090
SVB loan payable	27,361	—
Operating lease obligation, net of current portion	682	727
Common stock warrant liabilities	497	—
Deferred payroll tax, net of current portion	—	144
PPP loan payable, net of current portion	—	822
<b>Total liabilities</b>	<b>164,359</b>	<b>36,016</b>
<b>Commitments and contingencies (Note 13)</b>		
Redeemable convertible preferred stock (Series A, B, C and D) \$0.001 par value, 0 and 69,613,565 shares authorized as of December 31, 2021 and 2020, respectively, 0 and 69,613,562 shares outstanding as of December 31, 2021 and 2020, respectively; liquidation preference of \$0 and \$435,579 as of December 31, 2021 and 2020, respectively	—	420,989
<b>Stockholders' equity (deficit)</b>		
Preferred stock, \$0.0001 par value; 20,000,000 and 0 shares designated as of December 31, 2021 and 2020, respectively, 0 shares issued and outstanding as of December 31, 2021 and 2020	—	—
Common stock, \$0.0001 par value; 250,000,000 and 340,216,780 shares authorized as of December 31, 2021 and 2020, respectively; 103,003,646 and 5,822,396 shares issued and outstanding as of December 31, 2021 and 2020, respectively	10	1
Additional paid-in capital	536,737	37,778
Accumulated deficit	(414,573)	(388,096)
<b>Total stockholders' equity (deficit)</b>	<b>122,174</b>	<b>(350,317)</b>
<b>Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)</b>	<b>\$ 286,533</b>	<b>\$ 106,688</b>

The accompanying notes are an integral part of these financial statements.

**HUMACYTE, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
(in thousands except for share and per share amounts)

	Year Ended December 31,	
	2021	2020
<b>Grant Revenue</b>	\$ 1,263	\$ 1,491
<b>Operating expenses:</b>		
Research and development	61,341	54,078
General and administrative	21,130	12,013
Total operating expenses	82,471	66,091
<b>Loss from operations</b>	<b>(81,208)</b>	<b>(64,600)</b>
<b>Other income (expenses), net</b>		
Interest income	16	278
Change in fair value of contingent earnout liability	55,772	—
Interest expense	(4,348)	(2,202)
Gain on PPP loan forgiveness	3,284	—
Change in fair value of common stock warrant liabilities	56	—
Transaction costs expensed	(49)	—
Total other income (expenses), net	54,731	(1,924)
<b>Net loss and comprehensive loss</b>	<b>\$ (26,477)</b>	<b>\$ (66,524)</b>
<b>Net loss per share attributable to common stockholders, basic and diluted</b>	<b>\$ (0.66)</b>	<b>\$ (11.54)</b>
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	39,970,398	5,765,688

The accompanying notes are an integral part of these financial statements.

**HUMACYTE, INC.**  
**CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS'**  
**EQUITY (DEFICIT)**  
(in thousands except for share amounts)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount			
<b>Balance as of December 31, 2019</b>	<b>69,613,562</b>	<b>\$ 420,989</b>	<b>5,627,157</b>	<b>\$ 1</b>	<b>\$ 32,783</b>	<b>\$ (321,572)</b>	<b>\$ (288,788)</b>
Proceeds from the exercise of stock options	—	—	195,239	—	301	—	301
Stock-based compensation	—	—	—	—	4,694	—	4,694
Net loss	—	—	—	—	—	(66,524)	(66,524)
<b>Balance as of December 31, 2020</b>	<b>69,613,562</b>	<b>420,989</b>	<b>5,822,396</b>	<b>\$ 1</b>	<b>\$ 37,778</b>	<b>\$ (388,096)</b>	<b>\$ (350,317)</b>
Issuance of warrants in conjunction with debt	—	—	—	—	3,275	—	3,275
Conversion of redeemable convertible preferred stock into common stock in connection with the Merger and related PIPE financing	(69,613,562)	(420,989)	69,613,562	7	420,982	—	420,989
The merger and related PIPE financing, net of transaction costs and acquired liabilities	—	—	27,346,449	2	209,478	—	209,480
Public warrants assumed upon the merger, net of transaction costs	—	—	—	—	13,912	—	13,912
Contingent earnout liability recognized upon closing of the reverse recapitalization	—	—	—	—	(159,432)	—	(159,432)
Proceeds from the exercise of stock options	—	—	221,239	—	598	—	598
Stock-based compensation	—	—	—	—	10,146	—	10,146
Net loss	—	—	—	—	—	(26,477)	(26,477)
<b>Balance as of December 31, 2021</b>	<b>—</b>	<b>\$ —</b>	<b>103,003,646</b>	<b>\$ 10</b>	<b>\$ 536,737</b>	<b>\$ (414,573)</b>	<b>\$ 122,174</b>

The accompanying notes are an integral part of these financial statements.



**HUMACYTE, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)

	Year Ended December 31,	
	2021	2020
<b>Cash flows from operating activities</b>		
Net loss	\$ (26,477)	\$ (66,524)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	6,181	6,291
Stock-based compensation expense	10,146	4,694
Change in fair value of contingent earnout liability	(55,772)	—
Change in fair value of common stock warrant liabilities	(56)	—
Loss on disposal of property and equipment	—	177
Amortization expense	2,060	2,060
Non-cash operating lease costs	42	81
Amortization of SVB debt discount	977	—
Accrued interest on PPP loan obligation	11	22
Gain on PPP loan forgiveness	(3,284)	—
Payment of liabilities assumed in Merger	(14,461)	—
Changes in operating assets and liabilities:		
Accounts receivable	(63)	488
Prepaid expenses	(2,174)	(767)
Accounts payable	(197)	(889)
Accrued expenses	2,035	(1,408)
Operating lease obligation	(42)	(82)
Deferred payroll taxes	(116)	289
Net cash used in operating activities	(81,190)	(55,568)
<b>Cash flows from investing activities</b>		
Purchase of short-term investments (certificates of deposit)	(8,000)	—
Purchase of property and equipment	(220)	(318)
Proceeds from sale of property and equipment	—	50
Net cash used in investing activities	(8,220)	(268)
<b>Cash flows from financing activities</b>		
Proceeds from Merger and PIPE financing, net of offering costs paid	242,400	—
Payment of transaction costs related to Merger	(3,945)	—
Proceeds from the exercise of stock options	598	301
Proceeds from SVB loan	29,659	—
Proceeds from PPP loan	—	3,251
Payment of finance lease principal	(1,729)	(1,500)
Net cash provided by financing activities	266,983	2,052
Net increase (decrease) in cash and cash equivalents	177,573	(53,784)
Cash and cash equivalents at the beginning of the period	39,929	93,713
<b>Cash and cash equivalents at the end of the period</b>	<b>217,502</b>	<b>39,929</b>
<b>Supplemental disclosure</b>		
Cash paid for interest on SVB loan	\$ 1,123	\$ —
<b>Supplemental disclosure of noncash activities:</b>		
Operating lease right-of-use assets obtained in exchange for lease obligations	\$ —	\$ 36
Purchase of property and equipment in accounts payable	\$ 21	\$ 4
Issuance of warrants in conjunction with debt	\$ 3,275	\$ —
Unpaid liabilities assumed in connection with Merger	\$ 130	\$ —
Conversion of redeemable convertible preferred stock into common stock in connection with the reverse capitalization	\$ 420,989	\$ —
Contingent earnout liability recognized upon the closing of the reverse recapitalization	\$ 159,432	\$ —

The accompanying notes are an integral part of these financial statements.

**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

## **1. Organization and Description of Business**

### **Organization**

Humacyte, Inc. and subsidiary, or the Company, is pioneering the development and manufacture of off-the-shelf, universally implantable, bioengineered human tissues designed to improve the lives of patients and transform the practice of medicine. The Company is leveraging its technology platform to develop proprietary, bioengineered, acellular human tissues for use in the treatment of diseases and conditions across a range of anatomic locations in multiple therapeutic areas.

On August 26, 2021 (the “Closing Date”), Alpha Healthcare Acquisition Corp. (“AHAC”) consummated a merger pursuant to that certain Business Combination Agreement, dated as of February 17, 2021 (the “Merger Agreement”), by and among Humacyte, Inc., a Delaware Corporation (“Legacy Humacyte”), AHAC and Hunter Merger Sub, Inc. (“Merger Sub”). As contemplated by the Merger Agreement, Merger Sub merged with and into Legacy Humacyte, with Legacy Humacyte continuing as the surviving corporation and as a wholly owned subsidiary of AHAC (such transactions, the “Merger,” and, collectively with the other transactions described in the Merger Agreement, the “Reverse Recapitalization”). As a result of the Merger, AHAC was renamed Humacyte, Inc. (“New Humacyte”) and Legacy Humacyte was renamed Humacyte Global, Inc. The Merger is accounted for as a reverse recapitalization in accordance with U.S. GAAP, and under this method of accounting, AHAC is treated as the acquired company for financial reporting purposes and Legacy Humacyte is treated as the acquirer. Operations prior to the Merger are those of Legacy Humacyte.

Refer to Note 3 — Reverse Recapitalization for further details of the Merger.

### **Liquidity and Going Concern**

Since its inception in 2004, the Company has generated no product revenue and has incurred net losses and negative cash flows from operations in each year. To date, the Company has financed its operations primarily through the sale of equity securities and convertible debt, proceeds from the Reverse Recapitalization, borrowings under loan facilities and, to a lesser extent, through governmental and other grants. At December 31, 2021 and December 31, 2020, the Company had an accumulated deficit of \$414.6 million and \$388.1 million, respectively. The Company’s net losses were \$26.5 million and \$66.5 million for the years ended December 31, 2021 and 2020, respectively. Net cash flows used in operating activities were \$81.2 million and \$55.6 million during the years ended December 31, 2021 and 2020, respectively. Substantially all of the Company’s net losses resulted from costs incurred in connection with the Company’s research and development programs and from general and administrative costs associated with the Company’s operations. The Company expects to incur substantial operating losses and negative cash flows from operations for the foreseeable future as the Company advances its product candidates.

As of December 31, 2021, the Company had cash and cash equivalents and short-term investments of \$225.5 million. The Company believes its combined cash and cash equivalents and short-term investments on hand will be sufficient to fund operations, including clinical trial expenses and capital expenditure requirements, for at least 12 months from the issuance date of these financial statements.

### **Impact of COVID-19**

The COVID-19 pandemic, which began in December 2019 and has spread worldwide, has caused many governments to implement measures to slow the spread of the outbreak, including shelter-in-place orders and the mandatory shutdown of certain businesses. The outbreak and government measures taken in response have had a significant impact, both direct and indirect, on the Company’s business, as supply chains have been disrupted, and facilities and production have been suspended. The future progression of the pandemic and its effects on the Company’s business and operations are uncertain. The COVID-19 pandemic may affect the Company’s ability to initiate and complete preclinical studies, delay its clinical trials or future clinical trials, disrupt regulatory activities, or have other adverse effects on its business and operations. The pandemic has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, which could impact the Company’s ability to raise additional funds to support its operations. Moreover, the pandemic has significantly impacted economies worldwide and could result in adverse effects on the Company’s business and operations.

**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization and Description of Business (continued)**

To date, the COVID-19 pandemic has not resulted in material financial impacts or impairment losses in the carrying values of the Company's assets as a result of the pandemic and the Company is not aware of any specific related event or circumstance that would require it to revise the estimates reflected in these financial statements. The extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including current and future clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19, the actions taken to contain or treat it, and the duration and intensity of the related economic impact of the pandemic.

**2. Summary of Significant Accounting Policies****Basis of Presentation**

The Company has prepared the accompanying financial statements in conformity with accounting principles generally accepted in the United States of America, or U.S. GAAP. The Company's consolidated financial statements reflect the operations of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Unless otherwise noted, the Company has retroactively adjusted all common and preferred share and related share price information to give effect to the Exchange Ratio established in the Merger Agreement. Operations prior to the Merger are those of Legacy Humacyte.

**Use of Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates in the financial statements include stock-based compensation costs, right-of-use, or ROU assets, accruals for research and development activities, contingent earnout liability, fair value of common stock warrants, redeemable convertible preferred stock and income taxes. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ from those estimates.

**Segments**

The Company operates and manages its business as one reportable and operating segment. The Company is developing proprietary, bioengineered, acellular human tissues that are designed to be used in the treatment of diseases and conditions across a range of anatomic locations in multiple therapeutic areas. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of evaluating financial performance and allocating resources.

**Comprehensive loss**

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. There was no difference between net loss and comprehensive loss for the years ended December 31, 2021 and 2020.

**Cash and Cash Equivalents**

The Company considers all short-term, highly liquid investments, including certificates of deposit ("CDs") purchased with an original maturity of three months or less at the date of purchase, to be cash equivalents. Cash deposits are held with financial institutions with investment-grade ratings in the United States of America, or U.S. Cash deposits typically exceed federally insured limits. As of December 31, 2021, cash and cash equivalents consisted of cash on deposit with banks denominated in U.S. dollars, investments in money market funds, and CDs maturing within three months of their purchase date. At December 31, 2020, cash and cash equivalents consisted of cash on deposit with banks denominated in U.S. dollars and investments in money market funds.

**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

## **2. Summary of Significant Accounting Policies (continued)**

### **Short-term Investments**

The Company classifies its certificates of deposit as cash and cash equivalents or short-term investments and reassesses the appropriateness of the classification of its investments at the end of each reporting period. Certificates of deposit held for investment with an original maturity greater than three months are carried at amortized cost and reported as short-term investments on the consolidated balance sheets. The type of certificates of deposit that the Company invests in are not considered debt securities under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 320, Investments - Debt Securities.

As of December 31, 2021, the Company had approximately \$10.0 million in certificates of deposit. These cash deposits are deposited at a bank that is a member of the Certificate of Deposit Account Registry Service ("CDARS"), in which large deposits are divided into smaller amounts and placed with other FDIC insured banks which are also members of the CDARS network. Those members issue CDs in amounts under \$250,000, so that the entire deposit balance is eligible for FDIC insurance. The Company classified \$2.0 million as cash and cash equivalents and classified \$8.0 million of its certificates of deposit as short-term investments on its consolidated balance sheets as of December 31, 2021. The Company did not have any certificates of deposit as of December 31, 2020.

### **Revenue Recognition**

The Company's revenues generally consist of grant revenues, including revenues generated under government and other awarded grants.

#### ***Grant Revenue***

The Company generates revenue primarily from government and other awarded grants that reimburse the Company for certain allowable costs related to research and development efforts. These grants include the following terms:

The Department of Defense grants are for an award of \$4.0 million, all of which was recognized as revenue before the program ended, for work on bioengineered blood vessels for vascular trauma, which was awarded to the Company in September 2017 and ended in February 2020, and an award of \$7.1 million for work to support human tissue engineered blood vessels for vascular reconstruction in the injured warfighter, which was awarded to the Company in August 2017 and is ongoing. The Company has recognized revenue of \$1.3 million and \$1.1 million during the year ended December 31, 2021 and 2020, respectively, for reimbursement of certain allowable costs related to these grants.

The National Institutes of Health grant is for \$1.6 million for work to support bioengineered grafts for peripheral vascular disease, which was awarded to the Company in November 2013. The Company recognized \$1.6 million for the reimbursement of certain allowable costs related to the grant before this program ended in 2020. The Company recognized \$0.3 million during the year ended December 31, 2020, and no revenue during the year ended December 31, 2021, for reimbursement of certain allowable costs related to this grant.

The Company has determined that the grants are not within the scope of ASC 606 as they do not meet the definition of a contract with a customer. The Company has concluded that the grants meet the definition of a contribution and are nonexchange transactions and has applied the contribution accounting model in Subtopic 958-605, Not-for-Profit-Entities-Revenue Recognition by analogy.

The Company recognizes funding received from grants as revenue, rather than as a reduction of research and development expenses, because the Company is the principal in conducting the research and development activities and these grants are central to the Company's ongoing operations. The Company recognizes revenue only after the qualifying expenses related to the grants have been incurred and it is reasonably assured that the expenses will be reimbursed and the revenue will be collectible. The related costs incurred are included in research and development expense in the Company's consolidated statements of operations and comprehensive loss.

Revenue from grants not within the scope of ASC 606 was \$1.3 million and \$1.5 million for the years ending December 31, 2021 and 2020, respectively.

**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**2. Summary of Significant Accounting Policies (continued)**

***Revenue from Customers***

Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services and is recognized in an amount that reflects the consideration that an entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. ASC 606 also impacts certain other areas, such as the accounting for costs to obtain or fulfill a contract.

In addition, ASC 606 requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers.

For contracts where the period between when the Company transfers a promised good or service to the customer and when the customer pays is one year or less, the Company has elected the practical expedient to not adjust the promised amount of consideration for the effects of a significant financing component.

**Concentration of Credit Risk**

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents and short-term investments consisting of CDs. Total cash balances exceeded insured balances by the Federal Deposit Insurance Corporation as of December 31, 2021 and 2020. The company has cash equivalents that are invested in highly rated money market funds invested only in obligations of the U.S. government and its agencies.

The majority of the Company's revenue has been derived from government grants. The Company's grants which represented 10% or more of the Company's total revenue during the years ended December 31, 2021 and 2020 or accounts receivable balance as of December 31, 2021 and 2020 are as follows:

	2021		2020	
	Revenue	Accounts Receivable	Revenue	Accounts Receivable
Grant A	— %	—	—	—
Grant B	— %	— %	10 %	—
Grant C	100 %	100 %	67 %	100 %
Grant D	—	—	18 %	—
Total	100 %	100 %	95 %	100 %

All of the Company's revenues were generated from grants from government and other entities located in the United States, for the years ended December 31, 2021 and 2020.

**Net Loss per Share Attributable to Common Stockholders**

The Company follows the two-class method to compute basic and diluted net loss per share attributable to common stockholders when shares meet the definition of participating securities. The two-class method determines net loss per common share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to share in the earnings as if all income for the period had been distributed. During periods of loss, there is no allocation required under the two-class method since the redeemable convertible preferred stock did not have a contractual obligation to share in the Company's losses.

Basic net loss per share attributable to common stockholders is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period without consideration of potentially dilutive common stock. Diluted net loss per share attributable to common stockholders reflects the potential

**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**2. Summary of Significant Accounting Policies (continued)**

dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the Company unless inclusion of such shares would be anti-dilutive. As the Company has only incurred losses, basic and diluted net loss per share is the same.

The potential shares of common stock that were excluded from the computation of diluted net loss per share for each period because including them would have had an antidilutive effect were as follows:

	<b>December 31,</b>	
	<b>2021</b>	<b>2020</b>
Shares issuable upon conversion of Series A redeemable convertible preferred stock	—	18,421,897
Shares issuable upon conversion of Series B redeemable convertible preferred stock	—	24,137,647
Shares issuable upon conversion of Series C redeemable convertible preferred stock	—	11,241,283
Shares issuable upon conversion of Series D redeemable convertible preferred stock	—	15,812,735
Exercise of options under stock plan	6,711,192	4,813,262
Warrants to purchase common stock	5,588,506	32,961

The 15,000,000 Contingent Earnout shares are excluded from the anti-dilutive table for all the periods presented as such shares are contingently issuable until the share price of the Company exceeds specified thresholds that have not yet been achieved, or upon the occurrence of a change in control.

**Fair Value of Financial Instruments**

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in the principal or most advantageous market in an orderly transaction between market participants at the measurement date. ASC 820, *Fair Value Measurement and Disclosures*, establishes a hierarchy whereby inputs to valuation techniques used in measuring fair value are prioritized, or the fair value hierarchy. There are three levels to the fair value hierarchy based on reliability of inputs, as follows:

- Level 1 — Observable inputs that reflect unadjusted quoted prices for identical assets or liabilities in active markets.
- Level 2 — Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 — Unobservable inputs in which little or no market data exists, therefore requiring the Company to develop its own assumptions.

The Company evaluates assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them for each reporting period, utilizing valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The determination requires significant judgments to be made by the Company.

**Property and Equipment, Net**

Property and equipment, net are recorded at cost less accumulated depreciation. Expenditures for major additions and improvements are capitalized and minor replacements, maintenance, and repairs are charged to expense as incurred. When property and equipment are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet accounts and any resulting gain or loss is included in the results of operations for the respective period.

**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**2. Summary of Significant Accounting Policies (continued)**

Depreciation is calculated using the straight-line method over the estimated useful lives of the related assets. The estimated useful lives for significant asset categories are as follows:

<b>Property and equipment</b>	<b>Estimated Useful Lives (Years)</b>
Scientific equipment	5 – 7
Computer equipment	5
Software	3
Furniture and fixtures	5 – 7
Leasehold improvements	Lesser of useful life or life of lease
Construction in progress	N/A

**Impairment of Long-Lived Assets**

The Company reviews the carrying value of property and equipment for indicators of possible impairment whenever events and circumstances indicate that the carrying value of an asset or asset group may not be recoverable from the estimated future net undiscounted cash flows expected to result from its use and eventual disposition. In cases where estimated future net undiscounted cash flows are less than the carrying value, an impairment loss is recognized equal to an amount by which the carrying value exceeds the fair value of the asset or asset group. The factors considered by management in performing this assessment include current operating results, trends and prospects, the manner in which the property is used, and the effects of obsolescence, demand, competition, and other economic factors. Based on this assessment, during the years ended December 31, 2021 and 2020, respectively, the Company concluded there were no such events or changes in circumstances requiring review of the carrying amount of the Company's long-lived assets and there was no impairment during the years ended December 31, 2021 and 2020.

**Income Taxes**

Income taxes are computed using the asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company's financial statements. In estimating future tax consequences, the Company considers all expected future events other than enactment of changes in tax laws or rates. A valuation allowance is recorded, if necessary, to reduce net deferred tax assets to their realizable values if management does not believe it is more likely than not that the net deferred tax assets will be realized. As of December 31, 2021 and 2020, the Company has recorded a full valuation allowance against its deferred tax assets.

The Company applies the accounting guidance for uncertainties in income taxes, which prescribes a recognition threshold and measurement process for recording uncertain tax positions taken, or expected to be taken, in a tax return in the financial statements. Additionally, the guidance also prescribes the treatment for derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions. The Company accrues for the estimated amount of taxes for uncertain tax positions if it is more likely than not that the Company would be required to pay such additional taxes.

The Company recognizes the benefit of an income tax position only if it is more likely than not (greater than 50%) that the tax position will be sustained upon tax examination, based solely on the technical merits of the tax position. Otherwise, no benefit can be recognized. Assessing an uncertain tax position begins with the initial determination of the sustainability of the position and is measured at the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed. Additionally, the Company must accrue interest and related penalties, if applicable, on all tax exposures for which reserves have been established consistent with jurisdictional tax laws.

The Company has analyzed its filing positions in all significant Federal and state jurisdictions where it is required to file income tax returns, as well as open tax years in these jurisdictions. As of December 31, 2021 and 2020, the Company has determined that no uncertain tax positions would have a material impact on the financials statements of the Company. The Company is no longer subject to Federal, state, and local tax examinations by tax authorities for years before 2018

**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

## **2. Summary of Significant Accounting Policies (continued)**

although carry-forward attributes that were generated prior to 2018 may still be adjusted upon examination by the taxing authorities if they either have been or will be used in a future period. No income tax returns are currently under examination by taxing authorities.

As of December 31, 2021 and 2020, the Company had not recorded any amounts for unrecognized tax benefits. The Company's policy is to recognize interest and penalties related to uncertain tax positions in the provision for income taxes. As of December 31, 2021 and 2020, the Company had no accrued interest or penalties related to uncertain tax positions, and no amounts had been recognized in the Company's statements of operations and comprehensive loss.

### **Intellectual Property**

The Company seeks to protect its intellectual property by filing patent applications in the United States and abroad related to novel technologies and product candidates that it views as important to its business. The patent positions of biotechnology companies generally, including the Company's patent positions, is highly uncertain and involves complex legal and factual questions for which legal principles remain unresolved. Patent costs have been expensed as incurred as general and administrative expense.

### **Research and Development**

The Company expenses research and development costs as operating expenses as incurred. Research and development expenses consist primarily of:

- salaries and related overhead expenses for personnel in research and development functions, including stock-based compensation and benefits;
- fees paid to consultants and CROs, including in connection with clinical trials, and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work and statistical compilation and analysis; allocation of facility lease and maintenance costs;
- depreciation of leasehold improvements, laboratory equipment and computers;
- costs related to purchasing raw materials for and producing product candidates for clinical trials;
- costs related to compliance with regulatory requirements;
- costs related to the manufacturing scale-out initiative; and
- license fees related to in-licensed technologies.

### **Accrued Research and Development**

The Company has entered into various agreements with CROs and a CMO, which conduct preclinical studies and clinical trials and contract manufacturing activities. The Company's research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development provided, but not yet invoiced, are included in accrued expenses on the balance sheet. If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company will adjust the accrual accordingly. Payments made under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered. The Company terminated its agreement with its CMO on March 6, 2020. The remaining HAV inventory at the CMO was fully depleted during the year ended December 31, 2021.

### **Stock-Based Compensation**

The Company accounts for stock-based compensation for employees and non-employees measured at grant date, based on the fair value of the award. The Company measures the fair value of awards granted using the Black-Scholes option pricing model and recognizes the expense over the requisite service period using the straight-line method. Option valuation



**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

## **2. Summary of Significant Accounting Policies (continued)**

models, including the Black-Scholes option-pricing model, require the input of highly subjective assumptions, and changes in the assumptions used can materially affect the grant-date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility, the expected term of the award, and the fair value of the underlying common stock on the date of grant. Forfeitures are accounted for as they occur.

### **Common Stock Warrants**

In connection with the Merger, the Company assumed 5,000,000 publicly-traded warrants (“Public Warrants”) and 177,500 private placement warrants issued to AHAC Sponsor LLC (the “Sponsor”), Oppenheimer & Co. Inc. and Northland Securities, Inc. in connection with AHAC’s initial public offering (“Private Placement Warrants” and, together with the Public Warrants, the “Common Stock Warrants”). The Common Stock Warrants entitle the holder to purchase one share of the Company’s Common stock, par value \$0.0001 (“Common Stock”), at an exercise price of \$11.50 per share. The Public Warrants are publicly traded and are exercisable for cash unless certain conditions occur, such as the failure to have an effective registration statement related to the shares issuable upon exercise or redemption by the Company under certain conditions, at which time the warrants may be eligible for a cashless exercise. The Private Placement Warrants are non-redeemable for cash so long as they are held by the initial purchasers or their permitted transferees. If the Private Placement Warrants are held by someone other than the initial purchasers or their permitted transferees, the Private Placement Warrants are redeemable by the Company and exercisable by such holders on the same basis as the Public Warrants.

The Company evaluated the Common Stock Warrants to determine the appropriate financial statement classification upon the consummation of the Merger. The Common Stock Warrants are not mandatorily redeemable and are considered to be freestanding instruments as they are separately exercisable into common shares. As such, the Common Stock Warrants were not classified as liabilities under FASB ASC Topic 480, *Distinguishing Liabilities from Equity* (“ASC 480”). The Company then evaluated the Common Stock Warrants under FASB ASC Topic 815, *Derivatives and Hedging*.

The agreement governing the Common Stock Warrants includes a provision (“Replacement of Securities Upon Reorganization”), the application of which could result in a different settlement value for the Private Placement Warrants depending on their holder. Because the holder of an instrument is not an input into the pricing of a fixed-for-fixed option on the Company’s ordinary shares, the Private Placement Warrants are not considered to be “indexed to the Company’s own stock” and therefore are not classified in stockholders’ equity. As the Private Placement Warrants meet the definition of a derivative, the Company recorded these warrants as liabilities on the consolidated balance sheet at fair value, with subsequent changes in their respective fair values recognized in the consolidated statements of operations and comprehensive loss at each reporting date.

The Public Warrants are considered to be “indexed to the Company’s own stock”. The agreement provides that in the event of a tender or exchange offer made to and accepted by holders of more than 50% of the outstanding shares of the Company’s common shares, all holders of the Common Stock Warrants (both the Public Warrants and the Private Placement Warrants) would be entitled to receive cash for all of their Common Stock Warrants. As the Company has a single class of common stock, a qualifying cash tender offer of more than 50% of the Company’s common stock will always result in a change-in-control and would not preclude permanent equity classification of the Public Warrants. Based on this evaluation, the Company concluded that the Public Warrants meet the criteria to be classified within stockholders’ equity.

### **Contingent Earnout Liability**

In connection with the Reverse Recapitalization and pursuant to the Merger Agreement, Legacy Humacyte equity holders are entitled to receive as additional merger consideration of up to 15,000,000 shares of the Company’s Common Stock (the “Contingent Earnout Shares”), comprised of two separate tranches of 7,500,000 shares per tranche, for no consideration upon the occurrence of certain triggering events, including a change of control event that is not solely indexed to the common stock. In accordance with ASC 815-40, as the earnout shares were not indexed to the common stock, they were accounted for as a liability at the Reverse Recapitalization date and subsequently remeasured at each reporting date with changes in fair value recorded as a component of other (expense) income, net in the consolidated statements of operations and comprehensive loss.

**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**2. Summary of Significant Accounting Policies (continued)**

The estimated fair value of the Contingent Earnout Shares was determined using a Monte Carlo simulation using a distribution of potential outcomes on a monthly basis over a ten-year period prioritizing the most reliable information available. The assumptions utilized in the calculation were based on the achievement of certain stock price milestones, including the current Company common stock price, expected volatility, risk-free rate, expected term and expected dividend yield.

The Contingent Earnout Shares are categorized as a Level 3 fair value measurement (see “Fair Value of Financial Instruments” accounting policy described above) because the Company estimated projections over a ten-year period utilizing unobservable inputs. Contingent earnout payments involve certain assumptions requiring significant judgment and actual results can differ from assumed and estimated amounts.

**Leases**

The Company accounts for its leases under ASC 842, *Leases*. The Company determines if an arrangement is or contains a lease and the classification of that lease at inception of a contract. The Company’s operating lease assets are included in “operating lease right-of-use assets, net”, and the current and non-current portions of the operating lease liabilities are included in “operating lease obligation, current portion”, and “operating lease obligation, net of current portion”, respectively, on the balance sheets. The Company’s finance lease assets are included in “finance lease right-of-use assets, net”, and the current and non-current portions of the finance lease liabilities are included in “finance lease obligation, current portion”, and “finance lease obligation, net of current portion”, respectively, on the consolidated balance sheets.

Under this guidance, arrangements meeting the definition of a lease are classified as operating or finance leases, and are recorded on the balance sheet as both a right-of-use asset and lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company’s incremental borrowing rate. Lease right-of-use assets and lease obligations are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. Operating lease right-of-use assets are adjusted for (i) payments made at or before the commencement date, (ii) initial direct costs incurred, and (iii) tenant incentives under the lease. As the implicit rate for the operating leases were not determinable, the Company used an incremental borrowing rate based on the information available at the respective lease commencement dates in determining the present value of future payments. The incremental borrowing rate represents the interest rate the Company would expect to incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of a lease. The Company determined the incremental borrowing rate by considering various factors, such as its credit rating, interest rates of similar debt instruments of entities with comparable credit ratings, the lease term and the currency in which the lease was denominated. The Company considers a lease term to be the noncancelable period that it has the right to use the underlying asset, including any periods where it is reasonably certain the Company will exercise any option to extend the contract.

Lease expenses for minimum lease payments for operating leases are recognized on a straight-line basis over the lease term. Amortization expense of the right-of-use asset for finance leases is recognized on a straight-line basis over the lease term and interest expense for finance leases is recognized based on the incremental borrowing rate. Lease liabilities are increased by interest and reduced by payments each period, and the right of use asset is amortized over the lease term.

In calculating the right-of-use assets and lease liabilities, the Company has elected to combine lease and non-lease components for all asset classes. The Company excludes short-term leases, if any, having initial terms of 12 months or less from the new guidance as an accounting policy election, and recognizes rent expense on a straight-line basis over the lease term.

**Other Risks and Uncertainties**

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, successful discovery and development of its product candidates, the success of clinical trials and other studies for its product candidates, including for its ongoing V005 Phase II/III clinical trial and V007 Phase III clinical trial, the regulatory approval and commercialization of its HAVs and other product candidates, the expected size of the target populations for the Company’s product candidates, the degree of market acceptance of the HAVs, if approved,

**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**2. Summary of Significant Accounting Policies (continued)**

the availability of third-party coverage and reimbursement, development by competitors of new technological innovations, the ability to manufacture HAVs and other product candidates in sufficient quantities, expectations regarding the Company's strategic partnerships, dependence on third parties, key personnel and the ability to attract and retain qualified employees, protection of proprietary technology and confidentiality of trade secrets, compliance with governmental regulations, the impact of the COVID-19 pandemic, the Company's implementation and maintenance of effective internal controls, and the ability to secure additional capital to fund operations and commercial success of its product candidates.

Product candidates currently under development will require extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel, and infrastructure and extensive compliance-reporting capabilities. Even if the Company's commercialization efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales, and the Company may depend on certain strategic relationships to distribute its products, including the Company's strategic partnership with Fresenius Medical Care Holdings, Inc., ("Fresenius Medical Care") to sell, market and distribute its 6 millimeter HAV for certain specified indications outside the United States.

**Recently Adopted Accounting Pronouncements**

In December 2019, the FASB issued ASU 2019-12 "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes" ("ASU 2019-12"). The FASB issued this update to remove certain exceptions to the general principles in the Accounting Standards Codification ("ASC") Topic 740 and to improve consistent application of and simplify U.S. GAAP for other areas of ASC Topic 740 by clarifying and amending existing guidance. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company adopted ASU 2019-12 as of January 1, 2021. The adoption of the new guidance did not have a material impact on the Company's financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06, "Debt-Debt with Conversion and Other Options (Subtopic 470 – 20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity" ("ASU 2020-06"), which simplifies accounting for convertible instruments by removing major separation models required under current U.S. GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. Either a modified retrospective method of transition or a fully retrospective method of transition is permissible for the adoption of this standard. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2021, with early adoption permitted. The Company adopted ASU 2020-06 as of January 1, 2021. The adoption of this ASU had no impact on the Company's financial statements and related disclosures.

**Recently Issued Accounting Pronouncements**

In May 2021, the FASB issued ASU No. 2021-04, "Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options" ("ASU 2021-04"). The FASB issued this update to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity classified written call options (for example, warrants) that remain equity classified after modification or exchange. ASU 2021-04 is effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the amendments prospectively to modifications or exchanges occurring after the effective date of the amendments. The Company plans to adopt the standard effective January 1, 2022 and does not expect a material impact to its consolidated financial statements or disclosures.

In November 2021, the FASB issued ASU No. 2021-10, "Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance" ("ASU 2021-10") to improve financial reporting by requiring disclosures that increase the transparency of transactions with a government accounted for by applying a grant or contribution model by analogy, including (i) the types of transactions, (ii) an entity's accounting for those transactions, and (iii) the effect of those transactions on an entity's financial statements. ASU 2021-10 is effective for all entities within their scope for

**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

## **2. Summary of Significant Accounting Policies (continued)**

financial statements issued for annual periods beginning after December 15, 2021. Early adoption is permitted and an entity can elect to apply the amendments in this guidance prospectively or retrospectively. The Company plans to adopt this standard effective January 1, 2022 and does not expect a material impact to its consolidated financial statements or disclosures.

## **3. Reverse Recapitalization**

On August 26, 2021, Merger Sub, a wholly-owned subsidiary of AHAC, merged with Legacy Humacyte, with Legacy Humacyte surviving as a wholly-owned subsidiary of AHAC. At the effective time of the Merger:

- each outstanding share of Legacy Humacyte common stock was converted into approximately 0.26260 shares of the Company's common stock;
- each outstanding share of preferred stock of Legacy Humacyte was cancelled and converted into the aggregate number of shares of New Humacyte's common stock that would be issued upon conversion of the shares of Legacy Humacyte preferred stock based on the applicable conversion ratio immediately prior to the effective time, multiplied by approximately 0.26260; and
- each outstanding option or warrant to purchase Legacy Humacyte common stock was converted into an option or warrant, as applicable, to purchase a number of shares of the Company's common stock equal to the number of shares of Legacy Humacyte common stock subject to such option or warrant multiplied by approximately 0.26260, at an exercise price per share equal to the current exercise price per share for such option or warrant divided by approximately 0.26260;

in each case, rounded down to the nearest whole share.

In addition, upon the closing of the merger (the "Closing"), 2,500,000 Class B shares of AHAC (Founder Shares) automatically converted into shares of the Company's common stock, on a one-for-one basis.

Former holders of the Legacy Humacyte common stock and Legacy Humacyte preferred stock are eligible to receive up to an aggregate of 15,000,000 additional shares of the Company's common stock (the "Contingent Earnout Shares") in the aggregate in two equal tranches of 7,500,000 shares if the volume-weighted average closing sale price of the common stock is greater than or equal to \$15.00 and \$20.00, respectively, for any 20 trading days within any 30 consecutive trading day period. At the Closing on August 26, 2021, the Company recorded a liability ("Contingent Earnout Liability") of \$159.4 million, based on the estimated fair value of the 15 million Contingent Earnout Shares with a corresponding reduction of additional paid-in capital in the equity section of the Company's consolidated balance sheet.

Concurrently with the execution of the Merger Agreement, AHAC entered into subscription agreements (the "Subscription Agreements") with certain investors (the "PIPE Investors"). Pursuant to the Subscription Agreements, the PIPE Investors purchased an aggregate of 17,500,000 shares of the Company's common stock (the "PIPE Shares") in a private placement at a price of \$10.00 per share for an aggregate purchase price of \$175 million (the "PIPE Financing"). The PIPE Financing was consummated in connection with the Closing.

**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**3. Reverse Recapitalization (continued)**

The number of shares of the Company's common stock outstanding immediately following the consummation of the Merger was:

	<u>Shares</u>
Common stock of AHAC, outstanding prior to Merger	10,355,000
Less redemption of AHAC shares	<u>(3,008,551)</u>
Common stock of AHAC	7,346,449
AHAC Founder Shares	2,500,000
New Humacyte shares issued to PIPE Investors	<u>17,500,000</u>
Issuance of common stock upon reverse recapitalization and PIPE Financing	27,346,449
New Humacyte shares issued in Merger to Legacy Humacyte stockholders	<u>75,656,935 <sup>(1)</sup></u>
Total shares of common stock immediately after Merger	<u><u>103,003,384</u></u>

(1) Includes 69,613,562 shares of common stock issued upon conversion of Legacy Humacyte's redeemable convertible preferred stock.

The Merger is accounted for as a reverse recapitalization in accordance with U.S. GAAP. Under this method of accounting, AHAC is treated as the acquired company for financial reporting purposes and Legacy Humacyte is treated as the acquirer. This determination is primarily based on the fact that subsequent to the Merger, the Legacy Humacyte stockholders hold a majority of the voting rights of the combined company, Legacy Humacyte comprises all of the ongoing operations of the combined company, Legacy Humacyte comprises a majority of the carryover governing body of the combined company, and Legacy Humacyte's senior management comprises all of the senior management of the combined company. Accordingly, for accounting purposes, the Merger was treated as the equivalent of Legacy Humacyte issuing shares for the net assets of AHAC, accompanied by a recapitalization. The net assets of AHAC were stated at historical costs. No goodwill or other intangible assets were recorded. Operations prior to the Merger are those of Legacy Humacyte.

In connection with the Merger, the Company received \$242.4 million in proceeds from the Merger and related PIPE Financing. The Company incurred \$3.9 million of transaction costs, consisting of banking, legal, and other professional fees, of which \$3.9 million was recorded as a reduction of proceeds to additional paid-in capital, and less than \$0.1 million related to the Private Placement Warrants, which are classified as liabilities in the consolidated balance sheets, was expensed in the consolidated statements of operations and comprehensive loss. All transaction costs were paid as of December 31, 2021. Legacy Humacyte assumed \$15.2 million of liabilities, including PIPE Financing fees and legal fees, and \$0.1 million of assets from AHAC. Of the \$15.2 million of liabilities assumed from AHAC, as of December 31, 2021, \$0.1 million was included in accrued expenses.

**HUMACYTE, INC.**
**NOTES TO FINANCIAL STATEMENTS**
**4. Fair Value Measurements**

The Company's assets and liabilities that were measured at fair value on a recurring basis were as follows:

(\$ in thousands)	Fair Value Measured as of December 31, 2021			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Cash equivalents (money market funds)	\$ 208,821	\$ —	\$ —	\$ 208,821
Cash equivalents (certificates of deposit)	—	2,000	—	2,000
Short-term investments (certificates of deposit)	—	8,000	—	8,000
<b>Total financial assets</b>	<b>\$ 208,821</b>	<b>\$ 10,000</b>	<b>\$ —</b>	<b>\$ 218,821</b>
<b>Liabilities:</b>				
Contingent earnout liability	\$ —	\$ —	\$ 103,660	\$ 103,660
Common stock warrant liabilities (Private Placement Warrants)	—	—	497	497
<b>Total financial liabilities</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 104,157</b>	<b>\$ 104,157</b>

(\$ in thousands)	Fair Value Measured as of December 31, 2020			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Cash equivalents (money market funds)	\$ 35,623	\$ —	\$ —	\$ 35,623
<b>Total financial assets</b>	<b>\$ 35,623</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 35,623</b>

The following table presents a summary of the changes in the fair value of the Company's Level 3 financial instruments:

(\$ in thousands)	Contingent Earnout Liability	Private Placement Warrants
Fair value as of December 31, 2020	\$ —	\$ —
Private placement warrant liability acquired as part of the merger	—	(553)
Contingent earnout liability recognized upon the closing of the reverse recapitalization	(159,432)	—
Change in fair value included in other (expense) income	55,772	56
<b>Fair value as of December 31, 2021</b>	<b>\$ (103,660)</b>	<b>\$ (497)</b>

The fair value of the Contingent Earnout Liability and Private Placement Warrants liability are based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy.

In determining the fair value of the Contingent Earnout Liability, the Company used the Monte Carlo simulation value model using a distribution of potential outcomes on a monthly basis over a 10-year period prioritizing the most reliable information available. The assumptions utilized in the calculation were based on the achievement of certain stock price milestones, including the current Company common stock price, expected volatility, risk-free rate, expected term and expected dividend yield (see Note 9).

In determining the fair value of the Private Placement Warrants liability, the Company used the Monte Carlo simulation valuation model to estimate the fair value utilizing assumption including the current Company stock price, expected volatility, risk-free rate, expected term and expected dividend yield (see Note 9).

**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**4. Fair Value Measurements (continued)**

The Company's money market funds are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices. Certificates of deposit are carried at amortized cost in the Company's consolidated balance sheet, which approximates their fair value based on Level 2 inputs. The carrying values of other receivables, accounts payable and accrued expenses as of December 31, 2021 and 2020 approximated their fair values due to the short-term nature of these items.

**5. Property and Equipment, Net**

Property and equipment, net consist of the following:

(\$ in thousands)	As of December 31,	
	2021	2020
Scientific equipment <sup>(1)</sup>	\$ 27,641	\$ 27,412
Computer equipment	155	149
Software	335	335
Furniture and fixtures	988	988
Leasehold improvements	26,355	26,355
	55,474	55,239
Accumulated depreciation	(20,440)	(14,261)
Property and equipment, net	\$ 35,034	\$ 40,978

(1) Includes \$3.6 million and \$3.5 million for the years ended December 31, 2021 and 2020, respectively, related to scientific equipment not placed into service and therefore not being depreciated.

Depreciation expense totaled \$6.2 million and \$6.3 million for the years ended December 31, 2021 and 2020, respectively. All long-lived assets are maintained in the United States.

**6. Accrued Expenses**

Accrued expenses consisted of the following:

(\$ in thousands)	As of December 31,	
	2021	2020
Accrued external research, development and manufacturing costs	\$ 2,520	\$ 2,615
Accrued employee compensation and benefits	3,943	1,009
Accrued professional fees	294	968
Total	\$ 6,757	\$ 4,592

**7. Debt**

On April 30, 2020, the Company received loan proceeds in the amount of approximately \$3.3 million under the Paycheck Protection Program ("PPP"). All or portion of this loan and any accrued interest was eligible to be forgiven after a twenty four week period as long as the borrower used the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities, and maintains its payroll levels. The amount of the loan forgiven was to be reduced if the borrower terminated employees or reduced salaries during the twenty four week period. The unforgiven portion of the PPP loan was to be payable over two years at an interest rate of 1%, with a deferral of payments for the first ten months. On May 25, 2021, the PPP loan was forgiven and the Company recognized a gain from loan extinguishment in the amount of \$3.3 million during the year ended December 31, 2021.

**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**7. Debt (continued)**

On March 30, 2021, the Company entered into a term loan agreement with Silicon Valley Bank and SVB Innovation Credit Fund VIII, L.P., as amended in June and September 2021, which provides a term loan facility of up to \$50.0 million with a maturity date of March 1, 2025, or the Loan Agreement. The Company's obligations under the Loan Agreement are secured by substantially all of its assets except for its intellectual property. The Loan Agreement contains certain customary covenants, including, but not limited to, those relating to additional indebtedness, liens, asset divestitures, and affiliate transactions. If a minimum liquidity amount is not maintained, 50% of the outstanding principal and interest will become cash collateralized. As of December 31, 2021, the Company was in compliance with all covenants. The Company may use the proceeds of borrowings under the Loan Agreement as working capital and to fund its general business requirements.

The Loan Agreement provides that the term loans will be distributed in tranches. The initial term loan tranche of \$20.0 million was drawn on March 31, 2021, and on October 13, 2021 the Company borrowed an additional \$10.0 million under the Loan Agreement. Borrowings under the Loan Agreement are accounted for net of issuance costs which are being accreted to interest expense over the term of the loan using the effective interest method. As of December 31, 2021, two subsequent \$10.0 million term loan tranches were eligible to be disbursed at the request of the Company during specified draw periods between now and 2023 if certain business milestones and other requirements are met by the dates specified in the Loan Agreement. Borrowings bear interest at the greater of 7.5% or the Wall Street Journal Prime Rate plus 4.25% (7.5% as of December 31, 2021). Interest-only payments on the principal amount outstanding are due monthly beginning in the first month after the loan is dispersed. Repayment of principal may begin as soon as July 1, 2023 under the level of borrowing outstanding at December 31, 2021, and no later than April 1, 2024 if the remaining two loan tranches are drawn. The term loans may only be prepaid in full, and such prepayment requires 30 days' advance notice and is subject to a prepayment fee of 3.00% (with a step down to 2.00% after March 30, 2022, and a further step down to 1.00% after March 30, 2023). The Company is not obligated to pay a prepayment fee if the Company makes a prepayment after March 30, 2024.

In connection with the Loan Agreement, the Company granted warrants to the lenders to purchase shares of common stock at an exercise price of \$10.28 per share, of which 287,704 warrants were immediately exercisable. The warrants are classified within stockholders' equity as the settlement of the warrants is indexed to the Company's own stock. The Company recognized the fair value of the warrants immediately exercisable within stockholders' equity using a Black-Scholes valuation model at issuance.

At issuance, the Company initially determined that the funding of an additional tranche was not probable, and therefore no value was ascribed to the remaining 123,302 warrants that were only exercisable upon the funding of the additional tranche. As a result of the Company's additional \$10.0 million borrowings under the Loan Agreement on October 13, 2021, the warrants to purchase the additional 123,302 shares of the Company's common stock became exercisable at an exercise price of \$10.28 per share and the value of the warrants was recorded as of that date. The additional warrants are classified within stockholders' equity using a Black-Scholes valuation model, as the settlement of the warrants is indexed to the Company's own stock.

As of December 31, 2021, the fair value of warrants (\$3.3 million), a 5% final payment fee (\$1.5 million) and debt issuance costs (\$0.3 million) are being accreted to interest expense over the term of the loan using the effective interest method.

SVB loan payable and net discount or premium balances are as follows:

(\$ in thousands)	December 31, 2021
Principal amount of SVB loan payable	\$ 30,000
Final payment amount of SVB loan payable	1,500
Net premium associated with accretion of final payment and other debt issuance costs	(4,139)
SVB loan payable, current and noncurrent	27,361
Less SVB loan payable, current portion	—
SVB loan payable, noncurrent portion	\$ 27,361



**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**7. Debt (continued)**

Future minimum payments of principal on the Company's outstanding variable rate borrowings as of December 31, 2021 are as follows:

Year ending December 31:	(\$ in thousands)
2022	\$ —
2023	10,000
2024	17,143
2025	2,857
<b>Total future payments</b>	<b>\$ 30,000</b>

**8. Leases**

The Company's finance lease relates to its headquarters, which was substantially completed in June 2018 and leased through May 2033, and its operating lease relates to the land lease associated with its headquarters. During 2020 the Company had an operating lease for laboratory and office space in Ohio. In March 2020, the Company terminated this lease, effective September 30, 2020, and paid termination fees of less than \$0.1 million.

At December 31, 2021 and 2020, the Company had finance lease liabilities of \$23.1 million and \$24.8 million, respectively, and right-of-use assets of \$21.4 million and \$23.5 million, respectively, and operating lease liabilities of \$0.7 million and \$0.8 million, respectively, and right-of-use assets of \$0.7 million and \$0.8 million, respectively, all of which were included in the consolidated balance sheets.

The Company's leases do not require any contingent rental payments, impose any financial restrictions, or contain any residual value guarantees. Certain of the Company's leases include renewal options and escalation clauses; renewal options have been included in the calculation of the lease liabilities and right of use assets as the Company is reasonably certain to exercise the options due to the specialized nature of the leased building. Variable expenses generally represent the Company's share of the landlord's operating expenses. The Company does not act as a lessor in any lease arrangements.

The following summarizes quantitative information about the Company's leases:

(\$ in thousands)	Year Ended December 31,	
	2021	2020
Finance lease cost		
Amortization of right-of-use assets	\$ 2,060	\$ 2,060
Interest on lease liabilities	2,044	2,180
Total finance lease cost	4,104	4,240
Operating lease cost	105	152
Total lease cost	\$ 4,209	\$ 4,392

(\$ in thousands)	Year Ended December 31, 2021		Year Ended December 31, 2020	
	Finance Leases	Operating Leases	Finance Leases	Operating Leases
Operating cash flows from leases	\$ (2,044)	\$ (105)	\$ (2,180)	\$ (182)
Financing cash flows from leases	\$ (1,729)	\$ —	\$ (1,500)	\$ —
Weighted-average remaining lease term	5.04	5.74	5.52	6.24
Weighted-average discount rate	8.50 %	8.50 %	8.50 %	8.50 %

**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**8. Leases (continued)**

As of December 31, 2021, the maturities of the Company's lease liabilities were as follows:

(\$ in thousands)	Finance Leases	Operating Leases
2022	\$ 3,868	\$ 105
2023	3,965	105
2024	4,065	105
2025	4,167	105
2026	4,237	105
Thereafter	12,699	574
<b>Total</b>	<b>33,001</b>	<b>1,099</b>
Less: present value discount	(9,911)	(372)
<b>Lease liabilities</b>	<b>\$ 23,090</b>	<b>\$ 727</b>

**9. Stockholders' Equity (Deficit)****Redeemable Convertible Preferred Stock**

As of December 31, 2020 and immediately prior to the Merger, Legacy Humacyte had outstanding series A redeemable convertible preferred stock, series B redeemable convertible preferred stock, series C redeemable convertible preferred stock and series D redeemable convertible preferred stock, which are collectively referred to as "redeemable convertible preferred stock."

As of December 31, 2020, redeemable convertible preferred stock consisted of the following (in thousands, except share amounts):

	Redeemable Convertible Preferred Stock Authorized	Redeemable Convertible Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Issuance Price
Series A redeemable convertible preferred stock	18,421,897	18,421,897	\$ 74,079	\$ 74,079	\$ 4.0212
Series B redeemable convertible preferred stock	24,137,647	24,137,647	127,358	136,500	\$ 5.6550
Series C redeemable convertible preferred stock	11,241,286	11,241,283	70,704	75,000	\$ 6.6717
Series D redeemable convertible preferred stock	15,812,735	15,812,735	148,848	150,000	\$ 9.4859
	<u>69,613,565</u>	<u>69,613,562</u>	<u>\$ 420,989</u>	<u>\$ 435,579</u>	

In connection with the Merger, all previously issued and outstanding redeemable convertible preferred stock was converted into an equivalent number of shares of common stock of the Company on a one-for-one basis, then multiplied by the Exchange Ratio pursuant to the Merger Agreement.

**Common Stock**

On August 26, 2021, the Merger and related PIPE Financing was consummated and the Company issued 27,346,449 shares of common stock for proceeds of \$242.4 million. The Company incurred \$3.9 million of transaction costs, consisting of banking, legal, and other professional fees. Legacy Humacyte assumed \$15.2 million of liabilities, including PIPE Financing fees and legal fees, and \$0.1 million of assets from AHAC. Immediately following the Merger, there were 103,003,384 shares of common stock outstanding with a par value of \$0.0001.

As of December 31, 2021, the Company's Second Amended and Restated Certificate of Incorporation authorized the Company to issue 250,000,000 shares of common stock at a par value of \$0.0001 per share. The number of authorized

**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**9. Stockholders' Equity (Deficit) (continued)**

shares of common stock may be increased or decreased (but not below the number of shares thereof then outstanding or reserved for issuance) by the affirmative vote of the holders of a majority of the capital stock of the Company entitled to vote and may require a separate class vote of the common stock.

The holders of common stock are entitled to receive dividends from time to time as may be declared by the Company's board of directors. Through December 31, 2021, no dividends have been declared.

The holders of common stock are entitled to one vote for each share held with respect to all matters voted on by the common stockholders of the Company.

In the event of a reorganization of the Company, after payment to the preferred stockholders of their liquidation preferences, holders of common stock are entitled to share ratably in all remaining assets of the Company.

At December 31, 2021 and 2020, the Company had reserved common stock for future issuances as follows:

	December 31,	
	2021	2020
Conversion of Series A redeemable convertible preferred stock	—	18,421,897
Conversion of Series B redeemable convertible preferred stock	—	24,137,647
Conversion of Series C redeemable convertible preferred stock	—	11,241,286
Conversion of Series D redeemable convertible preferred stock	—	15,812,735
Common stock reserved for Contingent Earnout Shares	15,000,000	—
Exercise of options under stock plans	6,711,192	4,813,262
Issuance of options under stock plans	7,418,937	2,948,598
Shares available for grant under ESPP	1,030,033	—
Warrants to purchase common stock	5,588,506	32,961
	35,748,668	77,408,386

Upon the Closing on August 26, 2021, all of the outstanding redeemable convertible preferred stock was converted to Common Stock pursuant to the conversion rate effective immediately prior to the Merger and the Exchange Ratio and the remaining amount was reclassified to additional paid-in capital.

**Preferred Stock**

The Company's Second Amended and Restated Certificate of Incorporation provides the Company's board of directors with the authority to issue \$0.0001 par value preferred stock in one more series and to establish from time to time the number of shares to be included in each such series, by adopting a resolution and filing a certification of designations. Voting powers, designations, powers, preferences and relative, participating, optional, special and other rights shall be stated and expressed in such resolutions. There were 20,000,000 shares designated as preferred stock and none were outstanding as of December 31, 2021.

**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**9. Stockholders' Equity (Deficit) (continued)****Warrants**

Activity of warrants for the year ended December 31, 2021 is set forth below:

	Legacy Humacyte Common Stock Warrants	Private Placement Warrants	Public Warrants	Total Common Stock Warrants
<b>Outstanding as of December 31, 2020</b>	32,961	—	—	32,961
Common Stock Warrants issued to SVB	411,006	—	—	411,006
Common Stock Warrants as part of the Merger	—	177,500	5,000,000	5,177,500
Warrants exercised	(32,961)	—	—	(32,961)
<b>Outstanding as of December 31, 2021</b>	<b>411,006</b>	<b>177,500</b>	<b>5,000,000</b>	<b>5,588,506</b>

In conjunction with a long-term debt agreement entered into on March 15, 2006 and paid in full during 2011, the Company issued a warrant that gave the holder the right to purchase 32,961 shares of the Company's common stock at an exercise price of \$1.14 per share, which was outstanding as of December 31, 2020. The warrant was fully exercised on March 4, 2021. There was no activity for the warrant during the year ended December 31, 2020.

See Note 7 — Debt for a discussion of warrants issued in conjunction with the Company's Loan Agreement.

**Private Placement Warrants**

The Private Placement Warrants were initially recognized as a liability on the Closing Date, at a fair value of \$0.6 million, and the Private Placement Warrant liability was remeasured to fair value as of December 31, 2021, resulting in a gain of \$0.1 million for the year ended December 31, 2021, classified within Change in fair value of common stock warrant liabilities in the consolidated statements of operations and comprehensive loss.

The Private Placement Warrants were valued using the following assumptions under the Monte Carlo simulation value model:

	December 31, 2021	August 26, 2021
Market price of public stock	\$ 7.25	\$ 10.96
Exercise price	\$ 11.50	\$ 11.50
Expected term (years)	4.65	5.00
Expected share price volatility	61.0 %	32.5 %
Risk-free interest rate	1.21 %	0.68 %
Estimated dividend yield	0 %	0 %

**Public Warrants**

The Public Warrants may only be exercised for a whole number of shares and will expire five years after the completion of the Merger. The Public Warrants became exercisable 30 days after the completion of the Merger.

The Public Warrants were initially recognized as equity on the Closing Date at a fair value of \$2.80 per share. There were no exercises of the Public Warrants during the year ended December 31, 2021.

**Contingent Earnout Liability**

Following the Closing, former holders of Legacy Humacyte common and preferred shares may receive up to 15,000,000 additional shares of the Company's common stock in the aggregate, in two equal tranches of 7,500,000 shares of common stock per tranche. The first and second tranches are issuable if the closing volume weighted average price

**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**9. Stockholders' Equity (Deficit) (continued)**

("VWAP") per share of common stock quoted on the Nasdaq (or the exchange on which the shares of common stock are then listed) is greater or equal to \$15.00 and \$20.00, respectively, over any 20 trading days within any 30 consecutive trading day period.

Upon the Closing, the contingent obligation to issue Contingent Earnout Shares was accounted for as a liability because the triggering events that determine the number of Contingent Earnout Shares required to be issued include events that are not solely indexed to the common stock of Humacyte. The estimated fair value of the total Contingent Earnout Shares at the Closing on August 26, 2021, was \$159.4 million based on a Monte Carlo simulation valuation model using a distribution of potential outcomes on a monthly basis over a ten-year period using the most reliable information available. The Contingent Earnout Liability was remeasured to fair value as of December 31, 2021, resulting in the recording of a non-cash gain of \$55.8 million for the year ended December 31, 2021, classified within Change in fair value of contingent earnout liability in the consolidated statements of operations and comprehensive loss.

Assumptions used in the valuations are described below:

	December 31, 2021	August 26, 2021
Current stock price	\$ 7.25	\$ 10.96
Expected share price volatility	85.8 %	79.6 %
Risk-free interest rate	1.52 %	1.34 %
Estimated dividend yield	0 %	0 %
Expected term (years)	10.00	10.00

**10. Stock-based Compensation**

At Closing, the 2021 Long-Term Incentive Plan, or the 2021 Plan, and the 2021 Employee Stock Purchase Plan, or the ESPP, became effective. As of December 31, 2021, 7,418,937 and 1,030,033 shares of common stock were available under the 2021 Plan and ESPP, respectively. The 2021 Plan and ESPP provide that on January 1 of each year commencing January 1, 2022, the 2021 Plan and the ESPP reserve will automatically increase in an amount equal to the lesser of (a) 5% and 1%, respectively, of the number of shares of the Company's common stock outstanding on December 31 of the preceding year and (b) a number of shares of common stock determined by the Company's board of directors. In December 2021, the Company's board of directors determined that there would be no automatic increase in the number of shares reserved under the 2021 Plan or the ESPP on January 1, 2022.

Under the 2021 Plan, the Company can grant non-statutory stock options, or NSOs, incentive stock options, or ISOs, stock appreciation rights, restricted stock, restricted stock units, unrestricted stock, performance awards and other forms of awards. Under the ESPP, eligible employees are permitted to purchase shares of the Company's common stock at the lower of 85% of the closing trading price per share of the Company's common stock on the first day of the offering or 85% of the closing trading price per share on the exercise date, which will occur on the last day of each offering.

Prior to the Closing, Legacy Humacyte had two equity incentive plans, the 2015 Omnibus Incentive Plan, as amended, or the 2015 Plan, and the 2005 Stock Option Plan, or the 2005 Plan. As a result of the Merger, no further awards may be granted under either the 2015 plan or the 2005 Plan. All awards previously granted and outstanding as of the effective date of the Merger, which totaled 5,886,706 and 518,432 shares of common stock reserved for options issued under the 2015 Plan and 2005 Plan, respectively, were adjusted to reflect the impact of the Merger as set forth in the Merger Agreement, but otherwise remain in effect pursuant to their original terms. The shares underlying any award granted under the 2021 Plan or the 2015 Plan that are forfeited, cancelled or reacquired by the Company prior to vesting, that expire or that are paid out in cash rather than shares will become available for grant and issuance under the 2021 Plan.

The Company's stock option plans allow for the grant of awards that the Company believes aid in aligning the interests of these persons with those of its stockholders. The Company's board of directors determines the specific terms of equity incentive grants, including the exercise price per share and vesting period for option awards. Option awards are granted with an exercise price equal to the fair market value of the Company's common stock at the date of grant.

**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**10. Stock-based Compensation (continued)**

The Company has granted options that include either a service-based or performance-based vesting condition, or both, and a 10-year contractual term. The service-based vesting condition for the plans is generally satisfied over 36 to 48 months from the date of grant. The performance-based vesting conditions are satisfied upon the attainment of certain product development milestones. The Company recognizes stock-based compensation expense based on the grant date fair value of the awards measured using the Black-Scholes option pricing model. Compensation expense related to awards with service-based vesting conditions is recognized on a straight-line basis over the requisite service period.

Compensation expense related to awards with performance-based vesting conditions is recognized over the requisite service period using the accelerated attribution method to the extent achievement of the performance-based condition is probable. The Company does not recognize compensation expense related to awards with performance-based vesting conditions until it is probable that the performance-based vesting condition will be achieved. Forfeitures are accounted for as they occur.

Option awards under the Company's option plans generally provide for accelerated vesting of the unvested portions of any option award in the event of an involuntary termination, as such term is defined in the relevant stock option agreement, of a grantee's employment during the period that commences 30 days prior to the effective date of a corporate transaction and that ends 12 months following the effective date of such transaction. Additionally, the Company's board of directors may, in its sole discretion, accelerate the vesting of any unvested stock options in the event of a corporate transaction.

The Company estimated the fair value of the stock options on the date of grant using the following assumptions in the Black-Scholes option-pricing model:

	Year Ended December 31,	
	2021	2020
Estimated dividend yield	0 %	0 %
Expected share price volatility (weighted average and range, if applicable)	91.4% (90.7% to 93.1%)	91.5% (89.4% to 91.6%)
Risk-free interest rate (weighted average and range, if applicable)	0.78% (0.62% to 1.32%)	0.46% (0.34% to 0.75%)
Expected term of options (in years) (weighted average and range, if applicable)	6.05 (6.00 to 6.25)	6.00

- *Fair Value of Common Stock.* As the Company's common stock was not publicly traded prior to the Merger, the fair value of the shares of its common stock underlying the options has historically been determined by the Company's board of directors with input from management, after considering independent third-party valuation reports.
- *Expected Term.* The expected term represents the period that stock options are expected to be outstanding. The Company calculated the expected term using the simplified method for options, which is available where there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this method. For awards with multiple vesting-tranches, the times from grant until the mid-points for each of the tranches may be averaged to provide an overall expected term.
- *Expected Volatility.* The expected volatility was based on the historical share volatility of several publicly traded peer companies over a period of time equal to the expected term of the options, as the Company has a limited trading history to use the volatility of its common stock. For purposes of identifying these peer companies, the Company considered the industry, stage of development, size and financial leverage of potential comparable companies.
- *Risk-Free Interest Rate.* The risk-free interest rate was based on the yields of U.S. Treasury zero-coupon securities with maturities similar in duration to the expected term of the options.

**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**10. Stock-based Compensation (continued)**

- *Expected Dividend Yield.* The Company has not paid dividends on its common stock nor does it expect to pay dividends in the foreseeable future. Accordingly, the Company has estimated the dividend yield to be zero.

At December 31, 2021, there were 7,418,937 options remaining available for grant under the 2021 Plan. The Company has sufficient authorized and unissued shares to make all issuances currently available under the 2021 Plan.

The following tables show a summary of stock-based compensation expense included in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2021 and 2020, and remaining unrecognized cost as of December 31, 2021 and 2020:

(\$ in thousands)	Year Ended December 31,	
	2021	2020
Research and development	\$ 3,220	\$ 1,135
General and administrative	6,926	3,559
<b>Total</b>	<b>\$ 10,146</b>	<b>\$ 4,694</b>

(\$ in thousands)	As of December 31,	
	2021	2020
Unrecognized share-based compensation cost	\$ 13,346	\$ 5,789
Expected weighted average period compensation costs to be recognized (years)	2.3	1.7

A summary of option activity under the Company's stock option plans during the years ended December 31, 2021 and 2020 is presented below:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Options outstanding at December 31, 2020	4,813,262	\$ 6.04	6.6	\$ 20,422
Granted	2,250,617	10.25		
Exercised	(188,278)	2.98		
Forfeited	(164,409)	8.47		
Options outstanding at December 31, 2021	6,711,192	\$ 7.48	5.3	\$ 8,276
Vested and exercisable, December 31, 2021	4,642,546	\$ 6.28	3.6	\$ 8,276
Vested and expected to vest, December 31, 2021	6,711,192	\$ 7.48	5.3	\$ 8,276

The total intrinsic value of options exercised during the years ended December 31, 2021 and 2020 was \$1.4 million and \$1.4 million, respectively.

The weighted-average grant-date fair value per share of options granted during the years ended December 31, 2021 and 2020 was \$7.63 and \$7.26, respectively.

**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

## 11. Income Taxes

The Company did not record any income tax expense or benefit during the years ended December 31, 2021 and 2020. The Company has a net operating loss and has provided a valuation allowance against net deferred tax assets due to uncertainties regarding the Company's ability to realize these assets. All losses before income taxes arose in the U.S.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and deferred tax liabilities, including valuation allowances, are as follows:

(\$ in thousands)	As of December 31,	
	2021	2020
<b>Deferred tax assets:</b>		
Net operating loss	\$ 58,646	\$ 53,515
Capitalized research and development	36,830	32,337
Research credits	16,765	15,056
Stock-based compensation	1,323	2,519
Right of use lease liability	153	177
Accrued expenses	92	57
Other	1	1
<b>Total deferred tax asset</b>	<b>113,810</b>	<b>103,662</b>
Less: valuation allowance	(111,575)	(101,757)
<b>Total net deferred tax asset</b>	<b>2,235</b>	<b>1,905</b>
<b>Deferred tax liabilities:</b>		
Basis difference in fixed assets	(2,082)	(1,728)
Right of use lease assets	(153)	(177)
<b>Total deferred tax liability</b>	<b>(2,235)</b>	<b>(1,905)</b>
<b>Total net deferred tax asset/(liability)</b>	<b>\$ —</b>	<b>\$ —</b>

A valuation allowance is provided for deferred tax assets where the recoverability of the assets is uncertain. The determination to provide a valuation allowance is dependent upon the assessment of whether it is more likely than not that sufficient future taxable income will be generated to utilize the deferred tax assets. Based on the weight of the available evidence, which includes the Company's historical operating losses, lack of taxable income and the accumulated deficit, the Company provided a full valuation allowance against the deferred tax assets resulting from the tax loss and credits carried forward as of December 31, 2021 and December 31, 2020.

On November 18, 2021, North Carolina enacted the 2021 Appropriations Act, which included a gradual corporate income tax rate decrease from the current 2.5% to 0% by 2030. The Company is in a cumulative loss position and does not have significant deferred tax liabilities that can be utilized as a source of taxable income in the future. Therefore, the Company has reduced its North Carolina deferred tax assets, including the net operating losses, to zero, as no benefit is expected to be realized from these deferred tax assets prior to 2030 when there would be no income tax in North Carolina. The reduction in the value of the deferred tax assets resulted in \$6.9 million of tax expense, which was offset fully by the reduction in the corresponding valuation allowance. If the Company becomes profitable prior to 2030, the Company will recognize an income tax benefit related to the portion of its North Carolina deferred tax assets utilized.



**HUMACYTE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**11. Income Taxes (continued)**

The reasons for the difference between the actual income tax benefit for the years ended December 31, 2021 and 2020, and the amount computed by applying the statutory Federal income tax rate to losses before income taxes are as follows:

(\$ in thousands)	December 31,			
	2021		2020	
	Amount	Rate	Amount	Rate
Income tax benefit at statutory rate	\$ (5,560)	21.0 %	\$ (13,970)	21.0 %
State income taxes, net of federal benefit	(1,706)	6.4 %	(1,338)	2.0 %
Tax credits	(2,662)	10.1 %	(2,625)	3.9 %
Other nondeductible expenses	(11,991)	45.3 %	90	(0.1)%
Deferred rate changes	8,981	(33.9)%	16	0.0 %
Deferred tax true-up <sup>(1)</sup>	3,120	(11.8)%	(1,736)	2.6 %
Change in valuation allowance	9,818	(37.1)%	19,563	(29.4)%
Provision for income taxes	\$ —	0.0 %	\$ —	0.0 %

(1) The deferred tax true-up for 2021 primarily relates to executive compensation subject to IRC Section 162(m) limitations.

As of December 31, 2021 the Company had approximately \$278.5 million and \$278.9 million of Federal and state net operating losses, respectively. Of this amount, \$117.3 million of Federal net operating losses are subject to an 80% limitation on taxable income, do not expire and will carry forward indefinitely, while the remaining amount begins to expire in 2025. Some of these state net operating losses included in these amounts follow the Federal Tax Cuts and Jobs Act and are carried over indefinitely. The Company's state net operating losses began to expire in 2020 and will expire completely in 2036. The state operating loss carryforwards are inclusive of North Carolina net operating losses, which are recorded at a zero benefit.

As of December 31, 2021 and 2020, the Company had Federal and state research tax credit carryforwards of \$17.0 million and \$15.1 million, respectively. These credit carryforwards will begin to expire in 2025 and will expire completely in 2041.

Net operating loss carryforwards and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service, or IRS, and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders or groups over a three-year period in excess of 50% as defined under Sections 382 and 383 in the Internal Revenue Code, which could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has not determined whether there have been any cumulative ownership changes or the impact on the utilization of the loss carryforwards if such changes have occurred. A section 382 study will be performed at a time when forthcoming profitability is reasonably anticipated.

On March 27, 2020, the CARES Act was passed by the U.S. Congress and signed into United States law. The CARES Act, among other things, includes certain provisions for individuals and corporations (including a suspension on the application of the 80% limitation described above for taxable years beginning prior to January 1, 2021); however, these benefits did not materially impact the Company's income tax provision in the periods presented.

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## **12. Retirement Plan**

The Company maintains two defined contribution employee retirement plans, or 401(k) plans, for all employees upon their date of hire. The 401(k) plans are intended to qualify as tax-qualified plans under Section 401(k) of the Internal Revenue Code of 1986, as amended. The plans permit employees to contribute, on a pre-tax basis, a portion of their salary up to the Federally mandated limits. The Company matches an employee's contribution up to 4% of the employee's compensation. Contributions to the plans by the Company totaled \$0.6 million for each of the years ended December 31, 2021 and 2020.

## **13. Commitments and Contingencies**

### **Patent License Agreements**

#### *Duke University*

In March 2006, the Company entered into a license agreement with Duke University, or Duke, which was subsequently amended in 2011, 2014, 2015, 2018, 2019 and January 2022. Under this license agreement, Duke granted the Company a worldwide, exclusive, sublicensable license to certain patents related to decellularized tissue engineering, referred to as the patent rights, as well as a non-exclusive license to use and practice certain know-how related to the patent rights. The relevant licensed patent on decellularization of tissue expired in 2021. The Company has agreed to use commercially reasonable efforts to develop, register, market and sell products utilizing the patent rights, referred to as the licensed products. Any services provided to a third party utilizing licensed products are referred to as licensed services. The Company has also agreed to meet certain benchmarks in its development efforts, including as to development events, clinical trials, regulatory submissions and marketing approval, within specified timeframes. Under the license agreement, Duke retains the right to use the patent rights for its own educational and research purposes, and to provide the patent rights to other non-profit, governmental or higher-learning institutions for non-commercial purposes without paying royalties or other fees.

In connection with the Company's entry into the license agreement, the Company granted equity consideration to Duke in the form of 52,693 shares of the Company's common stock. Under the license agreement, the Company also agreed to pay Duke:

- a low single-digit percentage royalty on eligible sales of licensed products and licensed services, plus a low double-digit percentage of any sublicensing revenue;
- an annual minimum royalty beginning in 2012, which increases in the calendar year immediately following the first commercial sale of licensed products or licensed services (whichever occurs first); and
- an additional amount in license fees, as certain milestones are met.

The license agreement remains effective until the later of (i) the last of the patent rights expires or (ii) four years after the Company's first commercial sale, unless terminated earlier. Either party may terminate the agreement for fraud, willful misconduct or illegal conduct, or uncured material breach. Duke may terminate the agreement if the Company becomes insolvent. Duke may also terminate the license, convert the license into a non-exclusive license or seek assignment of any sublicense if the Company fails to reach diligence milestones within the applicable time period. If the Company abandons any claim, patent or patent application, its rights under the license with respect to such patent rights will be terminated in the territory in which the Company abandons such rights. The Company may terminate the license agreement unilaterally upon three months' prior notice to Duke. The Company agrees to indemnify Duke against certain third-party claims. Payments to Duke under the license agreement were immaterial during the periods presented.

#### *Yale University*

In February 2014, the Company entered into a license agreement with Yale University, ("Yale"), that granted the Company a worldwide license to the patents related to coatings for small-diameter vessels to inhibit clotting. The license granted under the agreement is exclusive in the field of engineered vascular tissues and tissues and extracellular matrix-

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

### 13. Commitments and Contingencies (continued)

based implants used for vascular repair, reconstruction and replacement (provided that all uses are vascular tissues within the range of 1 – 12mm in diameter), except that it is subject to Yale’s non-exclusive right, on behalf of itself and all other non-profit academic institutions, to use the licensed products for research, teaching, and other non-commercial purposes. The Company has agreed to pay to Yale an annual maintenance fee, increasing between the first and fourth anniversaries of the agreement up to a maximum of less than \$0.1 million per year for this license.

In August 2019, the Company entered into a license agreement with Yale, that granted the Company a worldwide license to the patents related to Bioartificial Vascular Pancreas (“BVP”). The license granted under the agreement is exclusive in the field of engineered vascular tissues that deliver pancreatic islet cells to patients, except that it is subject to Yale’s non-exclusive right, on behalf of itself and all other non-profit academic institutions, to use the licensed products for research, teaching, and other non-commercial purposes. The Company has agreed to pay to Yale an annual maintenance fee, increasing between the first and fourth anniversaries of the agreement up to a maximum of less than \$0.1 million per year for this license.

In August 2019, the Company entered into a license agreement with Yale, that granted the Company a worldwide license to the patents related to tubular prostheses. The license granted under the agreement is exclusive in the field of engineered urinary conduits, engineered tracheas/airways, and engineered esophagi, except that it is subject to Yale’s non-exclusive right, on behalf of itself and all other non-profit academic institutions, to use the licensed products for research, teaching, and other non-commercial purposes. The Company has agreed to pay to Yale an annual maintenance fee, increasing between the first and fourth anniversaries of the agreement up to a maximum of less than \$0.1 million per year for this license.

The Company has agreed to use reasonable commercial efforts to develop and commercialize the licensed patents and any licensed products and methods, and to use reasonable efforts to make the licensed products available to patients in low and low-middle income countries. The Company is also obligated to provide Yale periodically an updated and revised copy of its plan for each license, which must indicate progress of its development and commercialization. The Company may also sublicense the Company’s rights without Yale’s prior written consent, but such sublicense is subject to certain conditions.

In connection with its entry into the license agreement, the Company paid Yale upfront cash fees. The Company has also agreed to pay Yale:

- annual maintenance fees, increasing between the first anniversary of the agreement until the fifth anniversary for the coating and BVP licenses and until the fourth anniversary for the tubular prostheses license up to a maximum of less than \$0.1 million per year;
- milestone payments upon achievement of certain regulatory and commercial milestones of \$0.2 million and \$0.6 million;
- a low single-digit percentage royalty on worldwide net sales, subject to reductions for third-party license fees; and
- a low double-digit percentage of sublicensing income.

If the Company or any of its future sublicensees bring a patent challenge against Yale or assists another party in bringing a patent challenge against Yale, the license fees described above will be subject to certain increases and penalties.

The agreements expire on a country-by-country basis on the date on which the last of the patents in such country expires, lapses or is declared invalid. Yale may terminate the agreements if the Company fails to (i) provide written diligence reports, (ii) provide commercially reasonable diligence plans, (iii) implement the plans in accordance with the obligations under the agreements, or (iv) reach certain research and development milestones within the scheduled timeframe set forth in the agreements; however, any such termination right would be limited in scope to the country to which such failure relates. Yale may also terminate for the Company’s non-payment, uncured material breach, failure to obtain adequate insurance, bringing or assisting in bringing of a patent challenge against Yale, abandonment of the research and development of the Company’s products or insolvency. The Company may terminate the license agreements (i) on 90 days’ prior written notice to Yale, provided the Company is not in breach of the license agreements and has made all

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**13. Commitments and Contingencies (continued)**

required payments to Yale thereunder and (ii) on written notice to Yale following an uncured material breach. With respect to the license agreements related to small-diameter vessels and BVP, the Company's rights under the license agreements will also terminate automatically with respect to a patent application or patent within the licensed patents in a specified country if, upon receipt of written notice from Yale, the Company does not agree to pay the patent filing, prosecution and maintenance fees incurred by Yale for such patent applications or patents in the specified country. Under certain circumstances, Yale may, at its option, convert the exclusive licenses to non-exclusive licenses if the Company declines to initiate certain infringement or interference proceedings with respect to the licensed patents. The Company has agreed to indemnify Yale against certain third-party claims. Payments to Yale under the license agreement were immaterial during the periods presented.

**Legal Matters**

The Company currently is not aware of any legal proceedings or claims that management believes will have, individually or in the aggregate, a material adverse effect on the Company's business, financial condition, results of operations, or cash flows.

**Indemnification**

To the extent permitted under Delaware law, the Company has agreed to indemnify its directors and officers for certain events or occurrences while the director or officer is, or was serving, at the Company's request in such capacity. The indemnification period covers all pertinent events and occurrences during the director's or officer's service. The maximum potential amount of future payments the Company could be required to make under these indemnification arrangements is not specified in such arrangements; however, the Company has director and officer insurance coverage that is intended to reduce its exposure and enable the Company to recover a portion of any potential future amounts the Company could be required to make. To date, the Company has not incurred any costs as a result of such obligations and has not accrued any liabilities related to such obligations in the consolidated financial statements.

**14. Related Party Transactions***Fresenius Medical Care investments and distribution agreement*

In June 2018, the Company completed a \$150 million financing transaction pursuant to which Fresenius Medical Care purchased shares of series D redeemable convertible preferred stock that at the Closing of the Merger converted into 15,812,735 shares of the Company's common stock. In August 2021, Fresenius Medical Care invested \$25 million as part of the PIPE Financing and received 2.5 million shares of the Company's common stock.

In addition, the Company entered into a distribution agreement with Fresenius Medical Care in June 2018 which, as amended as of February 16, 2021, granted Fresenius Medical Care and its affiliates exclusive rights to develop outside the United States and EU and commercialize outside of the United States the Company's 6 millimeter x 42 centimeter HAV and all improvements thereto, and modifications and derivatives thereof (including any changes to the length, diameter or configuration of the foregoing), for use in vascular creation, repair, replacement or construction, including renal replacement therapy for dialysis access, the treatment of peripheral arterial disease, and the treatment of vascular trauma, but excluding coronary artery bypass graft, pediatric heart surgery, or adhering pancreatic islet cells onto the outer surface of the distribution product for use in diabetic patients. Within the United States, Fresenius Medical Care will collaborate with the Company in its commercialization of the product in the field, including adoption of the distribution product as a standard of care in patients for which such use is supported by clinical results and health economic analyses.

The Company is responsible for developing and seeking regulatory approval for the distribution product in the field in the United States. For countries outside the United States, the parties agreed to use commercially reasonable efforts to satisfy certain agreed minimum market entry criteria for the distribution product in the field in such country. For the EU, once such criteria have been satisfied for the applicable country, or if the parties otherwise mutually agree to obtain regulatory approval for the distribution product in the field in the applicable country, the Company agreed to use commercially reasonable efforts to obtain such regulatory approval (other than pricing approval), and Fresenius Medical Care agreed to use commercially reasonable efforts to obtain the corresponding pricing approval. For the rest of the world

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**14. Related Party Transactions (continued)**

(i.e., outside the United States and the EU), once such criteria have been satisfied for the applicable country, or if the parties otherwise mutually agree to obtain regulatory and pricing approval for the distribution product in the field in the applicable country, Fresenius Medical Care agreed to use commercially reasonable efforts to obtain such approvals, and the Company agreed to use commercially reasonable efforts to support Fresenius Medical Care in its efforts.

Under the distribution agreement, the Company grants an exclusive, sublicensable license to Fresenius Medical Care under the patents, know-how and regulatory materials controlled by the Company during the term to commercialize the distribution product in the field outside the United States, subject to the Company's retained rights to carry out its obligations under the distribution agreement. The Company also grants a non-exclusive, sublicensable license to Fresenius Medical Care under the patents, know-how and regulatory materials controlled by the Company during the term to develop the distribution product in accordance with the terms of the distribution agreement. In addition, the Company grants to Fresenius Medical Care, among other things, a perpetual, irrevocable, non-exclusive sublicensable license under the patents and know-how that primarily relate to the distribution product or its manufacture and that were created, conceived or developed solely or jointly by or on behalf of Fresenius Medical Care in the performance of its activities under the distribution agreement.

The distribution agreement provides that the Company will own all know-how and patents that primarily relate to the distribution product or its manufacture that are created, conceived or developed by or on behalf of either party in the performance of activities under the distribution agreement. Ownership of all other know-how, patents, materials and other intellectual property created, conceived or developed during the performance of activities under the distribution agreement will be determined in accordance with U.S. patent laws for determining inventorship.

The Company is obligated to make payments to Fresenius Medical Care based on a share of aggregate net sales by or on behalf of the Company of the distribution product in the United States in the field. Such revenue-share payments will be a percentage of net sales in the low double digits, without regard to the calendar year in which such net sales are attributable, until such time that the Company has paid to Fresenius Medical Care a certain total amount, at which time the revenue-share will decrease to a percentage of net sales in the mid-single digits. The amounts that Fresenius Medical Care will be obligated to pay the Company under the distribution agreement for sales of the distribution product in the field outside of the United States will vary. Fresenius Medical Care agreed to pay the Company initially, on a country-by-country basis for sales outside of the United States, the amount equal to the average cost of manufacturing the Company's distribution product plus a fixed dollar amount per unit. Following a specified period, on a country-by-country basis outside of the United States, Fresenius Medical Care will pay the Company a fixed percentage of net sales for each unit sold in such country, such that the Company will receive more than half of such net sales.

The distribution agreement will generally continue on a country-by-country basis until the later of (a) the tenth anniversary of the launch date of the distribution product in the relevant country or (b) the expiration of the last-to-expire valid claim of specified patents in such country. Each party is permitted to terminate the distribution agreement for insolvency of, or, under certain circumstances, including various cure periods, material breach by the other party. Subject to a cure period, Fresenius Medical Care may also terminate the distribution agreement in its entirety or on a country-by-country basis (i) for certain withdrawals of regulatory approval or (ii) for termination or expiration of any of our in-licenses that is necessary for the exercise of Fresenius Medical Care's rights, or the satisfaction of its obligations, under the distribution agreement. In addition, Fresenius Medical Care may terminate the distribution agreement for convenience on a country-by-country basis upon not less than 12 months' written notice to the Company, although Fresenius Medical Care is not permitted to give such notice prior to the end of the second year following launch of the distribution product in such country. Each party is required to indemnify one another for certain third-party claims.

*Arrangements with Dr. Niklason and Yale University*

In September 2016, the Company entered into a Memorandum of Understanding Regarding Scientific and Operational Leadership, or MOU, with Dr. Niklason in connection with her performance of various consulting activities for the Company.

The MOU provided for the Company to make a payment each year through 2023 to the academic institution with which Dr. Niklason was then affiliated, up to an aggregate amount of \$2.5 million for 2018 through 2023, and to pay Dr.

**HUMACYTE, INC.**  
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**14. Related Party Transactions (continued)**

Niklason reasonable consulting fees in consideration of the services she performed for the Company. For the year ended December 31, 2020, the Company made payments under the MOU of \$0.5 million, to, or on behalf of, Yale University, where Dr. Niklason serves as an Adjunct Professor in Anesthesia. The MOU was terminated effective November 9, 2020.

The following table shows a summary of related party expenses included in the statements of operations and comprehensive loss for the years ended December 31, 2021 and 2020:

(\$ in thousands)	Year Ended December 31,	
	2021	2020
Expenses under MOU	\$ —	\$ 500
License expenses	85	92
Other	91	28
Total	<u>\$ 176</u>	<u>\$ 620</u>

As of December 31, 2021 and December 31, 2020, the Company was a party to license agreements with Yale University, as described in Note 13 — Commitments and Contingencies above.

## **Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure**

None.

### **Item 9A. Controls and Procedures**

#### **Evaluation of Disclosure Controls and Procedures**

Disclosure controls and procedures are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is (i) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

As of December 31, 2021, our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2021.

#### **Management's Report on Internal Control Over Financial Reporting**

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting ("ICFR"), as allowed by the SEC for reverse acquisitions between an issuer and a private operating company when it is not possible to conduct an assessment of the private operating company's ICFR in the period between the consummation date of the reverse acquisition and the date of management's assessment of ICFR (pursuant to Section 215.02 of the SEC Division of Corporation Finance's Regulation S-K Compliance & Disclosure Interpretations). As discussed elsewhere in this Annual Report on Form 10-K, we completed the Merger on August 26, 2021, pursuant to which we acquired Legacy Humacyte. Prior to the Merger, we were a special purpose acquisition company formed for the purpose of effecting a merger. As a result, previously existing internal controls are no longer applicable or comprehensive enough as of the assessment date as our operations prior to the Merger were insignificant compared to those of the consolidated entity post-Merger. The design of ICFR for the Company post-Merger has required and will continue to require significant time and resources from management and other personnel. As a result, management was unable, without incurring unreasonable effort or expense, to conduct an assessment of our ICFR as of December 31, 2021.

#### **Attestation Report of the Registered Public Accounting Firm**

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting due to a transition period established by the rules of the SEC for newly public companies. We are an "emerging growth company" as defined in the JOBS Act. For as long as we remain an "emerging growth company," we are exempt from the auditor attestation requirement in the assessment of the effectiveness of our internal control over financial reporting.

#### **Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **Item 9B. Other Information**

None.

### **Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections**

None.

**Part III****Item 10. Directors, Executive Officers and Corporate Governance.**

The following table sets forth certain information regarding our current executive officers and directors:

<b>Name</b>	<b>Age</b>	<b>Position(s)</b>
<i>Executive Officers:</i>		
Laura E. Niklason	59	President, Chief Executive Officer and Director
Dale A. Sander	62	Chief Financial Officer, Chief Corporate Development Officer and Treasurer
Heather Prichard	44	Chief Operating Officer
William Tente, M.S.	64	Chief Regulatory Officer
William (B.J.) Scheessele	51	Chief Commercial Officer
<i>Non-Employee Directors:</i>		
Gordon M. Binder <sup>(2)(4)</sup>	86	Director
Emery N. Brown <sup>(2)</sup>	65	Director
Michael T. Constantino <sup>(1)(3)</sup>	59	Director
Brady W. Dougan	62	Director
Todd M. Pope <sup>(3)(4)</sup>	56	Director
Kathleen Sebelius <sup>(1)</sup>	73	Director and Chair
Rajiv Shukla <sup>(4)</sup>	47	Director
Max Wallace <sup>(2)(3)</sup>	70	Director
Susan Windham-Bannister <sup>(1)(4)</sup>	70	Director

(1) Member of the audit committee.

(2) Member of the nominating and governance committee.

(3) Member of the compensation committee.

(4) Member of the commercial committee.

**Executive Officers**

**Laura E. Niklason** is the founder of Legacy Humacyte. Dr. Niklason has served as our President and Chief Executive Officer and as a member of the Board since the Merger, and has served as President and Chief Executive Officer of Legacy Humacyte since November 2020 and as a member of the Legacy Humacyte board of directors since 2004. Dr. Niklason has served in a senior scientist capacity from 2005 through 2020. Dr. Niklason has also served as an adjunct professor at Yale University since November 2020 and previously served as the Nicholas M. Greene Professor of Anesthesiology and Biomedical Engineering at Yale University from 2006 to November 2020. She was inducted into the National Academy of Inventors in 2014 and was elected to the National Academy of Medicine and the National Academy of Engineering in 2015 and 2020, respectively. Dr. Niklason is currently on the board of directors of Self Study Inc., a private learning optimization technology company. Dr. Niklason holds a Ph.D. in Biophysics from the University of Chicago and an M.D. from the University of Michigan. Dr. Niklason completed her residency training in anesthesia and intensive care unit medicine at the Massachusetts General Hospital and completed post-doctoral scientific training at the Massachusetts Institute of Technology. Dr. Niklason is married to Mr. Dougan, a member of the Board.

We believe that Dr. Niklason is qualified to serve as a director based on her significant experience in the biotechnology industry, her extensive training in medicine and science and her role as the founder of Legacy Humacyte.

**Dale A. Sander** has served as our Chief Financial Officer, Chief Corporate Development Officer and Treasurer since the Merger. Mr. Sander has served as Legacy Humacyte's Chief Financial Officer and Treasurer since May 2021, as Legacy Humacyte's Chief Corporate Development Officer since November 2020 and as a member of the Legacy Humacyte board of directors since September 2015. He served as the Chief Financial Officer of Bryn Pharma, a privately



held life sciences company, from 2019 to 2021. Prior to that, Mr. Sander served as Chief Financial Officer of AVITA Medical Limited, a publicly traded regenerative medicine company, from 2017 to 2019, and as Senior Vice President, Global Accounting Officer at Sutherland Global Services, Inc. from 2012 to 2017. Mr. Sander served as a Senior Manager with Ernst & Young and holds a B.S. in Business Administration from San Diego State University.

**Heather Prichard** has served as our Chief Operating Officer since the Merger and previously served as Legacy Humacyte's Chief Operating Officer since March 2019. Dr. Prichard has served as Legacy Humacyte's Senior Vice President of Product Development from April 2016 to February 2019 and served in other management roles with Legacy Humacyte since 2012. Dr. Prichard joined Legacy Humacyte in 2008 and has been instrumental in leading the process and product development teams for the HAV through all phases of clinical development. Prior to joining Legacy Humacyte, Dr. Prichard held roles at The Procter & Gamble Company in research, development, and engineering from June 1999 to August 2002. Dr. Prichard holds a Ph.D. in Biomedical Engineering with a focus on investigating the healing response to implantable tissue engineered biomaterials from Duke University and a B.A. in Chemical Engineering from the Georgia Institute of Technology.

**William Tente** has served as our Chief Regulatory Officer since the Merger and has served as Legacy Humacyte's Chief Regulatory Officer since March 2018. Mr. Tente joined Legacy Humacyte in 2008 and served in a variety of leadership roles, including as Vice President of Manufacturing and Regulatory Affairs, prior to his promotion to Chief Regulatory Officer. Previously, Mr. Tente served as Vice President of Operations for Neurotech USA, Inc., a biotechnology company, from July 2002 to August 2007, Director of Operations of Chimeric Therapies, Inc., a former clinical-stage biotechnology company, from January 1998 to June 2002, and Director of Clinical Production at CytoTherapeutics, Inc., a former clinical-stage biotechnology company, from 1992 to 1998. Mr. Tente was elected to the United States Pharmacopeia (USP) Council of Experts in 1998 and served as the Chairman of its Expert Committee on Gene Therapy, Cell Therapy and Tissue Engineering Products from 2005 to 2010. Mr. Tente holds a B.S. and M.S. in cell biology and microbiology from the University of Rhode Island and studied at the W. Alton Jones Cell Sciences Center.

**William (B.J.) Scheessele** has served as Humacyte's Chief Commercial Officer since August 2021. He served as Executive Vice President of Global Marketing for Quest Medical Imaging Inc. from 2018 to 2021. Previously, Mr. Scheessele served as Vice President, Marketing at Sientra, Inc., a medical device company, from 2017 to 2018. Prior to that, he served as Vice President of North America Marketing and Canada Country Manager, among other roles in sales and marketing, at LifeCell Corporation, a regenerative medicine company, from 2007 to 2016, and as Vice President, North American Marketing and Reimbursement at Allergan plc, a global biopharmaceutical company, from 2016 to 2017, after its acquisition of LifeCell Corporation. Earlier in his career, Mr. Scheessele worked in business development and product management with Cordis Corporation, a medical device company and subsidiary of Johnson & Johnson, from 1998 to 2007. Mr. Scheessele earned a BSE in biomedical engineering and economics and an M.B.A. from Duke University.

Each of our executive officers serves at the discretion of the Board and will hold office until the election or qualification of his or her successor or until his or her earlier death, resignation or removal.

#### **Non-Employee Directors**

**Brady W. Dougan** has served as a member of our Board since the Merger. He previously served as the chair of the Legacy Humacyte board of directors from March 2019 to August 2021 and as a member of its board of directors since 2005. Since July 2015, Mr. Dougan has served as Chairman and Chief Executive Officer of Exos Securities ("Exos"). From May 2007 through June 2015, Mr. Dougan served as Chief Executive Officer and Member of the Executive Board of Credit Suisse Group AG and Credit Suisse AG, steering the bank through the financial crisis of 2008 and various reforms and changes in the banking industry. Prior to that time, Mr. Dougan served in various leadership positions at Credit Suisse. Mr. Dougan currently serves on the Board of Trustees for the University of Chicago. Mr. Dougan holds a B.A. in Economics and an M.B.A. in Finance from the University of Chicago. Mr. Dougan is married to Laura E. Niklason, Humacyte's President and Chief Executive Officer and a member of our Board.

We believe that Mr. Dougan is qualified to serve as a director based on his significant executive leadership experience and his extensive experience related to financing for public and private companies.

**Emery N. Brown** has served as a member of our Board since the Merger. Dr. Brown currently serves as the Warren M. Zapol Professor of Anaesthesia at Harvard Medical School and the Edward Hood Taplin Professor of Medical Engineering and Computational Neuroscience at the Massachusetts Institute of Technology. He has been on the faculty at Harvard Medical School and MIT since May 1992 and October 2005, respectively. Dr. Brown has also served as an anesthesiologist at Massachusetts General Hospital since May 1992. Dr. Brown currently serves on the Board of Trustees of the Guggenheim Foundation, the Board of Trustees of the Simmons Foundation, the National Academy of Medicine Forum on

Neurological Disorders and the board of PASCALL Systems, Inc., an early-stage medical device startup. Dr. Brown is a member of the National Academy of Inventors, the National Academy of Medicine, the National Academy of Sciences and the National Academy of Engineering. Dr. Brown holds an M.D. from Harvard Medical School, a Ph.D. and M.A. in statistics from Harvard University and a B.A. in applied mathematics from Harvard College.

We believe that Dr. Brown is qualified to serve as a director based on his extensive medical and scientific knowledge and experience.

**Kathleen Sebelius** is the chair of our Board. She has served as a member of our Board since the Merger and previously served as a member of the Legacy Humacyte board of directors since September 2015. Ms. Sebelius is the Chief Executive Officer of Sebelius Resources LLC. From April 2009 to June 2014, Ms. Sebelius served as Secretary of the Department of Health and Human Services, or HHS. Prior to serving as Secretary of HHS, Ms. Sebelius was the Governor of Kansas and served two terms as the Kansas insurance commissioner and four terms in the Kansas Legislature. Ms. Sebelius currently serves on the board of directors of the following public companies: Devoted Health, Inc., Include Health Inc. and Exact Sciences Corporation. She also serves as a director of the Kaiser Family Foundation. Ms. Sebelius co-chairs the Aspen Institute Health Strategy Group and serves on advisory boards for the Dole Institute of Politics, Solera Health, Out Leadership, the Estée Lauder Foundation, the University of Kansas College of Liberal Arts and Sciences, and Zipline. Ms. Sebelius holds a master of public administration degree from the University of Kansas and a B.A. in Political Science from Trinity Washington University.

We believe that Ms. Sebelius is qualified to serve as a director based on her distinguished leadership in the healthcare reimbursement industry, tenure in the public sector and experience with regulatory process and policies.

**Rajiv Shukla** has served as a member of our Board since the Merger. Mr. Shukla served as AHAC's Chairman and Chief Executive Officer since inception and has two decades of buyouts, investments and operations experience in the healthcare industry. Mr. Shukla served as Chairman and Chief Executive Officer of CNAC, a Nasdaq-listed special purpose acquisition company, from June 2017 to August 2019. CNAC raised \$144 million in proceeds from a Nasdaq initial public offering and successfully closed its initial business combination with DermTech, Inc., or DermTech, in August 2019. Since August 2019, Mr. Shukla has served as an independent director on the board of directors of InflammX Therapeutics, formerly known as Ocularis Therapeutics, a clinical stage biotech company. From June 2013 to May 2015, Mr. Shukla served as Chief Executive Officer of Pipavav Defence & Offshore Engineering Company (now Reliance Naval and Engineering Ltd.), an Indian listed shipbuilding and defense manufacturing company. Between 2008 and 2013, Mr. Shukla worked as an investor at ICICI Venture, Morgan Stanley Investment Management and Citi Venture Capital International. From 2001 to 2006, Mr. Shukla served as Senior Director at Pfizer, Inc. Mr. Shukla holds a masters in healthcare management and policy degree from Harvard University and received a bachelor's in pharmaceuticals from the Indian Institute of Technology.

We believe that Mr. Shukla is qualified to serve as a director based on the depth of his experience in the healthcare industry and in providing strategic guidance to numerous companies.

**Max Wallace** has served as a member of our Board since the Merger and previously served as a member of the Legacy Humacyte board of directors since June 2005. Mr. Wallace served as Chief Executive Officer of Accelerate Brain Cancer Cure, or ABC<sup>2</sup>, a not-for-profit corporation seeking to drive research and treatments for brain tumors from August 2008 to December 2019. Prior to joining ABC<sup>2</sup>, Mr. Wallace served as the Chief Executive Officer of TheraLogics, Inc. an early-stage biopharmaceutical company, and as President of Trimeris, Inc., a formerly public biopharmaceutical company founded by Mr. Wallace that created and brought to market a new class of drugs for the treatment of HIV, AIDS and other viral diseases and is now a part of Synageva BioPharma Corp. Mr. Wallace also founded and developed several other biopharmaceutical companies, including Cogent Neuroscience, Sphinx Pharmaceuticals Corporation, now a part of Eli Lilly & Company, and SARCO, Inc., now a part of PPD/Pharmaco, and co-founded and served as President of the North Carolina Bioscience Organization, the biotechnology industry's trade organization in North Carolina. Mr. Wallace holds a B.A. in English and Political Science from Duke University and a J.D. from the University of Florida.

We believe that Mr. Wallace is qualified to serve as a director based on the depth of his experience in the biotechnology industry, including his service in executive roles at multiple emerging biopharmaceutical companies and his oversight of the development and commercialization of innovative technologies.

**Susan Windham-Bannister** has served as a member of our Board since the Merger. Dr. Windham-Bannister has served as President and Chief Executive Officer of Biomedical Growth Strategies, LLC, a strategic advisory firm serving the life sciences and healthcare industries, since September 2015. From 2008 to 2015, Dr. Windham-Bannister served as founding President and Chief Executive Officer of the Massachusetts Life Sciences Initiative, a \$1 billion life sciences-

dedicated investment fund. Dr. Windham-Bannister currently serves on the board of directors of Aridis Pharmaceuticals, Inc., a public late-stage biopharmaceutical company. She is the Chair of the National Board of Directors of the Association for Women in Science (AWIS), serves on the board of directors of St. Jude's Children's Research Hospital, and Chairs the board of BioscienceLA, a nonprofit independent innovation catalyst organization. Dr. Windham-Bannister holds a Ph.D. in Health Policy and Management from the Florence Heller School at Brandeis University. She was a Post-Doctoral Fellow at Harvard University's John F. Kennedy School and a Fellow in the Center for Science and Policy (CSAP) at Cambridge University, Cambridge, England.

We believe that Dr. Windham-Bannister is qualified to serve as a director based on her status as an internationally recognized expert in innovation, market access, and market optimization strategies.

**Gordon M. Binder** has served as a member of our Board since the Merger. Mr. Binder served as the Chief Executive Officer of Amgen, Inc. from 1998 through 2000. Mr. Binder joined Amgen in 1982 as Chief Financial Officer, having previously served as the Chief Financial Officer of System Development Corporation, a computer system and software company, and in financial management positions at Litton Industries and Ford Motor Company. After retiring from Amgen, Mr. Binder founded Coastview Capital LLC, a biotech venture capital firm. Mr. Binder currently serves as Chairman of the Board of Directors of NEUVOGEN, Inc., a private immunoncology company. Mr. Binder has also served as the Chairman of BIO, the biotechnology industry trade association, and as Chairman of PHRMA, the pharmaceutical industry trade association. He has served as a member of the board of directors of the Massachusetts Institute of Technology, the California Institute of Technology, the American Enterprise Institute and Pepperdine University. Mr. Binder is a fellow of the American Academy of Arts and Sciences and is the author of *Science Lessons: What the Business of Biotech Taught Me About Management*. Mr. Binder holds a B.S. in electrical engineering from Purdue University and an M.B.A. from Harvard Business School, where he was a Baker Scholar.

We believe that Mr. Binder is qualified to serve as a director based on the depth of his experience in the life sciences industry, including his service in executive roles at Amgen.

**Michael T. Constantino** is a retired Ernst & Young LLP assurance partner who served in the Research Triangle Park region of North Carolina for over 30 years. From 2009 to 2012, he served as the Office Managing Partner for the combined Raleigh/Greensboro office of Ernst & Young with over 200 employees. Currently, Mr. Constantino serves as the member of the Board and the Chairman of the Audit Committee of 9 Meters Biopharma, Inc., a Nasdaq-listed clinical-stage biopharmaceutical company. He is also the Chair of the Board for the NC State Foundation and a member of the Board of The Green Chair Project, and serves on the Advisory Board for CREO, Inc., an RTP-based consultancy focused on growth management and data transformation services. Mr. Constantino holds a B.A. in both Accounting and Business Management from NC State University and is a North Carolina Certified Public Accountant, or CPA.

We believe that Mr. Constantino is qualified to serve as a director based on his extensive experience as a CPA and with SEC compliance matters and Sarbanes-Oxley internal controls.

**Todd M. Pope** has served as the President and Chief Executive Officer of WellAir Group Ltd., a leading clean air solutions company, since February 2021. Prior to its acquisition by WellAir, Mr. Pope served as the Executive Chairman of UV Innovators, LLC, a developer of medical-grade handheld UVC disinfection technology, from February 2017 to February 2021. From 2008 to 2019, Mr. Pope served as the Chief Executive Officer of TransEnterix, Inc. (now Asensus Surgical, Inc.), a medical device company. He also previously served as worldwide president of Cordis, a multi-billion-dollar division within Johnson & Johnson's medical device business. Mr. Pope currently serves as the Chairman of the Board of Directors of AdvaMed ACCEL and as a member of the Board of Directors of WELL.Co, a private digital health company. Mr. Pope also serves on the Kenan-Flagler Board of Visitors and the Educational Foundation for the University of North Carolina at Chapel Hill, where he is the immediate past Executive Chairman of the Board. Time Magazine named Mr. Pope one of the "50 most influential people in healthcare 2018." Mr. Pope holds a B.A. in Labor and Industrial Relations from the University of North Carolina.

We believe that Mr. Pope is qualified to serve as a director based on his extensive experience in key leadership positions at public and private companies within the healthcare industry.

## **Board Composition**

The Board directs the management of our business and affairs, as provided by Delaware law, and conducts its business through meetings of the Board and its standing committees.

The Board consists of ten members. Kathleen Sebelius serves as chair of the Board. The primary responsibilities of the Board are to provide risk oversight and strategic guidance to Humacyte and to counsel and direct our management. The Board meets on a quarterly basis and will convene additional meetings, as required.

Fresenius Medical Care has designated one representative to attend, in a non-voting observer capacity, all meetings of the Board.

The Board is divided into three classes of directors, with the directors serving three-year terms. Mr. Dougan and Mr. Wallace are currently Class I directors; Mr. Binder, Mr. Pope, Ms. Sebelius and Mr. Shukla are Class II directors; and Dr. Brown, Mr. Constantino, Dr. Niklason and Dr. Windham-Bannister are Class III directors. The term of office of the Class I directors will expire at the 2022 annual meeting of stockholders, which is the first annual meeting of stockholders following the initial classification of the Board. At the second annual meeting of stockholders following such classification, the term of office of the Class II directors will expire and Class II directors will be elected for a full term of three years. At the third annual meeting of stockholders following such classification, the term of office of the Class III directors will expire and Class III directors will be elected for a full term of three years.

### **Family Relationships**

Dr. Niklason, our President and Chief Executive Officer, is married to Mr. Dougan. Both Dr. Niklason and Mr. Dougan serve on the Board. There are no additional family relationships among the directors and executive officers of Humacyte.

### **Independence of Directors**

The Nasdaq listing standards generally define an “independent director” as a person who is not an executive officer or employee, or who does not have a relationship which, in the opinion of the company’s board of directors, would interfere with the exercise of independent judgment in carrying out his or her responsibilities as a director. In assessing director independence, the Board concluded that the independent directors have no conflict that might discourage critical review of the Company’s management and operations. The Board has determined that Gordon M. Binder, Emery N. Brown, Michael T. Constantino, Todd M. Pope, Kathleen Sebelius, Max Wallace and Susan Windham-Bannister are considered independent directors of Humacyte. The independent directors hold regularly scheduled meetings at which only independent directors are present.

### **Board Leadership Structure and Role in Risk Oversight**

The Board recognizes that the leadership structure and combination or separation of the Chief Executive Officer and chairperson roles is driven by the needs of Humacyte at any point in time. As a result, no policy exists requiring combination or separation of leadership roles, and Humacyte’s governing documents do not mandate a particular structure. The Board believes this structure will allow it the flexibility to establish the most appropriate structure for Humacyte at any given time.

The Board oversees the risk management activities designed and implemented by Humacyte’s management. The Board does not have a standing risk management committee, but rather executes its oversight responsibility both directly and through its standing committees. The Board also considers specific risk topics, including risks associated with Humacyte’s strategic initiatives, business plans and capital structure. Humacyte’s management, including our executive officers, are primarily responsible for managing the risks associated with the business and operations of the company and provide appropriate updates to the Board and the audit committee. The Board has delegated to the audit committee oversight of its risk management process, and the other committees of the Board also consider risks as they perform their respective committee responsibilities. All Board committees report to the Board as appropriate, including, but not limited to, when a matter rises to the level of a material or enterprise risk.

### **Committees of the Board of Directors**

The Board has an audit committee, a nominating and governance committee, a compensation committee, and a commercial committee. In addition, from time to time, special committees may be established under the direction of the Board when necessary to address specific issues. Copies of each Board committee’s charter are posted on Humacyte’s website at [www.humacyte.com](http://www.humacyte.com). Humacyte’s website and the information contained on, or that can be accessed through, such website are not deemed to be incorporated by reference in, and are not considered part of, this Annual Report on Form 10-K.

### ***Audit Committee***

The audit committee consists of Michael T. Constantino, Kathleen Sebelius, and Susan Windham-Bannister. Michael T. Constantino serves as the chairperson of the audit committee. The Board has determined that each of Michael T. Constantino, Kathleen Sebelius, and Susan Windham-Bannister is independent under Nasdaq listing standards and Rule 10A-3 of the Exchange Act. Each member of the audit committee is financially literate. The Board also has determined that Michael T. Constantino is an “audit committee financial expert” within the meaning of SEC regulations.

The audit committee has the following responsibilities, among others, as set forth in the audit committee charter:

- selecting a firm to serve as the independent registered public accounting firm to audit our financial statements;
- ensuring the independence of the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm and reviewing, with management and that firm, our interim and year-end operating results;
- establishing procedures for employees to anonymously submit concerns about questionable accounting or audit matters;
- considering the adequacy of our internal controls;
- reviewing material related party transactions or those that require disclosure; and
- pre-approving audit and non-audit services to be performed by the independent registered public accounting firm.

### ***Nominating and Governance Committee***

The nominating and governance committee consists of Gordon M. Binder, Emery N. Brown and Max Wallace. Max Wallace serves as the chairperson of the nominating and governance committee. The Board has determined that each of Gordon M. Binder, Emery N. Brown and Max Wallace is independent under Nasdaq listing standards.

The nominating and governance committee has the following responsibilities, among others, as set forth in the nominating and governance committee’s charter:

- identifying and recommending candidates for membership on the Board;
- reviewing and recommending our corporate governance guidelines and policies;
- overseeing the process of evaluating the performance of the Board;
- assisting the Board on corporate governance matters; and
- reviewing proposed waivers of the Code of Conduct and Ethics for directors and executive officers.

### ***Compensation Committee***

The compensation committee consists of Michael T. Constantino, Todd M. Pope and Max Wallace. Todd M. Pope serves as the chairperson of the compensation committee. The Board has determined that each of Michael T. Constantino, Todd M. Pope and Max Wallace is independent under applicable SEC rules and Nasdaq listing standards and a “non-employee director” as defined in Rule 16b-3 promulgated under the Exchange Act.

The compensation committee has the following responsibilities, among others, as set forth in the compensation committee’s charter:

- reviewing and approving, or recommending that the Board approve, the compensation of executive officers;
- reviewing and recommending to the Board the compensation of its directors;
- administering our stock and equity incentive plans;

- reviewing and approving, or making recommendations to the Board with respect to, incentive compensation and equity plans; and
- reviewing our overall compensation philosophy.

### **Commercial Committee**

The commercial committee consists of Gordon M. Binder, Todd M. Pope, Rajiv Shukla and Susan Windham-Bannister. The commercial committee does not have a chairperson. The commercial committee oversees issues related to manufacturing, pricing, market access, and sales. A majority of the members of the commercial committee — Gordon M. Binder, Todd M. Pope and Susan Windham-Bannister — are independent under applicable SEC rules and Nasdaq listing standards.

### **Code of Conduct and Ethics**

We have adopted a Code of Conduct and Ethics that applies to all officers, directors and employees of Humacyte and its subsidiaries. The Code of Conduct and Ethics codifies the business and ethical principles that govern all aspects of our business, reflecting our commitment to a culture of honesty, integrity and accountability. In addition to following the Code of Conduct and Ethics, officers, directors and employees are expected to seek guidance in situations where there is a question regarding compliance issues, whether with the letter or the spirit of our policies and applicable laws. The Code of Conduct and Ethics is available on Humacyte’s website at [www.humacyte.com](http://www.humacyte.com). Humacyte’s website and the information contained on, or that can be accessed through, such website are not deemed to be incorporated by reference in, and are not considered part of, this Annual Report on Form 10-K.

### **Compensation Committee Interlocks and Insider Participation**

None of the members of the compensation committee is currently one of Humacyte’s officers or employees. None of Humacyte’s executive officers currently serves, or has served during the last completed fiscal year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving or will serve as a member of Humacyte’s board of directors or compensation committee.

### **Item 11. Executive Compensation.**

Unless otherwise noted, as used in this section, “Humacyte” refers to Legacy Humacyte prior to the closing of the Merger and Humacyte, Inc. after the closing of the Merger; and the “Board” refers to the board of directors of Legacy Humacyte prior to the closing of the Merger and to the board of directors of Humacyte, Inc. after the closing of the Merger. Upon the closing of the Merger, the executive officers of Legacy Humacyte became executive officers of Humacyte.

This section provides an overview of Humacyte’s executive compensation programs as they relate to the executive officers named below (the “named executive officers”), including a narrative description of the material factors necessary to understand the information disclosed in the summary compensation table below. The Board, upon the recommendation of its compensation committee and with input from Humacyte’s Chief Executive Officer, has historically determined the compensation for Humacyte’s named executive officers. For the year ended December 31, 2021, Humacyte’s named executive officers were:

- Laura E. Niklason, President, Chief Executive Officer and a member of the Board;
- Rajiv Shukla, Chief Executive Officer of AHAC prior to the Merger and a member of the Board;
- Heather Prichard, Chief Operating Officer;
- Jeffrey H. Lawson, former Chief Surgical Officer and a former member of the Board.

## Summary Compensation Table

The following table presents information regarding the compensation awarded by, earned by or paid to Humacyte's named executive officers during the fiscal years ended December 31, 2021 and 2020.

Name and Principal Position	Year	Salary (\$)	Bonus (\$) <sup>(1)</sup>	Option Awards (\$) <sup>(2)</sup>	All Other Compensation (\$)	Total (\$)
Laura E. Niklason	2021	500,000	237,500	10,021,428 <sup>(4)</sup>	45,861 <sup>(6)</sup>	10,804,789
<i>President and Chief Executive Officer</i>	2020	75,000 <sup>(3)</sup>	—	20,006 <sup>(5)</sup>	106,277 <sup>(7)</sup>	201,283
Rajiv Shukla <sup>(8)</sup>	2021	—	—	98,159 <sup>(9)</sup>	17,255 <sup>(10)</sup>	115,414
<i>Chief Executive Officer of AHAC</i>	2020	—	—	—	—	—
Heather Prichard	2021	369,554 <sup>(11)</sup>	194,905 <sup>(12)</sup>	—	11,977 <sup>(14)</sup>	576,436
<i>Chief Operating Officer</i>	2020	371,917	80,000	20,006 <sup>(13)</sup>	11,783 <sup>(15)</sup>	483,706
Jeffrey H. Lawson <sup>(16)</sup>	2021	583,495	309,254 <sup>(18)</sup>	—	14,251 <sup>(20)</sup>	907,000
<i>Former Chief Surgical Officer</i>	2020	604,816 <sup>(17)</sup>	75,000	20,006 <sup>(19)</sup>	14,079 <sup>(21)</sup>	713,901

(1) The amounts reported here reflect annual cash bonuses for 2021 and 2020 paid under an employee bonus program.

(2) The amounts reported here do not reflect the actual economic value that may be realized by each named executive officer. In accordance with SEC rules, these amounts represent the grant date fair value of the option awards, calculated in accordance with Accounting Standards Update 2018-07, "Compensation — Stock Compensation (Topic 718)." For additional information regarding the assumptions used in calculating the grant date fair value of the stock options reported in this table, see "Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Estimates — Stock-Based Compensation."

(3) Dr. Niklason was appointed as Humacyte's President and Chief Executive Officer in November 2020. Accordingly, her salary for 2020 has been prorated to reflect the portion of the year during which she was employed by Humacyte. The \$75,000 in salary earned by Dr. Niklason for her services as Humacyte's President and Chief Executive Officer in 2020 was paid in January 2021.

(4) Reflects an option to purchase 1,312,984 shares of Humacyte common stock, which was granted in January 2021 in connection with Dr. Niklason's appointment as Humacyte's President and Chief Executive Officer.

(5) Reflects an option to purchase 2,625 shares of Humacyte common stock, which was granted in December 2020.

(6) Consists of \$15,461 in commuting and related travel expenses and \$28,167 for lodging expenses paid by Humacyte, and \$2,233 in life insurance premiums paid by Humacyte.

(7) Consists of \$4,388 in commuting and related travel expenses and \$58,954 for lodging expenses paid by Humacyte. The all other compensation column for Dr. Niklason also includes \$42,935 in fees earned or paid in cash for her service as a director from January 1, 2020 to the date of her appointment as President and Chief Executive Officer. For additional information regarding Humacyte's non-employee director compensation, see "— Director Compensation" below.

(8) Mr. Shukla served as the Chief Executive Officer and Chairman of the Board of Directors of AHAC until the closing of the Merger. Mr. Shukla did not receive any compensation in connection with his service as the Chief Executive Officer and Chairman of the Board of Directors of AHAC. Mr. Shukla currently serves as a member of our Board.

(9) Reflects an option to purchase 13,000 shares of Humacyte common stock, which was granted in October 2021 in connection with Mr. Shukla's service as a director following the Merger. For additional information regarding Humacyte's non-employee director compensation, see "— Director Compensation" below.

(10) Consists of \$17,255 in fees earned or paid in cash in connection with Mr. Shukla's service as a director following the Merger. For additional information regarding Humacyte's non-employee director compensation, see "— Director Compensation" below.

- (11) Reflects an increase in Dr. Prichard's annual base salary that became effective on February 8, 2021.
- (12) Consists of (i) a cash bonus in the amount of \$140,905 earned in 2021 and (ii) a cash bonus in the amount of \$54,000 for individual performance in 2020 that was contingent and payable upon the closing of the Merger.
- (13) Reflects an option to purchase 2,625 shares of Humacyte common stock, which was granted in December 2020.
- (14) Consists of \$11,600 in matching contributions under Humacyte's 401(k) plans and \$377 in life insurance premiums paid by Humacyte.
- (15) Consists of \$11,400 in matching contributions under Humacyte's 401(k) plans and \$383 in life insurance premiums paid by Humacyte.
- (16) On December 23, 2021, Humacyte and Dr. Lawson mutually agreed to end Dr. Lawson's employment with Humacyte, effective December 31, 2021. Dr. Lawson also resigned from the Board, effective December 31, 2021.
- (17) Dr. Lawson served as Humacyte's President and Chief Executive Officer from June 2018 through November 2020 and was appointed as Humacyte's Chief Surgical Officer in November 2020 in connection with Dr. Niklason's assumption of the role of President and Chief Executive Officer. Accordingly, his 2020 salary reflects (i) the compensation he earned as President and Chief Executive Officer, which reflects an increase in his annual base salary that became effective on January 27, 2020 and the compensation he earned as Chief Surgical Officer from the date of such appointment through December 31, 2020.
- (18) Consists of (i) a cash bonus in the amount of \$221,729 earned in 2021 and (ii) a cash bonus in the amount of \$87,525 for individual performance in 2020 that was contingent and payable upon the closing of the Merger.
- (19) Reflects an option to purchase 2,625 shares of Humacyte common stock, which was granted in December 2020.
- (20) Consists of \$11,600 in matching contributions under Humacyte's 401(k) plans, \$2,580 in life insurance premiums paid by Humacyte and \$71 for a gift card and related tax gross up payment given for a tenure milestone.
- (21) Consists of \$11,400 in matching contributions under Humacyte's 401(k) plans and \$2,679 in life insurance premiums paid by Humacyte.

#### **Narrative to Summary Compensation Table**

##### ***Base Salaries***

Dr. Niklason's annual base salary for 2021 was \$500,000. In connection with Dr. Niklason's appointment as Humacyte's President and Chief Executive Officer, her annual base salary of \$500,000 in 2020 was prorated for the portion of the year in which she served in those positions and paid in January 2021. The All Other Compensation column in the Summary Compensation Table above also includes \$42,935 in fees earned or paid in cash for Dr. Niklason's service as a director from January 1, 2020 to the date of her appointment as President and Chief Executive Officer.

Mr. Shukla did not receive any compensation in connection with his service as the Chief Executive Officer and Chairman of the Board of Directors of AHAC. The option awards and all other compensation columns in the Summary Compensation Table above include an option to purchase 13,000 shares of Humacyte common stock and \$17,255 in fees earned or paid in cash for Mr. Shukla's service as a director following the closing of the Merger.

Dr. Prichard's annual base salary for 2021 was \$370,800, which reflects an increase in annual base salary that became effective on February 8, 2021. Dr. Prichard's annual base salary for 2020 was \$360,000.

Dr. Lawson's annual base salary for 2021 was \$583,495. Dr. Lawson's annual base salary for 2020 was \$583,495, which reflects an increase in annual base salary that became effective on January 27, 2020.

##### ***Bonuses***

In 2021, Drs. Niklason, Prichard and Lawson earned cash bonuses as part of an employee bonus program. In addition, the Company awarded bonuses for individual performance during 2020 that were payable upon the closing of the Merger to Drs. Lawson and Prichard.



In 2020, Drs. Prichard and Lawson earned cash bonuses as part of an employee bonus program. Because Dr. Niklason did not assume the role of President and Chief Executive Officer until November 2020, she was not awarded a bonus for 2020.

### ***Equity Compensation***

Although Humacyte does not have a formal policy with respect to the grant of equity incentive awards to its executive officers, or any formal equity ownership guidelines applicable to them, Humacyte generally uses stock options to compensate its executive officers in the form of initial grants in connection with the commencement of employment and also at various other times during their employment. Accordingly, the Board, upon the recommendation of its compensation committee, periodically reviews the equity incentive compensation of the executive officers and from time to time has granted equity incentive awards to them in the form of incentive stock options. The details of equity grants made to Humacyte's named executive officers in 2021 are outlined below in "— Outstanding Equity Awards as of December 31, 2021."

The option award granted to Dr. Niklason in 2021 vests in equal annual installments on each of the first three anniversaries of November 9, 2020, subject to acceleration upon a corporate transaction (as defined in Humacyte's 2015 Omnibus Incentive Plan, as amended (the "2015 Plan")). For additional information regarding the option award granted to Mr. Shukla in connection with his service as a director following the Merger, see "— Director Compensation" below.

The option awards granted to Humacyte's named executive officers in 2020 vest as follows: (i) one-fifth on the first anniversary of the vesting commencement date, (ii) two-fifths in equal installments over a period of 24 months commencing on the first anniversary of the vesting commencement date, (iii) one-fifth upon the submission of a BLA, and (iv) one-fifth upon FDA approval of one of Humacyte's product candidates. In the event of a corporate transaction, which is defined in the 2015 Plan, to include certain change in control transactions, Dr. Niklason's and Dr. Lawson's option grants will vest automatically. With respect to Dr. Prichard's option awards, in the event of a corporate transaction, where the surviving entity assumes or replaces an option award and an involuntary termination (as such term is defined in the 2015 Plan or Humacyte's 2005 Stock Option Plan, as amended (the "2005 Plan")), as applicable, each of which is described below) of the executive officer's employment occurs within the period commencing 30 days prior to the effective date of the corporate transaction and ending 12 months following the effective date of such corporate transaction, the option award will vest in full on the date of such involuntary termination. Vesting rights otherwise cease upon termination of employment and exercise rights cease shortly after termination of employment, except that exercisability is extended in the case of death or disability. Both vesting and exercise rights cease immediately upon a termination of employment for cause, as defined in the 2015 Plan.

### ***Executive Employment Agreements and Other Arrangements***

Humacyte has entered into employment agreements with each of its named executive officers, other than Mr. Shukla, who did not receive any compensation in connection with his service as the Chief Executive Officer of AHAC. These agreements generally set forth the terms and conditions of employment, including base salary, bonus opportunities, initial awards of equity incentive compensation and standard employee benefit plan participation. The agreements also contain provisions that provide for certain payments upon termination of employment without cause or resignation for good reason, as such terms are defined in the relevant employment agreement. In the event that any provision of the employment agreements would cause Humacyte's named executive officers to incur additional tax or interest under Section 409A of the Code, Humacyte has agreed, upon the request of the named executive officer, to use reasonable business efforts to reform in good faith the provision to comply with Section 409A.

#### ***Laura E. Niklason***

Humacyte entered into an employment agreement with Laura E. Niklason, which became effective as of November 9, 2020, which provides for her at-will employment as Humacyte's President and Chief Executive Officer. Dr. Niklason's employment agreement provides for an initial annual base salary of \$500,000, which will be reviewed by the Board from time to time but may not be reduced except in connection with a uniform reduction of the salaries of all similarly situated executive officers. The amount of any such reduction in Dr. Niklason's salary may not exceed 10% of her then-current base salary. Dr. Niklason is also eligible to receive an annual incentive bonus of up to 50% of her then-current base salary. The amount of any bonus will be established annually based on objectives determined by Humacyte and Dr. Niklason, and awarded in the sole discretion of the Board. In general, except in the event that Dr. Niklason's employment is terminated without cause or she resigns for good reason, Dr. Niklason must remain employed on the date any annual incentive bonus is paid in order to receive such bonus.

Under the terms of her employment agreement, Humacyte awarded Dr. Niklason an additional stock option award in January 2021 entitling her to purchase 1,312,984 shares of Humacyte's common stock, one-third of which have vested as of the date of this Annual Report on Form 10-K. This stock option vests in equal annual installments on each of the first three anniversaries of November 9, 2020, subject to acceleration upon a corporate transaction (as defined in the 2015 Plan). Humacyte has also agreed to reimburse Dr. Niklason for the cost of an apartment and living expenses in Durham, North Carolina near the company's headquarters in an amount not to exceed \$60,000 annually.

In the event that Dr. Niklason's employment is terminated without cause or she resigns for good reason, including Humacyte's material breach of Dr. Niklason's employment agreement or an uncured material adverse change in Dr. Niklason's compensation, as each such term is defined in her employment agreement, Humacyte will be obligated to pay her (i) an amount equal to 12 months of her then-current base salary (payable in substantially equal installments on the same payroll schedule applicable to her immediately prior to the termination of her employment); (ii) a pro rata portion, calculated per diem, of her bonus for the then-current fiscal year (as well as any accrued, earned and unpaid bonus from the preceding fiscal year); and (iii) reimbursement for the cost to Dr. Niklason to continue her and her family's health insurance under the Consolidated Omnibus Budget Reconciliation Act ("COBRA") for a period of 12 months. Each of the severance payments described above is subject to Dr. Niklason's timely execution of a general release of potential claims against Humacyte and her compliance with her non-competition agreement.

*Heather Prichard*

On September 13, 2019, Humacyte entered into an employment agreement with Heather Prichard, which provides for her at-will employment as Humacyte's Chief Operating Officer. Dr. Prichard's employment agreement provided for an initial annual base salary of \$300,000, to be reviewed by Humacyte from time to time. Dr. Prichard is also eligible for consideration to receive an annual incentive bonus. The amount of any bonus will be established annually based on objectives determined by Humacyte and Dr. Prichard, and awarded in the sole discretion of the Board. In general, except in the event that Dr. Prichard's employment is terminated without cause or she resigns for good reason, Dr. Prichard must remain employed on the date any annual incentive bonus is paid in order to receive such bonus.

In the event that Dr. Prichard's employment is terminated without cause or she resigns for good reason, including Humacyte's material breach of Dr. Prichard's employment agreement or an uncured material adverse change in Dr. Prichard's compensation, as each such term is defined in her employment agreement, Humacyte will be obligated to pay her (i) an amount equal to six months of her then-current base salary (payable in substantially equal installments on the same payroll schedule applicable to her immediately prior to the termination of her employment) and (ii) a pro rata portion, calculated per diem, of her bonus for the then-current fiscal year (as well as any accrued, earned and unpaid bonus from the preceding fiscal year). Each of the severance payments described above is subject to Dr. Prichard's timely execution of a general release of potential claims against Humacyte and her compliance with her non-competition agreement.

*Jeffrey H. Lawson*

On June 19, 2018, Humacyte entered into an employment agreement with Jeffrey H. Lawson, which provided for his at-will employment. Dr. Lawson's employment agreement was subsequently amended, effective November 9, 2020, to reflect his transition to the role of Chief Surgical Officer. On December 23, 2021, the Company and Dr. Lawson mutually agreed to end Dr. Lawson's employment with the Company, effective December 31, 2021 (the "Separation Date"). Dr. Lawson also resigned from the Board, effective as of the Separation Date. Further details regarding the terms and conditions of Dr. Lawson's separation from Humacyte are outlined below in "— Separation and Release Agreement with Dr. Lawson." Dr. Lawson's employment agreement provided for an initial annual base salary of \$550,000, to be reviewed by the Board from time to time but that could not be reduced except in connection with a uniform reduction of the salaries of all similarly situated executive officers. The amount of any such reduction in Dr. Lawson's salary could not exceed 10% of his then-current base salary. Dr. Lawson was also eligible to receive an annual incentive bonus of up to 50% of his then-current base salary. The amount of any bonus would be established annually based on objectives determined by Humacyte and Dr. Lawson, and awarded in the sole discretion of the Board. In general, except in the event that Dr. Lawson's employment was terminated without cause or he resigned for good reason, Dr. Lawson must have remained employed on the date any annual incentive bonus is paid in order to receive such bonus.

Under the terms of his employment agreement, Humacyte awarded Dr. Lawson an initial stock option award entitling him to purchase 1,194,815 shares of Humacyte's common stock, which award has vested in full as of the date of this Annual Report on Form 10-K. The details of this and other historical equity grants made to Dr. Lawson are outlined below in "— Outstanding Equity Awards as of December 31, 2021."

### Separation and Release Agreement with Dr. Lawson

On December 23, 2021, the Company and Dr. Lawson mutually agreed to end Dr. Lawson’s employment with the Company, effective on the Separation Date. Dr. Lawson also resigned from the Board, effective as of the Separation Date. Pursuant to an executive separation and release agreement (the “Separation Agreement”) between the Company and Dr. Lawson, Dr. Lawson is eligible to receive the following severance benefits: (i) an amount equal to 12 months of his 2021 base salary (payable in substantially equal installments on the same payroll schedule applicable to him immediately prior to the Separation Date); (ii) a bonus payment equal to approximately \$221,730; and (iii) reimbursement for the cost to Dr. Lawson to continue his and his family’s health insurance under COBRA for a period of up to 12 months. In addition, the Separation Agreement provides that the exercise period for any stock options held by Dr. Lawson that are vested through the Separation Date will be extended through November 26, 2022. The Separation Agreement includes a customary release of claims by Dr. Lawson in favor of the Company.

### Changes to Named Executive Officer Compensation in Connection with the Merger

Humacyte has historically granted stock options with exercise prices that are equal to the fair market value of its common stock on the date of grant as determined by the Board. The exercise price of all stock options granted after the closing of the Merger are equal to the fair market value of shares of Humacyte common stock on the date of grant.

### Outstanding Equity Awards as of December 31, 2021

The following table provides information regarding outstanding stock options held by Humacyte’s named executive officers as of December 31, 2021. All awards in the table below that were granted prior to July 2015 were granted under the 2005 Plan, awards granted subsequent to such date but prior to the closing of the Merger were granted under the 2015 Plan and awards granted following the Merger were granted under the Humacyte, Inc. 2021 Long-Term Incentive Plan (the “2021 Plan”), each as described in more detail under “— Equity Incentive and Other Compensation Plans” below.

Name	Grant date	Number of securities underlying unexercised options (#) exercisable <sup>(1)</sup>	Number of securities underlying unexercised options (#) unexercisable	Option exercise price (\$)	Option expiration date
Laura E. Niklason	11/22/2013	262,596	—	1.19	11/22/2023
	09/01/2015	13,129	—	2.56	09/01/2025
	03/09/2016	157,558	—	2.56	03/09/2026
	09/14/2016	262,596	—	3.44	09/14/2026
	04/12/2018	131,298	—	6.54	04/12/2028
	12/14/2020	525	2,100	10.28	12/14/2030
	01/14/2021	437,660	875,324	10.28	01/14/2031
Rajiv Shukla <sup>(2)</sup>	10/13/2021	—	13,000	10.03	10/13/2031
Heather Prichard	12/14/2012	6,564	—	1.15	12/14/2022
	11/22/2013	78,779	—	1.19	11/22/2023
	12/11/2015	78,779	—	2.56	12/11/2025
	04/12/2018	157,557	—	6.54	04/12/2028
	12/14/2020	525	2,100	10.28	12/14/2030
Jeffrey H. Lawson	12/11/2015	90,595	—	2.56	12/11/2025 <sup>(3)</sup>
	12/15/2016	65,648	—	3.44	12/15/2026 <sup>(3)</sup>
	04/12/2018	118,168	—	6.54	04/12/2028 <sup>(3)</sup>
	06/28/2018	1,194,815	—	8.48	06/28/2028 <sup>(3)</sup>
	12/14/2020	525	—	10.28	12/14/2030 <sup>(3)(4)</sup>

(1) All options granted to Humacyte’s named executive officers (other than Mr. Shukla) that are reported in this table vest annually in three equal installments commencing on the first anniversary of the applicable vesting commencement date, except for the options granted on December 14, 2020, which vest as follows: (i) one-fifth on the first anniversary of the vesting commencement date, (ii) two-fifths in equal installments over a period of 24 months commencing on the first anniversary of the vesting commencement date, (iii) one-fifth upon the submission

of a BLA and (iv) one-fifth upon FDA approval of one of Humacyte's product candidates. The vesting commencement date for each option award is the same as the applicable grant date, except that (i) the vesting commencement date for the option award granted to Dr. Lawson on December 11, 2015 is October 1, 2015 and (ii) the vesting commencement date for the option award granted to Dr. Niklason on January 14, 2021 is November 9, 2020. The vesting of the options may be accelerated in connection with certain corporate transactions, which generally include certain change in control transactions and are more fully described in the applicable incentive plan.

- (2) Reflects an option to purchase 13,000 shares of Humacyte common stock, which was granted in October 2021 in connection with Mr. Shukla's service as a director following the Merger. This option vests on the following schedule: (i) one-fourth on the first anniversary of the vesting commencement date and (ii) 1/36 on the 13th of each month thereafter through October 13, 2025. For additional information regarding Humacyte's non-employee director compensation, see "— Director Compensation" below.
- (3) In connection with Dr. Lawson's severance arrangements, Dr. Lawson received an extension of time until November 26, 2022 to exercise his outstanding options that were vested as of the Separation Date.
- (4) Awards that were unvested as of the Separation Date were forfeited.

## **Equity Incentive and Other Compensation Plans**

### ***Bonus Plan***

The Humacyte, Inc. Annual Bonus Plan (the "Bonus Plan") became effective upon the completion of the Merger. The Bonus Plan is administered by the compensation committee and will remain in effect until terminated by the Board.

The Bonus Plan allows the compensation committee to grant cash incentive awards to eligible employees, including the named executive officers. Awards may, but need not, be subject to performance goals established by the compensation committee in its sole discretion, and such performance goals may be on the basis of any factors the compensation committee determines relevant, and may be on an individual, divisional, business unit, segment or company-wide basis. The performance goals may differ from participant to participant and from award to award. The compensation committee will have sole discretion to determine the extent to which performance goals have been satisfied and the actual award payout based on such performance.

The compensation committee may, in its sole discretion and at any time, increase, reduce or eliminate a participant's actual award payout. The actual award payout may be below, at or above a participant's target award, in the compensation committee's discretion. The compensation committee may determine the amount of any increase, reduction or elimination on the basis of such factors as it deems relevant, and is not required to establish any allocation or weighting with respect to the factors it considers.

Actual award payouts will be made in a cash lump sum as soon as practicable after the end of the particular performance period, but in no event later than March 15 of the calendar year immediately following the calendar year in which the applicable performance period ends. Participants will generally be required to remain continuously employed through the payment date in order to receive their actual award payout, unless otherwise determined by the compensation committee.

The Board has the authority to amend, suspend or terminate the Bonus Plan at any time and for any reason, provided that such change may not materially and adversely affect a participant's rights with respect to any earned bonus that has been paid. The compensation committee and the Board have the authority to amend or terminate any target award granted under the Bonus Plan at any time and for any reason.

### ***2021 Plan***

The 2021 Plan became effective as of the consummation of the Merger. Humacyte is authorized to grant equity and cash incentive awards to eligible service providers under the 2021 Plan. The 2021 Plan replaced the 2015 Plan on the date the 2021 Plan became effective, except that any awards previously granted under the 2015 Plan remained in effect pursuant to their original terms (other than with respect to the adjustment required under the Merger Agreement to reflect the Merger). No additional awards may be granted under the 2015 Plan.

### *Authorized Shares*

We initially reserved a pool of shares of common stock for issuance under the 2021 Plan equal to 7,725,253 shares. Such aggregate number of shares will automatically increase on January 1 of each year commencing on January 1, 2022, in an amount equal to 5% of the total number of shares of our capital stock outstanding on December 31 of the preceding year, unless the Board acts prior to January 1 of a given year to provide that the increase for such year will be a lesser number. In December 2021, the Board determined not to increase the number of shares of common stock available for grant under the 2021 Plan. Subject to the maximum aggregate number of shares that may be issued pursuant to all awards (the “Share Reserve”), the maximum aggregate number of shares which may be issued pursuant to the exercise of incentive stock options (“ISOs”) is 700,000,000 shares (the “ISO Limit”). The purpose of the ISO Limit is to comply with section 422 of the Code so that the 2021 Plan does not reach the ISO Limit before the Share Reserve by reason of shares being added back to the 2021 Plan as described below.

Shares issued under the 2021 Plan will include authorized but unissued or reacquired shares of common stock. Any shares of common stock underlying any awards that are (i) forfeited, cancelled, or reacquired by Humacyte prior to vesting, (ii) that expire, (iii) that are paid out in cash rather than shares, (iv) are tendered or withheld in payment of an award exercise or purchase price, (v) are tendered or withheld in satisfaction of tax withholding obligations with respect to an award or (vi) are not issued upon net settlement of a stock appreciation, will be added back to the shares of common stock available for issuance. The shares underlying any award granted under the 2015 Plan that are forfeited, cancelled or reacquired by Humacyte prior to vesting, that expire or that are paid out in cash rather than shares will become available for grant and issuance under the 2021 Plan. Any shares that are added back to the 2021 Plan for any reason may not be issued pursuant to ISOs. Shares underlying any substitute awards that Humacyte grants to employees, directors or consultants of a business that is acquired by Humacyte will not count against the number of shares reserved for issuance under the 2021 Plan.

### *Plan Administration*

The Board administers the 2021 Plan and is authorized to delegate any or all of its powers under the 2021 Plan to one or more committees. The Board or the committee administering the 2021 Plan is referred to herein as the “administrator.” The Board is permitted to delegate to one or more officers the power to grant awards to its employees and officers, subject to certain limitations.

### *Awards*

Under the 2021 Plan, the administrator has the authority to award nonstatutory stock options and ISOs, stock appreciation rights (“SARs”), restricted stock, restricted stock units (“RSUs”), unrestricted stock, performance awards and other forms of awards. All awards will be granted pursuant to an award agreement. Awards other than ISOs can be granted to employees, directors and consultants, but ISOs can only be granted to employees.

The administrator has the authority to set the terms of all awards. In particular, the administrator is authorized to determine the service-based or performance-based vesting criteria applicable to awards granted under the 2021 Plan, as set out in the award agreement. The award agreement will also specify any circumstances under which awards may be forfeited.

The value of all awards awarded under the 2021 Plan and all other cash compensation paid by Humacyte to any non-employee director on the Board in any calendar year for service as a non-employee director shall not exceed \$750,000, or \$1,000,000 for the calendar year in which the applicable non-employee director is initially elected or appointed to the Board.

*Options and SARs.* With respect to options and SARs, the administrator will determine the exercise price applicable thereto within the terms and conditions of the plan, provided that the exercise price per share subject to an option or SAR cannot be less than 100% of the fair market value of our common stock on the date of grant (however, an option may be granted with an exercise price lower than 100% of the fair market value on the date of grant of such award if such award is granted as a substitution for an option or SAR in accordance with the provisions and requirements of Section 409A and, if applicable, 424 of the Code). The administrator also has authority to determine the term of stock options and SARs granted under the 2021 Plan, up to a maximum of 10 years. The administrator may, but is not required to, permit a grantee to exercise any part or all of his or her stock options prior to full vesting. Except as otherwise provided in an award agreement, if an optionholder terminates employment or service for any reason other than disability, death or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. If an optionholder’s employment or service relationship ceases due to disability or death, or an optionholder dies within a

certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months. Options generally terminate immediately upon the termination of an optionholder's employment or service for cause. In no event may an option be exercised beyond the expiration of its term. Payment for shares issued upon the exercise of a stock option may be made either by certified or bank check, or such other means as the administrator may accept. Subject to the approval of the administrator, options may be exercised pursuant to such cashless exercise procedures as may be approved and implemented by the administrator from time to time, including pursuant to broker-assisted exercise transactions and/or net exercise procedures. The 2021 Plan does not permit the repricing of options or SARs without shareholder approval.

*Tax Limitations on ISOs.* The aggregate fair market value, determined at the time of grant, of shares of our common stock with respect to ISOs that are exercisable for the first time by an optionholder during any calendar year under all stock plans maintained by Humacyte may not exceed \$100,000. Options or portions thereof that exceed such limit will generally be treated as nonstatutory stock options. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of Humacyte's total combined voting power or that of any of Humacyte's affiliates unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (2) the option is not exercisable after the expiration of five years from the date of grant.

*Restricted Stock.* Except as otherwise provided in an award agreement, if a grantee of restricted stock terminates employment or service during the applicable restriction period, Humacyte has the right to repurchase all or part of the shares of restricted stock still subject to restriction from the grantee at the issue price or at another stated or formula price (or to require forfeiture if such shares were issued at no cost). Additionally, unless otherwise determined by the administrator, grantees of restricted stock are entitled to receive all dividends and other distributions paid with respect to their shares of restricted stock, subject to such terms and conditions as the administrator may determine.

*Restricted Stock Units.* An RSU may be settled in any form specified by the administrator in the restricted stock agreement, including but not limited to delivery of stock, cash, or a combination of cash and stock as deemed appropriate by the administrator. The administrator may, but need not, provide that grantees of RSUs will be paid or will accrue dividend equivalent payments on each date that dividends are paid with respect to Humacyte common stock prior to the settlement of their RSUs, subject to such terms and conditions as the administrator may determine. The treatment of any dividends or dividend equivalents shall be set forth in the RSU agreement at the time the award is granted.

*Performance Awards.* The 2021 Plan permits the grant of performance-based stock and cash awards that may vest or become earned and paid contingent upon the attainment of performance goals during a designated performance period, as determined by the administrator and set forth in the applicable award agreement. Performance goals may be based on a company-wide basis, with respect to one or more business units, divisions, subsidiaries, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices, and may be based on financial performance, achievement of strategic objectives, or any other organizational goals, all as determined by the administrator. Unless specified otherwise (i) in the award agreement at the time the award is granted or (ii) in such other document setting forth the performance goals at the time the goals are established, the Board will appropriately make adjustments in the method of calculating the attainment of performance goals for a designated performance period as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by Humacyte achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of common stock of Humacyte by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock based compensation and the award of bonuses under Humacyte's bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to expense under generally accepted accounting principles; and (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles. In addition, the Board retains the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of performance goals and to define the manner of calculating the performance criteria it selects to use for such performance period. Partial achievement of the specified criteria may result in the payment or vesting corresponding to the degree of achievement as specified in the award agreement or the written terms of a performance award.

*Other Awards.* The Board may issue other forms of awards, which may, but are not required to be, valued in whole or in part by reference to, or otherwise based on, Humacyte common stock, including the appreciation in value thereof (e.g., options or stock rights with an exercise price or strike price less than 100% of the fair market value at the time of grant) may also be granted. The Board will have sole and complete discretion to determine the persons to whom and the time or times at which such other awards will be granted, the number of shares of Humacyte (or the cash equivalent thereof) to be granted and all other terms and conditions of such other awards.

Under the 2021 Plan, awards generally are not transferable other than by will or the laws of descent and distribution, unless otherwise provided by the administrator. A grantee must satisfy all applicable federal, state, and local or other income and employment tax withholding obligations before Humacyte will deliver stock certificates (or other consideration payable pursuant to the award) or otherwise recognize ownership of shares under an award.

#### *Corporate Transactions and Recapitalizations*

In the event of a corporate transaction (as defined in the 2021 Plan), each outstanding award will be treated as the administrator determines. The administrator has the right to (1) accelerate the vesting of any or all outstanding stock options and SARs, in whole or in part; (2) make non-forfeitable any or all outstanding restricted stock or RSUs, in whole or in part; or (3) cancel or redeem awards in exchange for cash or another form of consideration, including substitute awards in respect of the capital stock of a successor corporation, all subject to any limitations imposed by applicable law and provided that, if the fair market value of common stock on the date of the corporate transaction does not exceed the exercise price of any option or SAR, the administrator may cancel that option or SAR without any payment of consideration. The administrator is not obligated to treat all stock awards or portions of stock awards in the same manner and is not obligated to take the same actions with respect to all participants.

In the event a successor or acquiring corporation (if any) refuses to assume, convert, replace or substitute awards pursuant to a corporate transaction, such awards shall have their vesting accelerate as to all shares subject to such awards (and any applicable right of repurchase fully lapse) immediately prior to the corporate transaction. In addition, in the event a successor or acquiring corporation (if any) refuses to assume, convert, replace or substitute awards pursuant to a corporate transaction, the administrator will notify the grantee that such award will be exercisable for a period of time determined by the committee in its sole discretion, and such award will terminate upon the expiration of such period. Except as otherwise provided in an award agreement, in the event a successor or acquiring corporation (if any) assumes or replaces an option pursuant to a corporate transaction, and there is an involuntary termination (as defined in the award agreement) of the optionholder's employment within the 30 days prior to the effective date of the corporate transaction or 12 months following such effective date, such option will vest in full.

Separately, in the event of a stock split or other change in the capital structure of Humacyte without the company's receipt of consideration, the 2021 Plan provides for appropriate adjustments, as applicable, to the maximum number and class of shares reserved for issuance under the 2021 Plan, the ISO limit, and the class and number of shares and exercise price or purchase price of outstanding awards under the 2021 Plan.

#### *Plan Amendment or Termination*

The Board has the authority to amend, suspend, or terminate the 2021 Plan, although certain material amendments require the approval of the company's stockholders, and amendments that would adversely affect the rights of any participant require the consent of that participant. In no event will any amendment increase the maximum number of shares of common stock with respect to which awards may be granted under the 2021 Plan without stockholder approval. No awards are permitted to be granted after August 24, 2031, and the 2021 Plan does not permit any awards to be granted while it is suspended or after it is terminated.

The administrator has the authority to amend, modify or terminate any outstanding award, but the grantee will be required to consent to such action unless the amendment, modification or termination would not materially and adversely affect the grantee's rights under the 2021 Plan, the change is permitted in connection with specified corporate transactions or capitalization adjustments, or the change is required or advisable for Humacyte, the 2021 Plan or the award to satisfy applicable law or accounting standards.

#### **ESPP**

The Humacyte, Inc. 2021 Employee Stock Purchase Plan (the "ESPP") became effective as of the consummation of the Merger. Under the ESPP, Humacyte is authorized to offer eligible employees the ability to purchase shares of Humacyte stock at a discount, subject to various limitations.

### *Administration*

Subject to the terms and conditions of the ESPP, the ESPP administrator will have discretionary authority to administer and interpret the ESPP and to determine the terms and conditions of the offerings of common stock to be made under the ESPP. Subject to applicable laws and regulations, the ESPP administrator is authorized to delegate administrative tasks under the ESPP to an officer of Humacyte or other individual or group. Interpretations and constructions of the ESPP administrator of any provision of the ESPP or of any rights thereunder will be conclusive and binding on all persons. No member of the Board or individual exercising administrative authority with respect to the ESPP will be liable for any action or determination made in good faith with respect to the ESPP.

### *Share Reserve*

The initial maximum number of shares of Humacyte common stock authorized for sale under the ESPP is equal to 1,030,033 shares. Such aggregate number of shares may, subject to the approval of the Board, increase on January 1 of each year beginning January 1, 2022, but not after the 10 year anniversary of the effective date of the ESPP, in an amount equal to 1% of the total number of shares of Humacyte's capital stock outstanding on December 31 of the preceding year, unless the Board acts prior to January 1 of a given year to provide that the increase for such year will be a lesser number. In December 2021, the Board determined not to increase the number of shares of common stock available for grant under the ESPP. In no event will the maximum aggregate number of shares available for issuance under the ESPP exceed 13,000,000 shares.

### *Eligibility*

Employees eligible to participate in the ESPP for a given offering generally include employees who are employed by Humacyte or one of its designated subsidiaries on the first day of the offering, subject to any other eligibility requirements that the ESPP administrator may choose to impose (within the limits permitted by the Code).

### *Participation*

Employees will enroll under the ESPP by completing an enrollment form permitting the deduction from their compensation of a whole percentage of their compensation during an offering, subject to a minimum of 1% and a maximum of 15%, or, to the extent permitted by the ESPP administrator for an offering, an employee may authorize a payroll deduction expressed as a flat dollar amount, subject to such terms, conditions and limits as may be established by the ESPP administrator for such offering. Accumulated deductions will be credited to a notional account and applied to the purchase of shares on the exercise date of the offering.

However, an employee will not be permitted to participate in an offering if, immediately after the option to purchase stock in the offering were granted, the employee would own (or be deemed to own through attribution) 5% or more of the total combined voting power or value of all classes of stock of Humacyte, or of a subsidiary or parent company of Humacyte. In addition, a participant may not purchase more than 5,000 shares in each offering or any lesser maximum number determined by the ESPP administrator. A participant may not be granted an option that permits the participant's rights to purchase shares of Humacyte common stock to accrue at a rate exceeding \$25,000 in fair market value of such stock (determined at the time the option is granted) under the ESPP or any other employee stock purchase plan of Humacyte and its parent and subsidiary companies during any calendar year.

### *Offering*

Under the ESPP, participants are offered the option to purchase shares of Humacyte common stock at a discount during offerings, the duration and timing of which will be determined by the ESPP administrator. However, in no event may an offering be longer than 27 months in length.

The option price for an offering will generally be the lower of 85% of the closing trading price per share of Humacyte common stock on the first day of the offering or 85% of the closing trading price per share on the exercise date, which will occur on the last day of each offering.

Unless a participant has withdrawn from participation in the ESPP before the exercise date of the applicable offering, the participant will be deemed to have exercised the participant's option in full as of such exercise date. Upon exercise, the participant will purchase the number of whole shares that the participant's accumulated payroll deductions will buy at the option price, subject to the participation limitations listed above.



A participant may cancel his or her payroll deduction authorization and withdraw from the offering at any time prior to the end of the offering. Upon withdrawal, the participant will receive a refund of the participant's notional account balance in cash without interest. If a participant withdraws from an offering, the participant may not later re-enroll in the same offering, but the participant may (if eligible) enroll in any later offering under the ESPP. If a participant wants to increase or decrease the rate of payroll withholding, the participant may do so effective for the next offering by submitting a new enrollment form before the offering for which such change is to be effective.

A participant may not transfer any rights under the ESPP other than by will or the laws of descent and distribution. During a participant's lifetime, options in the ESPP shall be exercisable only by such participant. The ESPP is unfunded, and all funds received by Humacyte under the ESPP may be combined with other corporate funds and used for any corporate purpose, unless otherwise required by applicable law.

#### *Adjustments*

In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination or exchange of shares, reclassification of shares, spin-off, or other similar change in capitalization or event, or any dividend or distribution to holders of Humacyte common stock other than an ordinary cash dividend, we will proportionately adjust the number and class of shares approved under the ESPP, the option price for an offering, and the maximum number of shares which a participant may elect to purchase in any single offering. In connection with a reorganization event (as defined in the ESPP), the ESPP administrator may take any of the following actions, or do any combination thereof: (i) determine that each outstanding option will be assumed or an equivalent option substituted by the acquiring or successor corporation (or an affiliate thereof); (ii) upon written notice to participants, provide that all outstanding options will become exercisable to the extent of accumulated payroll deductions as of a specified date that is more than 10 days before the effective date of the applicable reorganization event; (iii) upon written notice to participants, provide that all outstanding options will be cancelled and accumulated payroll deductions will be returned to participants; (iv) if the applicable transaction provides for cash payments to the holders of Humacyte common stock, provide for cash payments to participants in amounts based on the per-share amount of such cash payments to the shareholders; or (v) if Humacyte is liquidated or dissolved, provide that options to purchase stock under the ESPP will convert into the right to receive the liquidation proceeds (net of the option price).

#### *Amendment and Termination*

The ESPP administrator may amend, suspend or terminate the ESPP at any time. However, if the terms of the ESPP are amended to increase the number of shares approved for the ESPP or in a manner that would require stockholder approval under the rules of Nasdaq, other relevant listing authority or to qualify as an "employee stock purchase plan" under Section 423(b) of the Code, the ESPP administrator may not amend the ESPP without obtaining shareholder approval within 12 months before or after the date such amendment is adopted.

#### **2015 Omnibus Incentive Plan**

Humacyte's 2015 Plan was adopted by the Board and approved by its stockholders on July 10, 2015 and July 29, 2015, and amended on February 23, 2018 and June 6, 2018. The 2015 Plan replaced and terminated the 2005 Plan on the date the 2015 Plan was approved by Humacyte's stockholders, except that any awards previously granted under the 2005 Plan remained in effect pursuant to their terms. The 2015 Plan allowed the Humacyte Board to make equity incentive awards to Humacyte's employees, directors, and consultants. Humacyte has not granted and will not grant any additional awards under the 2015 Plan, as of the effective date of the 2021 Plan. Any awards previously granted under the 2015 Plan and outstanding as of the effective date of the Merger were adjusted to reflect the Merger as set forth in the Merger Agreement, but otherwise remain in effect pursuant to their original terms.

#### *Authorized Shares*

The maximum aggregate number of shares of Humacyte common stock that could be issued under the 2015 Plan was 7,090,200 shares, and the maximum aggregate number of shares which could be issued thereunder pursuant to ISOs was 7,090,200 shares, with both share figures adjusted for the Exchange Ratio of approximately 0.26260 as defined in the Merger Agreement.

Shares issued under the 2015 Plan included authorized but unissued or reacquired shares of Humacyte common stock. The shares of common stock underlying any awards that were forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise or purchase price or tax withholding, reacquired by Humacyte prior to vesting, or that expired were added back to the shares of common stock available for issuance under the 2015 Plan. Shares underlying any

award issued under the 2005 Plan that remained outstanding after the termination of the 2005 Plan could be returned to the 2015 Plan.

Subject to certain adjustments, the following limits applied to awards granted to any individual in the same fiscal year: (i) in the case of awards that were settled in shares, the maximum aggregate number of shares with respect to which awards may be granted (other than stock options or SARs) was three million, (ii) the maximum aggregate number of shares subject to options was five million, (iii) the maximum aggregate number of shares subject to SARs was three million, (iv) in the case of awards that were settled in cash based on the fair market value of Humacyte common stock, the maximum aggregate amount of cash that could be paid was equal to the per share fair market value of the relevant vesting, payment or settlement date, multiplied by the number of shares described in the preceding clause, and (v) in the case of all awards other than those described in (iv), the maximum aggregate amount of cash and other property (valued at its fair market value) other than shares that could be paid or delivered was \$5 million.

#### *Plan Administration*

The Board administers the 2015 Plan and may delegate any or all of its powers under the plan to one or more of its committees. The Humacyte Board or committee administering the plan is referred to as the administrator. The Humacyte Board could also delegate to one or more of Humacyte's officers the power to grant awards to its employees, directors and officers, subject to certain limitations. Subject to the terms of the 2015 Plan, the Humacyte Board had the authority to set the terms of all awards.

#### *Awards*

The administrator could grant awards under the 2015 Plan of nonstatutory and ISOs, SARs, restricted stock, RSUs, unrestricted stock awards and cash incentive awards. All awards were granted pursuant to an award agreement. Awards other than ISOs could be granted to employees, directors and consultants. ISOs could only be granted to employees.

The administrator determined the exercise price for a stock option or SAR within the terms and conditions of the 2015 Plan, provided that the exercise price per share subject to an option or SAR could not be less than 100% of the fair market value of Humacyte common stock on the date of grant. Options and SARs granted under the 2015 Plan become exercisable at the rate specified by the administrator in the award agreement. The award agreement specifies circumstances under which awards may be forfeited. The administrator determined the term of stock options and SARs granted under the 2015 Plan, up to a maximum of 10 years. An award agreement could permit a grantee to exercise any part or all of his or her stock options or SARs prior to full vesting. Any unvested shares received pursuant to such an exercise may be subject to a repurchase right in favor of Humacyte or to any other restriction the administrator determines to be appropriate.

Any shares of Humacyte's common stock awarded under any restricted stock award agreement may be subject to forfeiture to Humacyte in accordance with a vesting schedule determined by the administrator and award agreements for restricted stock and RSUs will be subject to restrictions imposed by the administrator, as it deems appropriate. Generally, if a grantee of restricted stock terminates employment or service during the applicable restriction period, Humacyte has the right to repurchase all or part of the shares of restricted stock still subject to restriction from the grantee at the issue price or at another stated or formula price.

#### *Corporate Transactions*

The 2015 Plan provided that in the event of specified corporate transactions (which consist of certain change in control transactions), each outstanding award would be treated as the administrator determines. The administrator could (1) accelerate the vesting of any or all outstanding stock options and SARs, in whole or in part; (2) make non-forfeitable any or all outstanding restricted stock or RSUs, in whole or in part; or (3) cancel or redeem awards in exchange for cash or another form of consideration, including substitute awards in respect of the capital stock of a successor corporation.

Humacyte's stock option agreements generally provide for accelerated vesting of the unvested portions of any option award in the event of an involuntary termination (as such term is defined in the relevant stock option agreement) of a grantee's employment during the period that commences 30 days prior to the effective date of a corporate transaction and that ends 12 months following the effective date of such transaction.

Additionally, the number and class of securities available under the 2015 Plan was, and the exercise price per share of each stock option or SAR and the repurchase price per share for each restricted stock award or RSU award are, subject to adjustment in the event of any stock split, reverse stock split, stock dividend, recapitalization, combination or exchange of shares, reclassification of shares, spin-off or other similar change in capitalization.

## **2005 Stock Plan**

Humacyte's 2005 Plan was adopted by the Board and approved by its stockholders in June 2005. The 2005 Plan generally allowed the Humacyte Board to make equity-based incentive awards to Humacyte's employees, officers, directors, and consultants. The maximum aggregate number of shares of Humacyte common stock that could be issued under the 2005 Plan was 2,198,504 shares, as adjusted for the Exchange Ratio of approximately 0.26260 as defined in the Merger Agreement. The 2015 Plan replaced the 2005 Plan on the date the 2015 Plan was approved by Humacyte's stockholders, except that any awards previously granted under the 2005 Plan remained in effect pursuant to their terms.

### *Plan Administration*

The 2005 Plan is administered by the Board. The Board could also delegate to one or more of Humacyte's officers the power to grant awards to other employees and officers. Subject to the terms of the 2005 Plan, the Board had the authority to fix the terms of all awards.

### *Awards*

Under the 2005 Plan, Humacyte could grant awards of nonstatutory and ISOs, performance shares, restricted stock, SARs, dividend equivalent awards, and other stock-based awards to employees, directors, officers and consultants. ISOs could only be granted to employees. All awards were granted pursuant to an award agreement.

The Board determined the exercise price for a stock option, within the terms and conditions of the 2005 Plan, provided that the exercise price of an ISO could not be less than the fair market value of Humacyte's common stock on the date of grant.

### *Corporate Transactions*

The 2005 Plan provided that, subject to certain accounting considerations, in the event of a change in control (as defined in the 2005 Plan), the Board could, in its sole discretion at any time upon the occurrence of a change in control, determine that all or a portion of a participant's outstanding options would become fully exercisable, and all or a portion of the restrictions on outstanding awards would lapse. Upon the occurrence of any transaction or event not constituting a change in control but which the Board deemed to be, or to be reasonably likely to lead to, an effective change in control, the Board could, in its sole discretion, declare all outstanding options to be fully exercisable and all restrictions on all outstanding awards to have lapsed as of such date as it might, in its sole discretion, declare, which could have been on or before the consummation of the transaction or event. The Board could also, in its sole discretion at any time, determine that all or a portion of a grantee's options would become fully or partially exercisable and that all or a part of the restrictions on all or portion of the outstanding awards would lapse as of the date that the Board might, in its sole discretion, declare.

### **401(k) Plans**

Humacyte maintains two 401(k) retirement savings plans ("the 401(k) Plans"), for its employees, including the named executive officers, who satisfy certain eligibility requirements. The 401(k) Plans are intended to qualify as tax-qualified plans under Section 401(k) of the Code. The named executive officers are eligible to participate in the 401(k) Plans on the same basis as Humacyte's other employees. The Code allows eligible employees to contribute, on a pre-tax basis, a portion of their salary, within prescribed limits, through contributions to the 401(k) Plans. Contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. Humacyte matches employee contributions up to 4% of each employee's compensation.

### **Director Compensation**

The following table sets forth information regarding compensation paid to Humacyte's non-employee directors during 2021. Prior to the Merger, Legacy Humacyte provided an annual cash retainer of \$50,000 for each of its non-employee directors. Following the closing of the Merger, our Board adopted a director compensation policy that provides for an annual cash retainer of \$50,000 for each of our non-employee directors and an additional cash retainer of (i) \$25,000 for the chair of the Board, (ii) \$7,500 for the chair of the audit committee and (iii) \$5,000 for the chair of each of the nominating and governance committee and the compensation committee. In addition, our director compensation policy provides for an annual equity grant consisting of (i) an option to purchase 13,000 shares of our common stock for newly appointed directors and (ii) an option to purchase 8,500 shares of our common stock for continuing directors.

Compensation paid to Mr. Shukla in connection with his service on the Board is outlined above in “— Summary Compensation Table.”

A director who is also a Humacyte employee receives no additional compensation for his or her service as a director. Drs. Niklason and Lawson did not receive any additional compensation for serving as a director in 2021. None of the AHAC directors prior to the Merger received any compensation for service on the board of directors of AHAC.

<b>Name</b>	<b>Fees Earned or Paid in Cash (\$)<sup>(1)</sup></b>	<b>Option Awards (\$)<sup>(2)(3)</sup></b>	<b>Total (\$)</b>
Gordon M. Binder	17,255	98,159	115,414
Emery N. Brown	17,255	98,159	115,414
Michael T. Constantino	19,844	98,159	118,003
Brady W. Dougan	50,000	64,181	114,181
Todd M. Pope	18,981	98,159	117,140
Kathleen Sebelius	58,628	64,181	122,809
Max Wallace	51,726	64,181	115,907
Susan Windham-Bannister	17,255	98,159	115,414
Dale A. Sander <sup>(4)</sup>	12,500	—	12,500
Robert Anderson <sup>(5)</sup>	32,745	—	32,745
Carrie S. Cox <sup>(6)</sup>	32,745	—	32,745
Robert Langer <sup>(7)</sup>	32,745	—	32,745

- (1) Fees earned or paid in cash have been prorated to reflect (i) the portion of the year during which each director served on the Board and (ii) the additional cash retainers provided for in our director compensation policy that was adopted following the Merger.
- (2) The amount reported here does not reflect the actual economic value that may be realized by the director. In accordance with SEC rules, this amount represents the grant date fair value of the option award, calculated in accordance with Accounting Standards Update 2018-07, “Compensation — Stock Compensation (Topic 718).” For additional information regarding the assumptions used in calculating the grant date fair value of the stock options reported in this table, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Estimates — Stock-Based Compensation.”
- (3) As of December 31, 2021, the following non-qualified stock option awards held by our directors were outstanding: (i) options held by Mr. Binder to acquire 13,000 shares of common stock, (ii) options held by Dr. Brown to acquire 13,000 shares of common stock, (iii) options held by Mr. Constantino to acquire 13,000 shares of common stock, (iv) options held by Mr. Dougan to acquire 38,697 shares of common stock, (v) options held by Mr. Pope to acquire 13,000 shares of common stock, (vi) options held by Ms. Sebelius to acquire 64,957 shares of common stock, Mr. Wallace to acquire 45,261 shares of common stock, (viii) options held by Dr. Windham-Bannister to acquire 13,000 shares of our common stock (ix) options held by Mr. Sander to acquire 452,975 shares of our common stock, (x) options held by the estate of Dr. Anderson to purchase 36,761 shares of our common stock and (xi) options held by Dr. Langer to purchase 36,761 shares of our common stock. Ms. Cox did not hold any options to purchase shares of our common stock as of December 31, 2021.
- (4) Mr. Sander served as a member of the Board in 2021 until the closing of the Merger. Mr. Sander received \$12,500 in connection with his service on the Board prior to becoming an employee of Humacyte in May 2021. The above table does not include compensation paid to Mr. Sander as an employee of Humacyte or pursuant to a consulting agreement between Humacyte and Mr. Sander that was effective from January 2021 through April 2021.
- (5) Dr. Anderson served as a member of the Board in 2021 until the closing of the Merger.
- (6) Ms. Cox served as a member of the Board in 2021 until the closing of the Merger.
- (7) Dr. Langer served as a member of the Board in 2021 until the closing of the Merger.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.****EQUITY COMPENSATION PLAN INFORMATION**

The following table presents information as of December 31, 2021, with respect to compensation plans under which shares of our common stock may be issued.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options (a)	Weighted Average Exercise Price of Outstanding Options (\$)(b)	Number of Securities Remaining Available for Future Issuances under Equity Compensation Plans (excluding securities reflected in column (a)) (c)
Equity Compensation Plans approved by security holders <sup>(1)</sup>	6,711,192	\$ 7.48	7,418,937
Equity Compensation Plans not approved by security holders	—	—	—
<b>Total</b>	<b>6,711,192</b>	<b>7.48</b>	<b>7,418,937</b>

(1) Includes the 2021 Plan, the 2015 Plan and the 2005 Plan.

For more information regarding our equity compensation plans, see Note 10 of the Notes to Consolidated Financial Statements included in this Annual Report on Form 10-K. In December 2021, the Board determined not to increase the number of shares of common stock available for grant under the 2021 Plan.

**SECURITY OWNERSHIP OF MANAGEMENT AND CERTAIN BENEFICIAL OWNERS**

The following table sets forth information regarding the beneficial ownership of shares of our common stock as of February 28, 2022:

- each person known by us to be the beneficial owner of more than 5% of our common stock;
- each of our named executive officers and directors; and
- all of our executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC. A person is a “beneficial owner” of a security if that person has or shares “voting power,” which includes the power to vote or to direct the voting of the security, or “investment power,” which includes the power to dispose of or to direct the disposition of the security, or has the right to acquire such powers within 60 days.

The beneficial ownership of shares of common stock is calculated based on 103,004,572 shares of Humacyte common stock outstanding as of February 28, 2022.

Unless otherwise noted in the footnotes to the following table, and subject to applicable community property laws, the persons and entities named in the table have sole voting and investment power with respect to their beneficially owned common stock.

Name and Address of Beneficial Owner <sup>(1)</sup>	Number of Shares Beneficially Owned	%
<b>Directors and Executive Officers of Humacyte</b>		
Laura E. Niklason <sup>(2)</sup>	23,406,639	22.4
Dale A. Sander <sup>(3)</sup>	118,429	*
Heather Prichard <sup>(4)</sup>	325,003	*
Jeffrey H. Lawson <sup>(5)</sup>	1,477,103	1.4
Brady W. Dougan <sup>(6)</sup>	23,406,639	22.4
Emery N. Brown	—	—
Kathleen Sebelius <sup>(7)</sup>	56,457	*
Rajiv Shukla <sup>(8)</sup>	1,964,789	1.9
Max Wallace <sup>(9)</sup>	86,747	*
Susan Windham-Bannister	—	—
Gordon M. Binder	—	—
Michael T. Constantino	2,500	*
Todd M. Pope	—	—
<b>All Directors and Executive Officers of Humacyte as a Group (14 Individuals)</b>	<b>26,322,329</b>	<b>25.0</b>
<b>Five Percent Holders</b>		
Ayabudge LLC <sup>(10)</sup>	20,452,504	19.9
Fresenius Medical Care Holdings, Inc. <sup>(11)</sup>	18,312,735	17.8
The GYF Trust <sup>(12)</sup>	8,942,078	8.7

\* Less than one percent.

- (1) Unless otherwise noted, the business address of each of the following entities and individuals is 2525 East North Carolina Highway 54, Durham, North Carolina 27713.
- (2) Consists of (i) 1,148,240 shares of common stock held by Dr. Niklason, (ii) 1,265,537 shares of common stock subject to options exercisable within 60 days of February 28, 2022 held by Dr. Niklason, (iii) 510,161 shares of common stock held by Mr. Dougan, (iv) 30,197 shares of common stock subject to options exercisable within 60 days of February 28, 2022 held by Mr. Dougan, and (v) 20,452,504 shares of common stock held by Ayabudge LLC. Dr. Niklason is married to Mr. Dougan and Mr. Dougan has sole voting and dispositive power over the shares held by Ayabudge LLC. By virtue of these relationships, Dr. Niklason may be deemed to share beneficial ownership of the securities held of record by Mr. Dougan and Ayabudge LLC.
- (3) Consists of 118,429 shares of common stock subject to options exercisable within 60 days of February 28, 2022.
- (4) Consists of (i) 2,625 shares of common stock and (ii) 322,378 shares of common stock subject to options exercisable within 60 days of February 28, 2022.
- (5) Consists of (i) 7,877 shares of common stock and (ii) 1,469,226 shares of common stock subject to options exercisable within 60 days of February 28, 2022. On December 23, 2021, Humacyte and Dr. Lawson mutually agreed to end Dr. Lawson's employment with Humacyte, effective December 31, 2021. Dr. Lawson also resigned from the Board, effective December 31, 2021.
- (6) Consists of (i) 510,161 shares of common stock held by Mr. Dougan, (ii) 30,197 shares of common stock subject to options exercisable within 60 days of February 28, 2022 held by Mr. Dougan, (iii) 1,148,240 shares of common stock held by Dr. Niklason, (iv) 1,265,537 shares of common stock subject to options exercisable within 60 days of

February 28, 2022 held by Dr. Niklason, and (v) 20,452,504 shares of common stock held by Ayabudge LLC. Mr. Dougan is married to Dr. Niklason and Mr. Dougan has sole voting, and dispositive power over the shares held by Ayabudge LLC. By virtue of these relationships, Mr. Dougan may be deemed to share beneficial ownership of the securities held of record by Dr. Niklason and Ayabudge LLC.

- (7) Consists of 56,457 shares of common stock subject to options exercisable within 60 days of February 28, 2022.
- (8) Consists of (i) 1,814,789 shares of common stock and (ii) Warrants to purchase 150,000 shares of common stock exercisable within 60 days of February 28, 2022.
- (9) Consists of (i) 49,986 shares of common stock and (ii) 36,761 shares of common stock subject to options exercisable within 60 days of February 28, 2022.
- (10) Mr. Dougan has sole voting and dispositive power over the shares held by Ayabudge LLC. Ayabudge LLC has pledged 18,930,004 shares to certain lenders in connection with a financing arrangement.
- (11) Based on a Schedule 13D filed by Fresenius Medical Care Holdings, Inc. and Fresenius Medical Care AG & Co. KGaA on September 2, 2021. The business address of Fresenius Medical Care Holdings, Inc. is 920 Winter Street, Waltham, Massachusetts 02451.
- (12) Based on a Schedule 13G filed by PTC Trustees GY Limited, as trustee of The GYF Trust, and Gavril Abramovich Yushvaev on September 8, 2021. Gavril Abramovich Yushvaev has sole voting and dispositive power over the shares held by PTC Trustees GY Limited. The address of the business office of PTC Trustees GY Limited as Trustee of The GYF Trust is 37 Metochiou Street, Agios Andreas, 1101 Nicosia, Cyprus.

### **Item 13. Certain Relationships and Related Transactions, and Director Independence**

#### **Policies and Procedures for Related Party Transactions**

Upon consummation of the Merger, the Board adopted a written Related Person Transactions Policy that sets forth Humacyte's policies and procedures regarding the notification, review, approval, ratification and disclosure of "related person transactions." For purposes of Humacyte's policy only, a "related person transaction" is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which Humacyte or any of its subsidiaries are participants involving an amount that exceeds \$120,000, in which any "related person" has or will have a direct or indirect material interest.

Transactions involving compensation for services provided to Humacyte as an employee or director will not be considered related person transactions under this policy. A "related person" is any executive officer, director, nominee to become a director, a holder of more than 5% of any class of Humacyte's voting securities, including any of their immediate family members and affiliates, including entities owned or controlled by such persons, and any entity that employs any of the foregoing persons, of which any of the foregoing persons is a general partner, officer or serves in a similar position, or in which any of the foregoing persons has a 10% percent or greater beneficial ownership interest.

Under the policy, the related person in question or, in the case of transactions with a holder of more than 5% of any class of Humacyte's voting securities, any director or employee with knowledge of a proposed transaction, must present information regarding the proposed related person transaction to the audit committee of the Board for review. To identify related person transactions in advance, Humacyte will rely on information supplied by its executive officers, directors and certain significant stockholders.

The audit committee will approve only those transactions that it determines are in Humacyte's best interests. The transactions described below under the subheadings "Pre-Merger AHAC Related Party Transactions" and "Legacy Humacyte Related Party Transactions" were entered into prior to the adoption of the Related Person Transactions Policy.

#### **Humacyte Related Party Transactions**

##### ***Investor Rights and Lock-up Agreement***

At the Effective Time, Humacyte and certain of the stockholders of Humacyte and Legacy Humacyte entered into an Investor Rights and Lock-up Agreement, pursuant to which, among other things, such stockholders (i) agreed not to effect any sale or distribution of any shares held by any of them during the one-year lock-up period described therein, subject to certain exceptions described below, and (ii) were granted certain registration rights with respect to certain shares of

securities held by them. Pursuant to the Investor Rights and Lock-up Agreement, the Sponsor and certain directors of AHAC prior to the Merger have, for a period of 10 years, unless such stockholders cease to collectively own at least 5% of our common stock at an earlier date, the right to designate, and the Board will nominate, one individual for election to the Board. In connection with the closing of the Merger, these stockholders designated Rajiv Shukla for election to the Board.

If the volume weighted average price (“VWAP”) of Humacyte common stock on Nasdaq, or any other national securities exchange on which the common stock is then traded, is greater than or equal to \$15.00 over any 20 trading days within any 30 trading day period following the closing of the Merger, then, commencing at least 180 days after the closing of the Merger, the lock-up period shall be deemed to have expired with respect to 50% of the shares of common stock held by each party subject to the Investor Rights and Lock-up Agreement. The lock-up period shall not apply to any shares purchased in the PIPE Investment by parties to the Investor Rights and Lock-up Agreement.

The foregoing description of the Investor Rights and Lock-up Agreement is subject to and qualified in its entirety by reference to the full text of the form of Investor Rights and Lock-up Agreement, a copy of which is attached as Exhibit 4.3 to this Annual Report on Form 10-K, and the terms of which are incorporated herein by reference.

#### ***Lock-up Agreement***

At the Effective Time, certain stockholders and option holders of Legacy Humacyte who did not enter into the Investor Rights and Lock-up Agreement entered into a lock-up agreement (the “Lock-up Agreement”) restricting their ability to transfer their shares of Humacyte common stock. The Lock-up Agreement has substantially the same terms as the lock-up provision contained in the Investor Rights and Lock-up Agreement, described above.

The foregoing description of the Lock-up Agreement is subject to and qualified in its entirety by reference to the full text of the form of Lock-up Agreement, a copy of which is attached as Exhibit 10.1 to this Annual Report on Form 10-K, and the terms of which are incorporated herein by reference.

#### ***Indemnification Agreements***

In connection with consummating the Merger, Humacyte entered into customary indemnification agreements with the directors and executive officers of Humacyte following the Merger.

#### **Pre-Merger AHAC Related Party Transactions**

##### ***Founder Shares***

On July 20, 2020, AHAC issued 2,875,000 shares of its Class B Common Stock to the Sponsor for \$25,000, or approximately \$0.01 per share (the “Founder Shares”). The Founder Shares included an aggregate of up to 375,000 shares that were subject to forfeiture if the over-allotment option granted to the underwriters in connection with AHAC’s initial public offering was not exercised by the underwriters in full. The over-allotment option was not exercised by the underwriters and therefore, as of December 31, 2020, 2,500,000 Founder Shares were issued and outstanding. Each Founder Share was converted into one share of Humacyte common stock at the closing of the Merger.

##### ***Promissory Note — Related Party***

On July 1, 2020, AHAC issued an unsecured promissory note to the Sponsor, pursuant to which AHAC may borrow up to an aggregate principal amount of \$300,000 to be used for a portion of the expenses of AHAC’s initial public offering. This loan was non-interest bearing, unsecured, and due on the earlier of (a) March 31, 2021 or (b) the date on which AHAC completed the Initial Public Offering. As of December 31, 2020, AHAC had \$95,136 in borrowings outstanding under the promissory note. The note was paid in full in January 2021 out of offering proceeds not held in the Trust Account.

##### ***Administrative Service Fee***

AHAC agreed to pay an affiliate of the Sponsor a monthly fee of an aggregate of \$10,000 for general and administrative services including office space, utilities and secretarial and administrative support. This arrangement terminated upon completion of the Merger. For the period July 1, 2020 through December 31, 2020, AHAC accrued \$34,334 of administrative fees as a due to related party payable.



### ***Underwriting Agreement***

On September 22, 2020, the underwriters of AHAC's initial public offering were paid an underwriting discount of 2.0% of the gross proceeds of the offering, or \$2,000,000. In addition, the underwriters were entitled to a deferred underwriting fee of 3.5% of the gross proceeds of the initial public offering upon the completion of the Merger. The underwriters have agreed that up to 1% of the deferred underwriting fee may be re-directed to other member firms of the Financial Industry Regulatory Authority, Inc. ("FINRA") that have provided services in connection with the identification and consummation of a business combination, in the sole discretion of AHAC; provided, that all such payments to other FINRA member firms may only be made if permitted under applicable law.

AHAC was permitted to reduce the deferred underwriting fee by up to 50% based on stockholders redeeming their shares for their pro-rata amount of the proceeds in the Trust Account; provided, however, that (a) the underwriters' maximum deferred underwriting fee reduction based on stockholder redemptions would be 50% regardless of whether stockholder redemptions exceeded 50%; and (b) any sums paid to other advisors as discussed above, would be credited against the reduction of and added back to the deferred underwriting fee payable to the underwriters; and (c) under no circumstance would the deferred underwriting fee be less than 1.75% of the gross proceeds of the initial public offering. AHAC paid to the underwriters aggregate deferred underwriting fees of \$2,446,902 upon consummation of the Merger.

### **Legacy Humacyte Related Party Transactions**

#### ***PIPE Investment***

In connection with the execution of the Merger Agreement, AHAC entered into the Subscription Agreements with the PIPE Investors, pursuant to which the PIPE Investors agreed to purchase, and AHAC agreed to sell to the PIPE Investors, an aggregate of 17,500,000 shares of AHAC's Class A common stock, for a purchase price of \$10.00 per share and an aggregate purchase price of \$175 million, in the PIPE Investment. Such shares were issued immediately prior to the Effective Time.

The table below sets forth the number of shares of AHAC's Class A common stock that were purchased by Legacy Humacyte's related parties (which shares were converted into Humacyte common stock on a one-for-one basis at the closing of the Merger):

<b>Related Person</b>	<b>Shares of Class A Common Stock</b>	<b>Cash Purchase Price</b>
Ayabudge LLC	1,522,500	\$ 15,225,000
Fresenius Medical Care Holdings, Inc	2,500,000	\$ 25,000,000
PTC Trustees GY Limited as Trustee of The GYF Trust	1,800,000	\$ 18,000,000

AHAC is party to an engagement letter with Exos pursuant to which Exos acted as a private placement agent to AHAC in connection with the PIPE Investment. Exos received a \$5.5 million fee upon the closing of the PIPE Investment. AHAC also agreed to indemnify Exos as is customary with respect to placement agent arrangements.

Brady Dougan, a member of Humacyte's Board and the prior chairman of the Legacy Humacyte board of directors, is the founder and chief executive officer of Exos. Laura Niklason, Humacyte's chief executive officer and president, is the spouse of Brady Dougan.

#### ***Stockholder Support Agreement***

In connection with the execution of the Merger Agreement, certain Legacy Humacyte stockholders, who held 77.1% of Legacy Humacyte's outstanding capital stock, entered into a support agreement pursuant to which they agreed to vote in favor of the Merger, among other items, at a meeting of Legacy Humacyte stockholders called to approve the Merger (or to act by written consent approving the Merger).

#### ***Other Transactions***

##### ***Distribution Agreement with Fresenius Medical Care***

In June 2018, Legacy Humacyte entered into a distribution agreement with Fresenius Medical Care, pursuant to which Fresenius Medical Care has the exclusive right to develop outside of the United States and EU and commercialize outside

of the United States, among other things, our 6 millimeter x 42 centimeter HAV and all improvements thereto, and modifications and derivatives thereof (including any changes to the length, diameter, or configuration of the foregoing), referred to as the distribution product, for use in in vascular creation, repair and, replacement or construction (including renal replacement therapy for dialysis access, the treatment of vascular trauma, and the treatment of PAD, but excluding coronary artery bypass graft, pediatric heart surgery, or adhering pancreatic islet cells onto the outer surface of the distribution product for use in diabetic patients). For additional information regarding the terms of the distribution agreement, see “Business — Distribution.”

*Arrangements with Yale University*

Legacy Humacyte made research gifts to Yale University of \$500,000 in 2018, \$422,000 in 2019 and \$500,000 in 2020, for use toward research efforts in regenerative medicine. Legacy Humacyte also entered into three license agreements with Yale University and has made payments of license fees and other expenses to Yale, as described further in the section titled “Business — Intellectual Property.”

*Employment Agreement with William Tente*

On September 13, 2019, Legacy Humacyte entered into an employment agreement with William Tente, which provides for his at-will employment as our Chief Regulatory Officer. Mr. Tente’s employment agreement provided for an initial annual base salary of \$319,300, to be reviewed by Humacyte from time to time. Mr. Tente is also eligible for consideration to receive an annual incentive bonus. The amount of any bonus will be established annually based on objectives determined by Humacyte and Mr. Tente, and awarded in the sole discretion of the Humacyte Board. In general, except in the event that Mr. Tente’s employment is terminated without cause or he resigns for good reason, Mr. Tente must remain employed on the date any annual incentive bonus is paid in order to receive such bonus.

In the event that Mr. Tente’s employment is terminated without cause or he resigns for good reason, including Humacyte’s material breach of Mr. Tente’s employment agreement or an uncured material adverse change in Mr. Tente’s compensation, as each such term is defined in his employment agreement, Humacyte will be obligated to pay him (i) an amount equal to six months of his then-current base salary (payable in substantially equal installments on the same payroll schedule applicable to her immediately prior to the termination of his employment) and (ii) a pro rata portion, calculated per diem, of his bonus for the then-current fiscal year (as well as any accrued, earned and unpaid bonus from the preceding fiscal year). Each of the severance payments described above is subject to Mr. Tente’s timely execution of a general release of potential claims against Humacyte and his compliance with his non-competition agreement.

*Consulting Agreement with Dale Sander*

In January 2021, Legacy Humacyte entered into a consulting agreement with Dale Sander. Under the consulting agreement, Legacy Humacyte paid Mr. Sander a consulting fee of \$25,000 per month and reimbursed his reasonable and documented expenses. In connection with the entry into this consulting agreement, the Legacy Humacyte board of directors granted to Mr. Sander an option to purchase 700,000 shares of Legacy Humacyte common stock at an exercise price per share of \$2.699. This consulting agreement was terminated effective as of April 29, 2021.

**Item 14. Principal Accountant Fees and Services**

PricewaterhouseCoopers LLP (“PwC”) served as the independent registered public accounting firm of Legacy Humacyte prior to the Merger, and was appointed on August 24, 2021 to serve as Humacyte’s independent registered public accounting firm to audit Humacyte’s consolidated financial statements for the fiscal year ending December 31, 2021. Marcum LLP (“Marcum”) served as AHAC’s independent registered public accounting firm prior to the Merger.

The following is a summary of the aggregate fees billed for services provided by PwC for the fiscal years ended December 31, 2021 and 2020.

(\$ in thousands)	Year Ended December 31,	
	2021	2020
Audit Fees	\$ 580,122	\$ 280,000
Audit-related Fees	1,059,513	10,000
Tax Fees	17,630	31,000
All Other Fees	2,900	—
<b>Total Fees</b>	<b>\$ 1,660,165</b>	<b>\$ 321,000</b>

*Audit Fees.* Audit fees consist of fees billed for professional services rendered by PwC for the audit of our annual consolidated financial statements and review of financial statements included in our Quarterly Reports on Form 10-Q or services that are normally provided by our independent registered accounting firm in connection with statutory and regulatory filings or engagements. The above amounts include interim review procedures and audit fees, as well as attendance at audit committee meetings.

*Audit-Related Fees.* Audit-related services consist of fees billed for assurance and related services that are reasonably related to performance of the audit or review of our financial statements and are not reported under “Audit Fees”, including incremental fees related to the Form S-4 for the Merger and other registration statements filed by us. These services include attest services that are not required by statute or regulation and consultations concerning financial accounting and reporting standards.

*Tax Fees.* Tax fees consist of fees billed for professional services rendered by PwC for tax compliance, tax advice, and tax planning.

*All Other Fees.* All other fees consist of fees billed for all other services.

The following is a summary of the aggregate fees billed for services provided by Marcum for the fiscal years ended December 31, 2021 and 2020.

(\$ in thousands)	Year Ended December 31,	
	2021	2020
Audit Fees	\$ 47,380	\$ 40,170
Audit-related Fees	84,718	—
Tax Fees	—	—
All Other Fees	—	—
<b>Total Fees</b>	<b>\$ 132,098</b>	<b>\$ 40,170</b>

*Audit Fees.* Audit fees consist of fees billed for professional services rendered by Marcum for the audit of AHAC’s annual consolidated financial statements and review of financial statements included in AHAC’s Quarterly Reports on Form 10-Q or services that are normally provided by AHAC’s independent registered accounting firm in connection with statutory and regulatory filings or engagements. The above amounts include interim review procedures and audit fees, as well as attendance at audit committee meetings.

*Audit-Related Fees.* Audit-related services consist of fees billed for assurance and related services that are reasonably related to performance of the audit or review of our financial statements and are not reported under “Audit Fees”, including incremental fees related to the Form S-4 for the Merger in 2021 and AHAC’s initial public offering in 2020. These services include attest services that are not required by statute or regulation and consultations concerning financial accounting and reporting standards.

*Tax Fees.* Tax fees consist of fees billed for professional services rendered by Marcum for tax compliance, tax advice, and tax planning.

*All Other Fees.* All other fees consist of fees billed for all other services.

### **Pre-Approval Policy**

Our audit committee has responsibility for appointing, setting compensation and overseeing the work of our independent registered public accounting firm. In recognition of this responsibility, the audit committee has established a policy to pre-approve all audit and permissible non-audit services provided by the independent registered public accounting firm. Prior to the engagement of the independent registered public accounting firm, the audit committee pre-approves services by category of service and estimated cost as further noted in the engagement letter. The fees are budgeted as part of the Company's annual/periodic budgeting and forecasting process, and the audit committee requires the independent registered public accounting firm and management to report actual fees versus the budget periodically throughout the year by category of service. During the year, circumstances may arise when it may become necessary to engage the independent registered public accounting firm for additional services not contemplated in the original pre-approval. In those instances, the audit committee requires specific pre-approval before engaging the independent registered public accounting firm for such services.

Prior to the Merger, all of the services listed in the table above provided by Marcum were pre-approved by AHAC in accordance with its policies then in effect. Following the Merger, all of the services provided by PwC were pre-approved by our audit committee.

**Part IV****Item 15. Exhibits and Financial Statement Schedules.**

(a) The following financial statements are included in this Annual Report on Form 10-K:

*(1) List of Financial Statements:*

The financial statements required by this item are listed in Item 8, “Financial Statements and Supplementary Data” herein.

*(2) List of Financial Statement Schedules:*

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or notes thereto.

*(3) List of Exhibits:*

Exhibit No.	Description
2.1*	<a href="#">Business Combination Agreement, dated as of February 17, 2021, by and among Alpha Healthcare Acquisition Corp., Hunter Merger Sub, Inc. and Humacyte, Inc. (incorporated by reference to Annex A to the proxy statement/prospectus contained in Humacyte, Inc.'s Registration Statement on S-4/A, filed with the SEC on August 2, 2021).</a>
3.1	<a href="#">Second Amended and Restated Certificate of Incorporation of Humacyte, Inc. (incorporated by reference to Exhibit 3.1 to Humacyte, Inc.'s Current Report on Form 8-K, filed with the SEC on August 27, 2021).</a>
3.2	<a href="#">By Laws of Humacyte, Inc. (incorporated by reference to Exhibit 3.2 to Humacyte, Inc.'s Current Report on Form 8-K, filed with the SEC on August 27, 2021).</a>
4.1	<a href="#">Warrant Agreement, dated September 17, 2020, by and between Alpha Healthcare Acquisition Corp. and Continental Stock Transfer &amp; Trust Company, as warrant agent (incorporated by reference to Exhibit 4.1 to Alpha Healthcare Acquisition Corp.'s Annual Report on Form 10-K/A, filed with the SEC on May 14, 2021).</a>
4.2	<a href="#">Form of Subscription Agreement (incorporated by reference to Exhibit 10.3 to Humacyte, Inc.'s Registration Statement on S-4/A, filed with the SEC on August 2, 2021).</a>
4.3*	<a href="#">Form of Investor Rights and Lock-up Agreement (included in Exhibit 2.1).</a>
4.4	<a href="#">Warrant to Purchase Common Stock, dated March 30, 2021 (incorporated by reference to Exhibit 10.6.1 to Humacyte, Inc.'s Registration Statement on S-4/A, filed with the SEC on June 14, 2021).</a>
4.5	<a href="#">Warrant to Purchase Common Stock, dated March 30, 2021 (incorporated by reference to Exhibit 10.6.2 to Humacyte, Inc.'s Registration Statement on S-4/A, filed with the SEC on June 14, 2021).</a>
4.6!	<a href="#">Description of the Company's securities registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended.</a>
10.1	<a href="#">Form of Lock-up Agreement (incorporated by reference to Exhibit 10.1 to Humacyte, Inc.'s Registration Statement on S-4/A, filed with the SEC on August 2, 2021).</a>
10.2	<a href="#">Loan and Security Agreement, dated March 30, 2021, by and among Silicon Valley Bank, SVB Innovation Credit Fund VIII, L.P. and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.6 to Humacyte, Inc.'s Registration Statement on S-4/A, filed with the SEC on June 14, 2021).</a>
10.2.1	<a href="#">First Amendment to Loan and Security Agreement, dated June 30, 2021, by and among Silicon Valley Bank, SVB Innovation Credit Fund VIII, L.P. and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.6.1 to Humacyte, Inc.'s Registration Statement on S-4/A, filed with the SEC on July 23, 2021).</a>
10.2.2	<a href="#">Second Amendment to Loan and Security Agreement, dated as of September 17, 2021, by and among Humacyte, Inc., Humacyte Global, Inc., Silicon Valley Bank and SVB Innovation Credit Fund VIII, L.P. (incorporated by reference to Exhibit 10.2.2 to Humacyte, Inc.'s Registration Statement on Form S-1, filed with the SEC on September 17, 2021).</a>
10.3^	<a href="#">Distribution Agreement, dated June 25, 2018, by and between Fresenius Medical Care Holdings, Inc. and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.6 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.3.1^	<a href="#">First Amendment to Distribution Agreement, dated October 2, 2019, by and between Fresenius Medical Care Holdings, Inc. and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.6.1 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>

Exhibit No.	Description
10.3.2^	<a href="#">Second Amendment to Distribution Agreement, effective as of February 16, 2021, by and between Fresenius Medical Care Holdings, Inc. and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.6.2 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.4^	<a href="#">Exclusive License Agreement, dated February 25, 2014, by and between Yale University and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.8 to Humacyte, Inc.'s Registration Statement on S-4/A, filed with the SEC on June 14, 2021).</a>
10.5^	<a href="#">Exclusive License Agreement, dated August 13, 2019, by and between Yale University and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.9 to Humacyte, Inc.'s Registration Statement on S-4/A, filed with the SEC on June 14, 2021).</a>
10.6^	<a href="#">Exclusive License Agreement, dated August 25, 2019, by and between Yale University and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.10 to Humacyte, Inc.'s Registration Statement on S-4/A, filed with the SEC on June 14, 2021).</a>
10.7^	<a href="#">Exclusive Patent License Agreement, dated March 14, 2006, between Duke University and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.10 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.7.1^	<a href="#">First Amendment to Exclusive Patent License Agreement, dated February 25, 2011, between Duke University and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.10.1 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.7.2^	<a href="#">Second Amendment to Exclusive Patent License Agreement, dated April 24, 2014, between Duke University and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.10.2 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.7.3^	<a href="#">Third Amendment to Exclusive Patent License Agreement, dated June 26, 2015, between Duke University and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.10.3 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.7.4^	<a href="#">Fourth Amendment to Exclusive Patent License Agreement, dated January 2, 2018, between Duke University and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.10.4 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.7.5^	<a href="#">Fifth Amendment to Exclusive Patent License Agreement, dated December 31, 2019, between Duke University and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.10.5 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.7.6^!	<a href="#">Sixth Amendment to Exclusive Patent License Agreement, dated January 10, 2022, between Duke University and Humacyte Global, Inc.</a>
10.8^	<a href="#">Supply Agreement, dated January 9, 2014, between SeraCare Life Sciences, Inc. and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.11 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.8.1^	<a href="#">First Amendment to Supply Agreement, dated October 12, 2018, between SeraCare Life Sciences, Inc. and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.11.1 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.8.2^ *	<a href="#">Second Amendment to Supply Agreement, dated March 24, 2021, between SeraCare Life Sciences, Inc. and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.12.2 to Humacyte, Inc.'s Registration Statement on S-4/A, filed with the SEC on June 14, 2021).</a>
10.9^ *	<a href="#">Supply Agreement, dated June 1, 2020, between Confluent Medical Technologies and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.13 to Humacyte, Inc.'s Registration Statement on S-4/A, filed with the SEC on June 14, 2021).</a>
10.10+*	<a href="#">Executive Employment Agreement, dated February 3, 2021, between Laura Niklason, M.D., Ph.D. and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.13 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.11+*	<a href="#">Executive Employment Agreement, dated June 19, 2018, between Jeffrey Lawson, M.D. and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.14 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.11.1+*	<a href="#">Amendment to Executive Employment Agreement, dated February 3, 2021, between Jeffrey Lawson, M.D. and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.14.1 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.11.2+!	<a href="#">Executive Separation and Release Agreement, dated December 23, 2021, between Jeffrey Lawson, M.D. and Humacyte, Inc.</a>
10.12+*	<a href="#">Executive Employment Agreement, dated September 13, 2019, between Heather Prichard, Ph.D. and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.16 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>

<b>Exhibit No.</b>	<b>Description</b>
10.13+	<a href="#">Humacyte, Inc. 2021 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.4 to Humacyte, Inc.'s Current Report on Form 8-K, filed with the SEC on August 27, 2021).</a>
10.13.1+	<a href="#">Form of Stock Option Agreement under Humacyte, Inc. 2021 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.4.1 to Humacyte, Inc.'s Current Report on Form 8-K, filed with the SEC on August 27, 2021).</a>
10.14+	<a href="#">Humacyte, Inc. 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.5 to Humacyte, Inc.'s Current Report on Form 8-K, filed with the SEC on August 27, 2021).</a>
10.15+	<a href="#">Humacyte, Inc. Annual Bonus Plan (incorporated by reference to Exhibit 10.8 to Humacyte, Inc.'s Current Report on Form 8-K, filed with the SEC on August 27, 2021).</a>
10.16+	<a href="#">Humacyte, Inc. 2005 Stock Option Plan (incorporated by reference to Exhibit 10.18 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.16.1+	<a href="#">First Amendment of Humacyte, Inc. 2005 Stock Option Plan, dated March 31, 2008 (incorporated by reference to Exhibit 10.18.1 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.16.2+	<a href="#">Second Amendment of Humacyte, Inc. 2005 Stock Option Plan, dated October 28, 2011 (incorporated by reference to Exhibit 10.18.2 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.16.3+	<a href="#">Third Amendment of Humacyte, Inc. 2005 Stock Option Plan, dated November 22, 2013 (incorporated by reference to Exhibit 10.18.3 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.16.4+	<a href="#">Form of Incentive Stock Option Agreement under Humacyte, Inc. 2005 Stock Option Plan (incorporated by reference to Exhibit 10.18.4 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.16.5+	<a href="#">Form of Nonqualified Stock Option Agreement under Humacyte, Inc. 2005 Stock Option Plan (incorporated by reference to Exhibit 10.18.5 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.17+	<a href="#">Humacyte, Inc. 2015 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.19 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.17.1+	<a href="#">First Amendment to Humacyte, Inc. 2015 Omnibus Incentive Plan, dated February 23, 2018 (incorporated by reference to Exhibit 10.19.1 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.17.2+	<a href="#">Second Amendment to Humacyte, Inc. 2015 Omnibus Incentive Plan, dated June 6, 2018 (incorporated by reference to Exhibit 10.19.2 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.17.3+	<a href="#">Form of Incentive Stock Option Agreement under Humacyte, Inc. 2015 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.19.3 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.17.4+	<a href="#">Form of Nonqualified Stock Option Agreement under Humacyte, Inc. 2015 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.19.4 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.18+	<a href="#">Form of Indemnity Agreement by and between Humacyte, Inc. and each of its directors and executive officers (incorporated by reference to Exhibit 10.23 to Humacyte, Inc.'s Registration Statement on S-4/A, filed with the SEC on July 1, 2021).</a>
10.19	<a href="#">Lease Agreement, dated December 31, 2015, between ARE-NC Region No. 5, LLC and Humacyte, Inc. (incorporated by reference to Exhibit 10.22 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.19.1	<a href="#">First Amendment to Lease, dated September 30, 2016, between ARE-NC Region No. 5, LLC and Humacyte, Inc. (incorporated by reference to Exhibit 10.22.1 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.19.2	<a href="#">Second Amendment to Lease, dated February 8, 2017, between ARE-NC Region No. 5, LLC and Humacyte, Inc. (incorporated by reference to Exhibit 10.22.2 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.19.3	<a href="#">Third Amendment to Lease, dated April 21, 2017, between ARE-NC Region No. 5, LLC and Humacyte, Inc. (incorporated by reference to Exhibit 10.22.3 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
10.19.4	<a href="#">Fourth Amendment to Lease, dated October 31, 2017, between ARE-NC Region No. 5, LLC and Humacyte, Inc. (incorporated by reference to Exhibit 10.22.4 to Humacyte, Inc.'s Registration Statement on S-4, filed with the SEC on March 23, 2021).</a>
21.1	<a href="#">Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to Humacyte, Inc.'s Current Report on Form 8-K, filed with the SEC on August 27, 2021).</a>

Exhibit No.	Description
23.1!	<a href="#">Consent of PricewaterhouseCoopers LLP.</a>
31.1!	<a href="#">Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
31.2!	<a href="#">Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
32.1!	<a href="#">Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
32.2!	<a href="#">Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101!	The following materials from Humacyte, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2021, formatted in Inline XBRL (Inline eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 31, 2021 and 2020, (ii) Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2021 and 2020,, (iii) Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) for the years ended December 31, 2021 and 2020, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2021 and 2020, and (v) Notes to Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

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! Filed herewith.

\* Annexes, schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The registrant agrees to furnish supplementally a copy of any omitted attachment to the Securities and Exchange Commission on a confidential basis upon request.

^ Certain confidential information contained in this exhibit, market by brackets, has been omitted because the information (i) is not material and (ii) would be competitively harmful if disclosed.

+ Management contract or compensatory plan or arrangement.

**Item 16. Form 10-K Summary.**

None.



**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Act of 1934, as amended, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

**HUMACYTE, INC.**

By: /s/ Laura E. Niklason  
 Name: Laura E. Niklason, M.D., Ph.D.  
 Title: President and Chief Executive Officer

Date: March 29, 2022

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Name	Position	Date
<u>/s/ Laura E. Niklason</u> Laura E. Niklason, M.D., Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 29, 2022
<u>/s/ Dale A. Sander</u> Dale A. Sander	Chief Financial Officer, Chief Corporate Development Officer and Treasurer (Principal Financial and Accounting Officer)	March 29, 2022
<u>/s/ Kathleen Sebelius</u> Kathleen Sebelius	Director	March 29, 2022
<u>/s/ Gordon M. Binder</u> Gordon M. Binder	Director	March 29, 2022
<u>/s/ Emery N. Brown</u> Emery N. Brown, M.D., Ph.D.	Director	March 29, 2022
<u>/s/ Michael T. Constantino</u> Michael T. Constantino	Director	March 29, 2022
<u>/s/ Brady W. Dougan</u> Brady W. Dougan	Director	March 29, 2022
<u>/s/ Todd M. Pope</u> Todd M. Pope	Director	March 29, 2022
<u>/s/ Rajiv Shukla</u> Rajiv Shukla	Director	March 29, 2022
<u>/s/ Max Wallace</u> Max Wallace, J.D.	Director	March 29, 2022
<u>/s/ Susan Windham-Bannister</u> Susan Windham-Bannister, Ph.D.	Director	March 29, 2022

**DESCRIPTION OF THE COMPANY'S SECURITIES  
REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES  
EXCHANGE ACT OF 1934, AS AMENDED**

The authorized capital stock of Humacyte, Inc. (f/k/a Alpha Healthcare Acquisition Corp.), a Delaware corporation (“we,” “us,” “our,” or the “Company”), consists of: (i) 250,000,000 shares of common stock, \$0.0001 par value per share (“Common Stock”), and (ii) 20,000,000 shares of preferred stock, \$0.0001 par value per share (“Preferred Stock”).

The following description summarizes the material terms of our capital stock and does not purport to be complete. It is subject to, and qualified in its entirety by reference to, our second amended and restated certificate of incorporation (the “Charter”), our By Laws (the “Bylaws”), that certain Warrant Agreement, dated September 17, 2020, by and between the Company and Continental Stock Transfer & Trust Company, as warrant agent (the “Warrant Agreement”) and applicable provisions of the Delaware General Corporation Law (“DGCL”). Our Charter, Bylaws and the Warrant Agreement are included as exhibits to the Annual Report on Form 10-K, of which this Exhibit 4.6 forms a part. We encourage you to carefully read our Charter, Bylaws, the Warrant Agreement and the applicable provisions of the DGCL for additional information.

## **Common Stock**

### ***General***

Under the Charter, we have the authority to issue 250,000,000 shares of Common Stock. Our Common Stock is listed on the Nasdaq Global Select Market under the symbol “HUMA.” The rights, preferences and privileges of holders of our Common Stock are subject to, and may be adversely affected by, the rights of holders of shares of any series of the Preferred Stock we may designate and issue in the future.

### ***Common Stock Outstanding***

The outstanding shares of our Common Stock are, and any shares of Common Stock issued upon conversion of securities convertible into our Common Stock will be, duly authorized, validly issued, fully paid and non-assessable.

### ***Voting Rights***

Holders of record of our Common Stock are entitled to one vote for each share held on all matters to be voted on by stockholders. Unless specified in our Charter or Bylaws, or as required by applicable provisions of the DGCL or applicable stock exchange rules, the affirmative vote of a majority of our shares of Common Stock that are voted is required to approve any such matter voted on by our stockholders.

Our board of directors is divided into three classes, each of which will generally serve for a term of three years with only one class of directors being elected in each year. There is no cumulative voting with respect to the election of directors, with the result that the holders of more than 50% of the shares voted for the election of directors can elect all of the directors.

### ***Rights Upon Liquidation***

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, after payment or provision for payment of the debts and other liabilities of the Company, the holders of shares of Common Stock are entitled to receive all the remaining assets

of the Company available for distribution to its stockholders, ratably in proportion to the number of shares held by them, subject to applicable law and the rights, if any, of the holders of any outstanding series of the Preferred Stock.

### ***Dividend Rights***

Subject to applicable law and the rights, if any, of the holders of any outstanding series of the Preferred Stock, the holders of our Common Stock are entitled to receive ratable dividends when, as and if declared by our board of directors out of funds legally available therefor and will share equally on a per share basis in such dividends and distributions.

### ***Other Rights***

Our stockholders have no conversion, preemptive or other subscription rights. There are no sinking fund or redemption provisions applicable to the Common Stock.

### **Redeemable Warrants**

As of December 31, 2021, 5,177,500 warrants to purchase shares of our Common Stock were outstanding at an exercise price of \$11.50 per share, subject to adjustment as discussed below, and the warrants were exercisable for 5,177,500 shares of our Common Stock.

### ***Public Stockholders' Warrants***

Each whole warrant entitles the registered holder to purchase one share of our Common Stock at an exercise price of \$11.50 per share, subject to adjustment as discussed below, at any time. Pursuant to the Warrant Agreement, a warrant holder may exercise its warrants only for a whole number of shares of Common Stock. This means that only a whole warrant may be exercised at any given time by a warrant holder.

The warrants will expire at 5:00 p.m., New York City time, on August 26, 2026, or earlier upon redemption or liquidation.

We will not be obligated to deliver any shares of Common Stock pursuant to the exercise of a warrant and will have no obligation to settle such warrant exercise unless a registration statement under the Securities Act of 1933, as amended (the "Securities Act"), with respect to the shares of Common Stock underlying the warrants is then effective and a prospectus relating thereto is current, subject to our satisfying our obligations described below with respect to registration. No warrant will be exercisable and we will not be obligated to issue shares of Common Stock upon exercise of a warrant unless Common Stock issuable upon such warrant exercise has been registered, qualified or deemed to be exempt under the securities laws of the state of residence of the registered holder of the warrants. In the event that the conditions in the two immediately preceding sentences are not satisfied with respect to a warrant, the holder of such warrant will not be entitled to exercise such warrant and such warrant may have no value and expire worthless. In no event will we be required to net cash settle any warrant.

We have registered the shares of Common Stock issuable upon exercise of the warrants. During any period when we will have failed to maintain an effective registration statement for the shares of Common Stock issuable upon exercise of the warrants, the holders of the warrants may exercise the warrants on a "cashless basis" in accordance with Section 3(a)(9) of the Securities Act or another exemption, provided that such exemption is available. If that exemption, or another exemption, is not available, holders will not be able to exercise their warrants on a cashless basis.

Once the warrants become exercisable, we may call the warrants for redemption:

- in whole and not in part;
- at a price of \$0.01 per warrant;
- upon not less than 30 days' prior written notice of redemption given after the warrants become exercisable (the "30-day redemption period") to each warrant holder; and
- if, and only if, the reported last sale price of the Common Stock equals or exceeds \$18.00 per share (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within a 30-trading day period commencing once the warrants become exercisable and ending three business days before we send the notice of redemption to the warrant holders.

If and when the warrants become redeemable by us, we may not exercise our redemption right if the issuance of shares of Common Stock upon exercise of the warrants is not exempt from registration or qualification under applicable state blue sky laws or we are unable to effect such registration or qualification.

We have established the last of the redemption criteria discussed above to prevent a redemption call unless there is at the time of the call a significant premium to the warrant exercise price. If the foregoing conditions are satisfied and we issue a notice of redemption of the warrants, each warrant holder will be entitled to exercise its warrant prior to the scheduled redemption date. However, the price of our Common Stock may fall below the \$18.00 redemption trigger price (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) as well as the \$11.50 warrant exercise price after the redemption notice is issued.

If we call the warrants for redemption as described above, our management will have the option to require any holder that wishes to exercise its warrant to do so on a "cashless basis." In determining whether to require all holders to exercise their warrants on a "cashless basis," our management will consider, among other factors, our cash position, the number of warrants that are outstanding and the dilutive effect on our stockholders of issuing the maximum number of shares of Common Stock issuable upon the exercise of our warrants. If our management takes advantage of this option, all holders of warrants would pay the exercise price by surrendering their warrants for that number of shares of Common Stock equal to the quotient obtained by dividing (x) the product of the number of shares of Common Stock underlying the warrants, multiplied by the difference between the exercise price of the warrants and the "fair market value" (defined below) by (y) the fair market value. The "fair market value" for this purpose means the average reported last sale price of the Common Stock for the 10 trading days ending on the third trading day prior to the date on which the notice of redemption is sent to the holders of warrants. If our management takes advantage of this option, the notice of redemption will contain the information necessary to calculate the number of shares of Common Stock to be received upon exercise of the warrants, including the "fair market value" in such case. Requiring a cashless exercise in this manner will reduce the number of shares to be issued and thereby lessen the dilutive effect of a warrant redemption. If we call our warrants for redemption and our management does not take advantage of this option, AHAC Sponsor LLC (the "Sponsor") and its permitted transferees would still be entitled to exercise their placement warrants for cash or on a cashless basis using the same formula described above that other warrant holders would have been required to use had all warrant holders been required to exercise their warrants on a cashless basis.

A holder of a warrant may notify us in writing in the event it elects to be subject to a requirement that such holder will not have the right to exercise such warrant, to the extent that after giving effect to such exercise, such person (together with such person's affiliates), to the warrant agent's actual knowledge, would beneficially own in excess of 4.9% or 9.8% (or such other amount as a holder may specify) of the shares of Common Stock outstanding immediately after giving effect to such exercise.

If the number of outstanding shares of Common Stock is increased by a stock dividend payable in shares of Common Stock, or by a split-up of shares of Common Stock or other similar event, then, on the effective date of such stock dividend, split-up or similar event, the number of shares of Common Stock issuable on exercise of each whole warrant will be increased in proportion to such increase in the outstanding shares of Common Stock. A rights offering to holders of Common Stock entitling holders to purchase shares of Common Stock at a price less than the fair market value will be deemed a stock dividend of a number of shares of Common Stock equal to the product of (i) the number of shares of Common Stock actually sold in such rights offering (or issuable under any other equity securities sold in such rights offering that are convertible into or exercisable for Common Stock) and (ii) one (1) minus the quotient of (x) the price per share of Common Stock paid in such rights offering divided by (y) the fair market value. For these purposes (i) if the rights offering is for securities convertible into or exercisable for Common Stock, in determining the price payable for Common Stock, there will be taken into account any consideration received for such rights, as well as any additional amount payable upon exercise or conversion and (ii) fair market value means the volume weighted average price of Common Stock as reported during the 10 trading day period ending on the trading day prior to the first date on which the shares of Common Stock trade on the applicable exchange or in the applicable market, regular way, without the right to receive such rights.

In addition, if we, at any time while the warrants are outstanding and unexpired, pay a dividend or make a distribution in cash, securities or other assets to the holders of Common Stock on account of such shares of Common Stock (or other shares of our capital stock into which the warrants are convertible), other than (a) as described above, (b) certain ordinary cash dividends, or (c) to satisfy the redemption rights of the holders of Common Stock in connection with a stockholder vote to amend our Charter with respect to any other provision relating to stockholders' rights, then the warrant exercise price will be decreased, effective immediately after the effective date of such event, by the amount of cash and/or the fair market value of any securities or other assets paid on each share of Common Stock in respect of such event.

If the number of outstanding shares of our Common Stock is decreased by a consolidation, combination, reverse stock split or reclassification of shares of Common Stock or other similar event, then, on the effective date of such consolidation, combination, reverse stock split, reclassification or similar event, the number of shares of Common Stock issuable on exercise of each warrant will be decreased in proportion to such decrease in outstanding shares of Common Stock.

Whenever the number of shares of Common Stock purchasable upon the exercise of the warrants is adjusted, as described above, the warrant exercise price will be adjusted by multiplying the warrant exercise price immediately prior to such adjustment by a fraction (x) the numerator of which will be the number of shares of Common Stock purchasable upon the exercise of the warrants immediately prior to such adjustment, and (y) the denominator of which will be the number of shares of Common Stock so purchasable immediately thereafter.

In case of any reclassification or reorganization of the outstanding shares of Common Stock (other than those described above or that solely affects the par value of such shares of Common Stock), or in the case of any merger or consolidation of us with or into another corporation (other than a consolidation or merger in which we are the continuing corporation and

that does not result in any reclassification or reorganization of our outstanding shares of Common Stock), or in the case of any sale or conveyance to another corporation or entity of the assets or other property of us as an entirety or substantially as an entirety in connection with which we are dissolved, the holders of the warrants will thereafter have the right to purchase and receive, upon the basis and upon the terms and conditions specified in the warrants and in lieu of the shares of our Common Stock immediately theretofore purchasable and receivable upon the exercise of the rights represented thereby, the kind and amount of shares of stock or other securities or property (including cash) receivable upon such reclassification, reorganization, merger or consolidation, or upon a dissolution following any such sale or transfer, that the holder of the warrants would have received if such holder had exercised their warrants immediately prior to such event. However, if less than 70% of the consideration receivable by the holders of Common Stock in such a transaction is payable in the form of Common Stock in the successor entity that is listed for trading on a national securities exchange or is quoted in an established over-the-counter market, or is to be so listed for trading or quoted immediately following such event, and if the registered holder of the warrant properly exercises the warrant within thirty days following public disclosure of such transaction, the warrant exercise price will be reduced as specified in the Warrant Agreement based on the Black-Scholes value (as defined in the Warrant Agreement) of the warrant. The purpose of such exercise price reduction is to provide additional value to holders of the warrants when an extraordinary transaction occurs during the exercise period of the warrants pursuant to which the holders of the warrants otherwise do not receive the full potential value of the warrants in order to determine and realize the option value component of the warrant. This formula is to compensate the warrant holder for the loss of the option value portion of the warrant due to the requirement that the warrant holder exercise the warrant within 30 days of the event. The Black-Scholes model is an accepted pricing model for estimating fair market value where no quoted market price for an instrument is available.

The warrants are issued in registered form under the Warrant Agreement. The Warrant Agreement provides that the terms of the warrants may be amended without the consent of any holder to cure any ambiguity or correct any mistake, but requires the approval by the holders of at least a majority of the then outstanding public warrants to make any change that adversely affects the interests of the registered holders of public warrants.

The warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price (or on a cashless basis, if applicable), by certified or official bank check payable to us, for the number of warrants being exercised. The warrant holders do not have the rights or privileges of holders of Common Stock and any voting rights until they exercise their warrants and receive shares of Common Stock. After the issuance of shares of Common Stock upon exercise of the warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

No fractional shares will be issued upon exercise of the warrants. If, upon exercise of the warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round down to the nearest whole number of shares of Common Stock to be issued to the warrant holder.

### ***Placement warrants***

The placement warrants have terms and provisions that are identical to those of the public stockholders' warrants described above, including as to exercise price, exercisability and exercise period. They are exercisable on a cashless basis and will not be redeemable by us so long as they are held by the Sponsor, the underwriters of our initial public offering (the "Underwriters") or their permitted transferees. The Sponsor, the Underwriters or their permitted

transferees, have the option to exercise the placement warrants on a cashless basis. If the placement warrants are held by holders other than the Sponsor, the Underwriters or their permitted transferees, the placement warrants will be redeemable by us and exercisable by the holders on the same basis as the public stockholders' warrants described above. In addition, for as long as the placement warrants are held by the Underwriters or their designees or affiliates, they may not be exercised after five years from the effective date of the registration statement in connection with our initial public offering in accordance with FINRA Rule 5110(f)(2)(G)(i).

If holders of the placement warrants elect to exercise them on a cashless basis, they would pay the exercise price by surrendering their warrants for that number of shares of Common Stock equal to the quotient obtained by dividing (x) the product of the number of shares of Common Stock underlying the warrants, multiplied by the difference between the exercise price of the warrants and the "fair market value" (defined below) by (y) the fair market value. The "fair market value" for this purpose shall mean the average reported last sale price of the Common Stock for the 10 trading days ending on the third trading day prior to the date on which the notice of warrant exercise is sent to the warrant agent. The reason that we have agreed that these warrants will be exercisable on a cashless basis so long as they are held by the Sponsor, the Underwriters or their permitted transferees is because it was not known at the time of our initial public offering whether they would be affiliated with us following our initial business combination. If they were to have remained affiliated with us, their ability to sell our securities in the open market would have been significantly limited. We have policies in place that prohibit insiders from selling our securities except during specific periods of time. Even during such periods of time when insiders will be permitted to sell our securities, an insider cannot trade in our securities if he or she is in possession of material non-public information. Accordingly, unlike public stockholders who typically could sell the shares of Common Stock issuable upon exercise of the warrants freely in the open market, the insiders could be significantly restricted from doing so.

## **Certain Anti-Takeover Provisions of Delaware Law and our Charter and Bylaws**

### ***Delaware Anti-Takeover Statute***

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. This statute prevents certain Delaware corporations, under certain circumstances and for three years following the date that the stockholder became an interested stockholder, as defined below, from engaging in a "business combination" with:

- a stockholder who owns 15% or more of our outstanding voting stock (otherwise known as an "interested stockholder");
- an affiliate of an interested stockholder; or
- an associate of an interested stockholder.

A "business combination" includes a merger or sale of more than 10% of our assets. However, the above provisions of Section 203 do not apply if:

- our board of directors approves the transaction that made the stockholder an interested stockholder, prior to the date of the transaction;
- after the completion of the transaction that resulted in the stockholder becoming an interested stockholder, that stockholder owned at least 85% of our voting stock outstanding at the time the transaction commenced, other than statutorily excluded shares of common stock; or

- on or subsequent to the date of the transaction, the transaction is approved by our board of directors and authorized at a meeting of our stockholders, and not by written consent, by an affirmative vote of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

### ***Classified Board of Directors***

Our board of directors is divided into three classes, Class I, Class II and Class III, with members of each class serving staggered three-year terms. Our Charter provides that the authorized number of directors may be changed only by resolution of the board of directors. As a result, in most circumstances, a person can gain control of our board only by successfully engaging in a proxy contest at two or more annual meetings. Subject to the terms of any Preferred Stock, any or all of the directors may be removed from office at any time, but only for cause and only by the affirmative vote of holders of 66 2/3% of the voting power of all then outstanding shares of our capital stock entitled to vote generally in the election of directors, voting together as a single class. Any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

### ***Authorized but Unissued Shares***

Our authorized but unissued Common Stock and Preferred Stock are available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

### ***Stockholder Action and Special Meetings***

Our Charter provides that any action required or permitted to be taken by the stockholders of the Company must be effected by a duly called annual or special meeting of such stockholders and may not be effected by written consent of the stockholders. Our Charter further provides that meetings of stockholders of the Company may be called only by the Chairman of the board of directors, the Chief Executive Officer of the Company, or the board of directors pursuant to a resolution adopted by a majority of thereof, and that the ability of the stockholders of the Company to call a special meeting is specifically denied.

### ***Exclusive Forum Selection***

Our Charter requires, to the fullest extent permitted by law, that derivative actions brought in our name, actions against directors, officers and employees for breach of fiduciary duty, arising pursuant to any provision of the DGCL, Charter or Bylaws, or governed by the internal affairs doctrine, may be brought only in the Court of Chancery in the State of Delaware and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel except any action (i) as to which the Court of Chancery in the State of Delaware determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within 10 days following such determination), (ii) which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery or (iii) for which the Court of Chancery does not have subject matter jurisdiction. Any person or entity purchasing or otherwise acquiring any interest in shares of our



capital stock shall be deemed to have notice of and consented to the forum provisions in the Charter.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims. We cannot be certain that a court will decide that this provision is either applicable or enforceable, and if a court were to find the choice of forum provision contained in our Charter to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

Our Charter provides that the exclusive forum provision is applicable to the fullest extent permitted by applicable law. Notwithstanding the foregoing, the choice of forum provision will not apply to claims brought to enforce any liability or duty created by the Securities Act, the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or any other claim for which the federal courts have exclusive jurisdiction. Unless the Company consents in writing to the selection of an alternative forum, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

## SIXTH AMENDMENT TO EXCLUSIVE PATENT LICENSE AGREEMENT

This Sixth Amendment (this “Sixth Amendment”), effective as of January 10, 2022 (“EFFECTIVE DATE”), amends the Exclusive Patent License Agreement, effective March 14, 2006, as amended by the First Amendment to Exclusive Patent License Agreement, effective as of February 25, 2011, the Second Amendment to Exclusive Patent License Agreement, effective as of April 24, 2014, the Third Amendment to Exclusive patent License Agreement, dates as of June 26, 2015, the Fourth Amendment to Exclusive Patent License Agreement, effective as of January 2, 2018, and the Fifth Amendment to Patent Exclusive Patent License Agreement, effective as of December 31, 2019 (as so amended, the “Agreement”), between Duke University, a nonprofit educational and research institution organized under the laws of North Carolina (“DUKE”) having its principal office in Durham, North Carolina, and Humacyte, Inc., a corporation organized under the laws of Delaware (“COMPANY”) with its corporate headquarters and principal office at 2525 East NC Highway 54, Durham, NC 27713. All capitalized terms used herein but not otherwise defined herein shall have the meanings set forth for such terms in the Agreement.

WHEREAS, COMPANY has been engaged in good faith and reasonable commercial efforts to commercialize the PATENT RIGHTS and develop, register, market and sell LICENSED PRODUCTS, and desires to effect an amendment to the DUE DILIGENCE SCHEDULE.

WHEREAS, the Agreement requires that any change or modification to the Agreement and the DUE DILIGENCE SCHEDULE set forth in a written instrument executed by both DUKE and COMPANY.

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein and in the Agreement, the parties hereby agree as follows:

1. The obligation described in the last bullet of the DUE DILIGENCE SCHEDULE is hereby deleted in its entirety and replaced with the following:

- [\*\*\*]
- [\*\*\*]

2. Of Paragraph 3.01(f)(iv) of the Agreement is hereby deleted in its entirety and replaced with the following:

- (iv) US\$[\*\*\*]
- (v) US\$[\*\*\*]

3. Upon the EFFECTIVE DATE, each reference in the Agreement to (i) “this Agreement” “hereunder”, “hereof”, “herein” or words of like import shall mean and be a reference to the Agreement as amended hereby, and (ii) to the “DUE DILIGENCE SCHEDULE” shall mean and be a reference to the DUE DILIGENCE SCHEDULE as amended hereby.

4. All terms, conditions and provisions of the Agreement not expressly amended, modified or deleted by this Sixth Amendment shall continue in full force and effect and are hereby ratified by the parties. This Sixth Amendment is binding on and inures to the benefit of the parties and their permitted heirs, successors and assigns.

5. The Agreement, together with any exhibits and appendices affixed thereto, all as modified by this Sixth Amendment, constitutes the entire and exclusive agreement between DUKE and COMPANY with respect to the subject matters hereof and thereof.

6. This Sixth Amendment shall be construed as having been entered into in the State of North Carolina and shall be interpreted in accordance with and its performance governed by the laws of the State of North Carolina, without regard to any choice-of-law or conflict-of-law provision that would dictate the application of the law of another jurisdiction.

7. This Sixth Amendment may be executed in multiple counterparts, all of which shall be considered one and the same agreement, and shall become effective when each party hereto shall have received counterparts hereof signed by each of the other parties hereto. If any signature is delivered by facsimile transmission or by PDF, such signature shall create a valid and binding obligation of the party executing (or on whose behalf the signature is executed) with the same force and effect as if such facsimile or PDF signature were an original thereof.

(Signature Page Follows)

(Signature Page to Sixth Amendment to Exclusive Patent License Agreement)

IN WITNESS WHEREOF, the parties have duly executed this Sixth Amendment as of the date first written above.

DUKE UNIVERSITY

HUMACYTE, INC.

By: /s/ Robin L. Rasor  
Name: Robin L. Rasor  
Title: Assoc. VP, Office for  
Translation & Commercialization

By: /s/ Laura E. Niklason  
Name: Laura E. Niklason  
Title: President and Chief Executive Officer

## EXECUTIVE SEPARATION AND RELEASE AGREEMENT

This Executive Separation and Release Agreement (“Agreement”) is entered into by and between Humacyte, Inc. (“Humacyte”) and Jeffrey Lawson, M.D., Ph.D. (“Executive”), effective as of the date signed by Executive (the “Effective Date”). Humacyte and Executive are collectively referred to as the “Parties.”

WHEREAS, Executive entered into an Executive Employment Agreement with Humacyte, effective June 19, 2018 (“Employment Agreement”), and executed Amendment 1 to the Employment Agreement, effective November 9, 2020 (“Amendment 1”);

WHEREAS, Executive served as Humacyte’s President and Chief Executive Officer pursuant to the Employment Agreement and currently serves as Humacyte’s Chief Surgical Officer pursuant to Amendment 1 to the Employment Agreement;

WHEREAS, Executive has served as a member of the Board of Directors of Humacyte and Humacyte Global, Inc. (the “Board”) since July 2018;

WHEREAS, Executive and Humacyte have mutually agreed to end Executive’s employment with Humacyte, and Humacyte shall terminate the Employment Agreement and Amendment 1 to the Employment Agreement without Cause, effective December 31, 2021 (the “Separation Date”);

WHEREAS, Executive desires to resign from the Board of Directors of Humacyte and Humacyte Global, Inc., effective as of the Separation Date; and

WHEREAS, pursuant to the Employment Agreement, Executive is entitled to certain separation payments in connection with the termination of Executive’s employment without Cause and, in order to assist Executive in his transition and acknowledge Executive’s past contributions, Humacyte desires to provide Executive with certain additional benefits to which he is not otherwise entitled;

NOW, THEREFORE, in consideration of the covenants, benefits, and payments set forth in this Agreement, Humacyte and Executive agree as follows:

1. **Separation Payments.** Provided that Executive executes this Agreement without revoking it during the revocation period described in Section 5, Humacyte shall provide the following payments to Executive pursuant to the Employment Agreement, which Executive agrees constitutes good and valuable consideration for each and all of his promises set forth in this Agreement:

- a) A total amount of **\$583,495.12**, less any applicable taxes and withholdings, which is equal to twelve (12) months of Executive’s current base salary with payment of such amount to be made in substantially equal installments on the same payroll schedule applicable to Executive immediately prior to his separation from service. Such payments shall commence no later than on the first such payroll date following the sixtieth (60th) day after the Separation Date, provided that Executive has returned by such sixtieth (60th) day an executed copy of this Agreement without modification and the seven-day revocation period has expired;
- b) An amount of **\$221,728.15**, less any applicable taxes and withholdings, which represents a bonus payment equal to ninety-five percent (95%) of forty percent (40%) of Executive’s current base salary, with such amount to be paid no later than March 15, 2022; and
- c) Reimbursement to Executive for the cost to continue Executive’s and his family’s health insurance under the Consolidated Omnibus Budget Reconciliation Act of 1985 (“COBRA”) for a period of twelve (12) months immediately following the Separation

Date. Executive agrees that if Executive becomes covered under another employer's group health plan or otherwise ceases to be eligible for COBRA during the 12-month period, Executive must immediately notify Humacyte of such event and may no longer be entitled to continued COBRA payments by Humacyte.

Executive's entitlement to the payments set forth in this section is subject to his full compliance with his obligations under the Agreement, including Section 8 (Non-Disparagement) of the Agreement. Executive agrees that he will forfeit any right to the above-described payments if he breaches his obligations under this Agreement; in the event of such breach, Humacyte will immediately cease making payments to Executive and Executive must immediately return any payments made by Humacyte under this section. Aside from the payments set forth above, each party is responsible for its own costs, attorneys' fees, and expenses. In addition, the cash payments described above are the only cash payments payable in connection with Executive's separation under this Agreement, the Employment Agreement, and Amendment 1.

2. **Exercise of Stock Options.** Executive and Humacyte are parties to incentive stock option agreements, dated as of December 11, 2015, December 15, 2016, April 12, 2018 and June 28, 2018 (collectively, the "Option Agreements"). Contingent upon Executive's signing and not revoking this Agreement and pursuant to actions taken by Humacyte's Board under its authority granted under the 2015 Omnibus Incentive Plan, each Option Agreement is hereby amended, effective as of the Separation Date, to replace Section 4(b) in its entirety to state: "(b) November 26, 2022 or, if earlier, the date on which the Company determines that the Participant has violated Section 8 (Non-Disparagement) of that certain Executive Separation and Release Agreement entered into by the Company and the Participant." In furtherance of Executive's ability to exercise each such option, Humacyte will take commercially reasonable efforts to facilitate a broker-dealer sale and remittance procedure with one or more of the broker dealers making a market in Humacyte's shares pursuant to which Executive will provide written instructions to such broker-dealer to effect the immediate sale of some or all of the purchased shares purchased in connection with such exercise and remit to Humacyte sufficient funds to cover the aggregate exercise price payable for the purchased shares and any resulting tax withholding liability. Humacyte acknowledges and agrees that any exercise of Executive's options after the Separation Date and any subsequent sale of resulting shares is not subject to the pre-clearance requirements of Section VII of Humacyte's Insider Trading Policy. Executive acknowledges and agrees that he is not entitled to this benefit under the Employment Agreement or any Option Agreements, but that Humacyte desires to provide such benefit to Executive in connection with his separation from Humacyte and resignation from the Board.

3. **Resignation.** Executive hereby resigns from the Board of Directors of Humacyte and Humacyte Global, Inc., effective as of the Separation Date.

4. **Release of Claims.** Except for Humacyte's obligations under this Agreement, Executive releases and forever discharges Humacyte and its subsidiaries, divisions, affiliates, parents, successors, assigns, and all of their respective insurers, attorneys, and past and present officers, directors, trustees, employees, members of the Board, and agents (collectively, the "Released Parties") from any and all claims, actions, complaints, grievances, liabilities, obligations, losses, damages, fees, costs, causes of action, suits, rights, and demands, of any and every nature whatsoever, known or unknown, suspected or unsuspected, disclosed or undisclosed (collectively, "Claims") arising out of or relating to any acts or omissions that occurred before the Effective Date of this Agreement, to the greatest extent permissible under applicable law. This includes, but is not limited to, all Claims that Executive may have under any federal, state, local, or municipal laws or the common law and all Claims arising out of or relating to his employment or the termination of that employment.

However, nothing in this Agreement releases or affects Executive's right to file, or to participate in, any charge, complaint, investigation or proceeding before the U.S. Equal Employment Opportunity Commission or any other federal, state or local government body or agency. If any such charge, complaint, investigation, or proceeding is filed, Executive waives, to the maximum extent permissible

under applicable law, the right to receive any personal monetary or equitable relief from such charge, complaint, investigation or proceeding. This Agreement does not limit Executive's right to receive an award for information provided to any securities regulatory agency or authority. In addition, nothing in this Agreement releases or affects any rights Executive may have to: (a) Executive's own vested accrued employee benefits under Humacyte's ERISA-covered health, welfare, or retirement benefit plans as of Executive's Separation Date; (b) benefits and/or the right to seek benefits under applicable workers' compensation and/or unemployment compensation statutes; (c) any right to defense or indemnification Executive may have pursuant to the by-laws of Humacyte or under any agreement between Executive and Humacyte; or (d) pursue claims which by law cannot be waived by signing this Agreement.

5. **Waiver of Claims Under the Age Discrimination in Employment Act.** Executive recognizes that, in signing this Agreement, Executive is knowingly and voluntarily waiving his right to pursue any and all claims under the Age Discrimination in Employment Act, 29 U.S.C. § 626 *et seq.* ("ADEA"), arising prior to the date that Executive executes this Agreement. Executive understands that Executive has been given, and may take, twenty-one (21) days from the date this Agreement is presented to Executive to consider whether to execute this Agreement, and agrees that any changes, whether material or immaterial, to the Agreement before he signs it will not restart the running of the twenty-one days. Executive is further advised that he may wish to consult with an attorney prior to execution of this Agreement. Once Executive has executed this Agreement, he may revoke the Agreement at any time during the seven (7) day period following Executive's execution of the Agreement. Revocation by Executive shall be effective only upon his written notice delivered to Humacyte's CEO, Laura Niklason, within that seven (7) day period. After seven (7) days have passed following Executive's execution of this Agreement, Executive's execution of this Agreement shall be final and irrevocable.

6. **Return of Property.** Executive certifies that he has returned to Humacyte all original forms and copies of data (including work product, financial data, documents and computer data, regardless of form or medium), documents, and equipment (including keys, devices, and software) in his possession or control that relate to the business of Humacyte or that contain Confidential Information, as defined under the Proprietary Information, Inventions and Non-Competition Agreement ("Proprietary Information Agreement") between Executive and Humacyte, effective June 19, 2018. Executive affirms that he has not retained any data, documents (including copies and abstracts thereof), materials, or other property belonging to Humacyte, or any confidential information regarding a third party that he obtained during the course of his employment by Humacyte, except for information regarding Executive's own compensation and benefits.

7. **Cooperation.** Executive agrees to assist and cooperate with Humacyte to ensure a smooth transition of Executive's work responsibilities, including by participating in any exit interview requested by Humacyte. At any time following the Separation Date, Executive will (1) execute all documents and perform all lawful acts which Humacyte considers necessary or advisable to secure its rights hereunder and to carry out the intent of this Agreement and the intent of the Proprietary Information Agreement; and (2) provide any information as Humacyte or members of Humacyte's Board may reasonably request with respect to any Humacyte-related transaction or other matter in which Executive was involved in any way while employed by Humacyte. Executive further agrees to reasonably assist and cooperate with Humacyte in connection with the defense, prosecution, government investigation, or internal investigation of any claim or matter that may be made against, concerning, or by Humacyte. Such assistance and cooperation shall include, upon reasonable request, timely, comprehensive, and truthful disclosure of all relevant facts known to Executive, including through in-person interview(s) with Humacyte's executives, Board members, representatives of a government agency, or outside counsel for Humacyte. Any such assistance by Executive shall occur at times mutually convenient for Executive and Humacyte, and Humacyte will undertake reasonable efforts to ensure that any such assistance does not interfere with any duties or obligations that Executive may have to a third party, including any future employer. Executive shall be entitled to reimbursement

for all properly documented expenses incurred in connection with rendering services under this section, including, but not limited to, reimbursement for all reasonable travel, lodging, and meal expenses.

8. **Non-Disparagement.** Executive covenants and agrees that he will not at any time—whether directly, indirectly, or through any entity in which Executive is an officer, director, member, partner, employee, consultant, or shareholder—make any communication, verbally or written, that disparages, defames, criticizes, or otherwise reflects adversely upon Humacyte, Humacyte’s businesses, processes, services, methods of doing business, strategic decisions, or products, or any of Humacyte’s past, present, or future officers, directors, employees, Board members, consultants, successors, affiliates, parents, investors, customers, business partners, constituents, or trustees. In addition, Executive agrees not to take any other action (whether through Executive’s statements, communications, or conduct) that is intended to, or that could reasonably be expected to, adversely affect the competitive standing or reputation of Humacyte, any of Humacyte’s products, or any of Humacyte’s directors, officers, Board members, agents, or employees. By way of example and without limitation, Executive understands and agrees that any statements, communications, or conduct that disparages or intends to disparage Humacyte’s products, clinical trials, strategic decisions, or leadership team is prohibited under this section.

Executive understands and agrees that any violation of this section would constitute a material breach of this Agreement and would irreparably harm Humacyte. Accordingly, **any violation by Executive of this section at any time will result in the immediate forfeiture of his entitlement to payments under Section 1 and the immediate expiration of the stock options subject to the Option Agreements, notwithstanding the extension provided for under Section 2 of this Agreement.** However, nothing in this Agreement restricts or impedes, or shall be deemed to restrict or impede, Executive from (i) exercising protected rights, to the extent that such rights cannot be waived by agreement, (ii) providing truthful testimony or information pursuant to subpoena, court order, or similar legal process, (iii) providing truthful information to any government agency or body, or (iv) complying with any applicable law, regulation, or order, provided that such compliance does not exceed that required by the law, regulation, or order. To the extent not prohibited by law, Executive shall promptly provide written notice of any such order requiring his compliance to Humacyte’s CEO, Laura Niklason.

Humacyte agrees that it will instruct its executive leadership team and members of its Board of Directors not to make any communication, verbally or written, that disparages, criticizes, or otherwise reflects adversely upon Executive or Executive’s performance as a Board member or an employee of Humacyte; **provided that** Executive understands and agrees that any disclosure by Humacyte to any government agency or pursuant to any applicable law, regulation, or order shall not constitute a violation of this section.

9. **Communications; References.** In connection with Executive’s separation, Executive shall cooperate with Humacyte to coordinate external communications concerning Executive’s separation and to designate individuals to whom reference requests shall be directed. Executive will be invited to provide input on such external communications, though Humacyte shall have final approval on all communications within Humacyte and externally. Executive agrees that he will not communicate with any of Humacyte’s employees or consultants, or with any individuals or entities outside of Humacyte, about any matters relating to Humacyte’s business without the prior written consent of Humacyte’s CEO, unless such communication is required by applicable law, regulation, or order, provided, however, that communications in furtherance of Executive’s cooperation obligation under Section 7 above will not constitute a violation of this section, and provided further, that if contacted by a third party regarding a matter related to Humacyte’s business, it will not be a violation of this section for Executive to refer to Humacyte’s published external communications nor to refer the third party to an appropriate contact at Humacyte. Humacyte acknowledges that the Executive will continue to engage in the practice of medicine after the Separation Date, and nothing in this Agreement will prohibit or interfere with Executive’s practice of medicine, including his ability to discuss with patients the use or application of Humacyte’s products. Executive further agrees that he does not have any rights to future employment with Humacyte or any of Humacyte’s subsidiaries, affiliates, successors, or assigns.



10. **Section 409A; Tax Liability.** All payments and benefits under this Agreement are intended to be exempt from Section 409A of the Internal Revenue Code of 1986, as amended, and the Treasury regulations thereunder (“Section 409A”) and this Agreement shall be interpreted consistent with that intent. Notwithstanding the foregoing, Executive understands and agrees that Humacyte makes no representations as to the tax consequences of any consideration or benefits provided hereunder, and that Executive is solely responsible for any and all income, excise, or other taxes imposed on Executive with respect to any and all compensation or other benefits provided to Executive. No provision of this Agreement shall transfer to Humacyte any tax obligations that otherwise are the responsibility of Executive, in each case without regard to the amount withheld, and Humacyte shall have no obligation to secure favorable tax treatment for Executive with respect to any payments under this Agreement. Each payment to Executive under this Agreement shall be treated as a separate payment for purposes of Section 409A.

11. **Governing Law; Arbitration.** This Agreement shall be governed by, and construed in accordance with, the laws of the State of North Carolina. Except as provided in Section 12 of this Agreement, any dispute, controversy, or claim arising out of or relating to Executive’s employment with Humacyte, the termination of Executive’s employment by Humacyte, or any alleged breach of this Agreement by Humacyte shall be submitted to and decided by binding arbitration in Wake County, North Carolina in accordance with the Labor/Employment Rules of the American Arbitration Association (“AAA”). Each Party shall pay its own costs of arbitration, except that any fees and charges of the arbitrator shall be split equally by the Parties, unless the arbitrator’s award specifies otherwise.

12. **Remedies.** In the event of a breach or threatened breach by Executive of the Proprietary Information Agreement or of Sections 6, 7, 8, or 9 of this Agreement, Executive hereby consents and agrees that money damages would not afford an adequate remedy to Humacyte and that Humacyte shall be entitled to seek a temporary or permanent injunction or other equitable relief against such breach or threatened breach from any court of competent jurisdiction, without the necessity of showing any actual damages, and without the necessity of posting any bond or other security. Any equitable relief shall be in addition to, not in lieu of, legal remedies, monetary damages, or other available relief.

13. **Enforcement; Attorneys’ Fees.** If either Party commences legal action to enforce the provisions of this Agreement (or, in the case of Humacyte, any of the post-employment obligations referenced in the Proprietary Information Agreement), the prevailing Party in such legal action will be entitled to recover from the non-prevailing Party all reasonable costs incurred in connection with such legal action, including court costs, reasonable attorneys’ fees, and all other related expenses incurred in connection with such legal action, to the maximum extent permitted by applicable law. Any actions taken by Humacyte to enforce the terms of this Agreement shall not release Executive from any of his obligations or promises under the Agreement, including under Sections 4, 5, 6, 7, 8, and 9.

14. **Severability.** If any provision of this Agreement is determined to be so broad as to be unenforceable, such provision shall be interpreted to be only so broad as is enforceable, and that provision will be enforced to the greatest extent permitted by law. In the event that any provision is determined to be entirely unenforceable, such provision shall be deemed severable, such that all other provisions of this Agreement shall remain valid and binding.

15. **Modification; No Waiver.** This Agreement may not be amended or modified except by an agreement in writing signed by both Parties. The drafting of this Agreement shall be deemed a mutual endeavor by the Parties and shall not be construed against any single party as the drafter. The failure of any party to enforce any term of this Agreement shall not be deemed a waiver of that term or any other term of this Agreement.

16. **Assignment.** This Agreement shall inure to the benefit of Humacyte and its successors and assigns, and Humacyte may freely assign this Agreement at any time. Because this Agreement is personal to Executive, Executive may not assign this Agreement in whole or in part.

17. **Entire Agreement.** Executive acknowledges that Humacyte has made no representations or promises to Executive other than those contained in this Agreement and that this Agreement sets forth the entire agreement between Executive and Humacyte pertaining to the subject matter of this Agreement and supersedes any previous agreements or understandings between Executive and Humacyte, except that (i) Executive acknowledges that this Agreement shall be read in conjunction with—and does not in any way modify, limit, or restrict—the continuing obligations of Executive to Humacyte as set forth in the Proprietary Information Agreement, which remains in full force and effect consistent with applicable law, and (ii) the Option Agreements shall remain in full force and effect, other than as explicitly amended by this Agreement and the actions contemplated hereunder.

18. **Acknowledgments and Representations.** Executive agrees with and affirms the following:

- a) Except for the amounts to be paid under this Agreement, Executive has been paid and/or has received all leave (paid or unpaid), compensation, wages, bonuses, commissions and/or benefits to which he may be entitled and that no other leave (paid or unpaid), compensation, wages, bonuses, commissions and/or benefits are due to him;
- b) Executive has no known workplace injuries or occupational diseases relating to his employment; and
- c) Executive has fully read this Agreement, understands its contents, agrees to the provisions it contains, and hereby executes it voluntarily and knowingly.

19. **Counterparts.** This Agreement may be executed in multiple counterparts, each of which shall be deemed to be and have the same force and effect as an original, and all of which, taken together, shall constitute and be construed as a single agreement. A copy of an executed original shall have the same force and effect as an original.

\* \* \* \* \*

PLEASE READ THIS AGREEMENT CAREFULLY. IT CONTAINS A RELEASE OF ALL KNOWN AND UNKNOWN CLAIMS THAT CAN BE RELEASED UNDER THE LAW. BY SIGNING THIS AGREEMENT, EXECUTIVE ACKNOWLEDGES THAT HE HAS READ THIS AGREEMENT IN ITS ENTIRETY AND FULLY UNDERSTANDS ALL OF ITS TERMS.

IN WITNESS WHEREOF, the undersigned have executed this Agreement as of the date signed below.

**EXECUTIVE**

Date: 12/23/2021

/s/ Jeffrey Lawson  
Jeffrey Lawson, M.D., Ph.D.

**HUMACYTE, INC.**

Date: 12/23/2021

By: /s/ Laura E. Niklason  
Laura E. Niklason, M.D., Ph.D.  
President & Chief Executive Officer

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-260561) of Humacyte, Inc. of our report dated March 29, 2022 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP  
Raleigh, North Carolina  
March 29, 2022

## CERTIFICATION

I, Laura E. Niklason, certify that:

1. I have reviewed this Annual Report on Form 10-K of Humacyte, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2022

By: /s/ Laura E. Niklason

Name: Laura E. Niklason, M.D., Ph.D.

Title: President and Chief Executive Officer

## CERTIFICATION

I, Dale A. Sander, certify that:

1. I have reviewed this Annual Report on Form 10-K of Humacyte, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2022

By: /s/ Dale A. Sander

Name: Dale A. Sander

Title: Chief Financial Officer, Chief Corporate Development  
Officer and Treasurer

**CERTIFICATION**

In connection with the Annual Report on Form 10-K of Humacyte, Inc. (the “Company”) for the fiscal year ended December 31, 2021 (the “Report”), as filed with the Securities and Exchange Commission on the date hereof, I, Laura E. Niklason, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 29, 2022

By: /s/ Laura E. Niklason

Name: Laura E. Niklason, M.D., Ph.D.

Title: President and Chief Executive Officer

**CERTIFICATION**

In connection with the Annual Report on Form 10-K of Humacyte, Inc. (the "Company") for the fiscal year ended December 31, 2021 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, I, Dale A. Sander, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 29, 2022

By: /s/ Dale A. Sander

Name: Dale A. Sander

Title: Chief Financial Officer, Chief Corporate  
Development Officer and Treasurer